UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

Plaintiffs are States and local governments that share the fundamental duty of protecting the health and safety of our residents, including our most vulnerable residents. Plaintiffs both regulate and serve as health care providers and health insurers and are thus directly invested in ensuring that our residents have timely access to appropriate health care services. At the same time, Plaintiffs respect the conscience rights of health care workers and providers and, consistent with federal statutes, have put in place practices and procedures to accommodate those rights without sacrificing patient care.

In January 2018, the United States Department of Health and Human Services ("Department") proposed to radically upend the status quo under a sweeping regulation that would give nearly every individual and entity involved in the provision of health care the categorical right to deny lawful and medically necessary treatment, services, and information to patients, based on the objector's personal views. In doing so, the Department disregarded Congress's carefully tailored conscience-protection statutes and proposed instead a one-size-fits-all scheme that redefines key statutory terms, grants the Department sweeping investigative and compliance authority, and allows the Department to terminate billions of dollars in federal funds to Plaintiffs under deeply unclear criteria.

Thousands of commenters—including not only many of the Plaintiffs but also nearly every leading health care organization in the United States—urged the Department to refrain from making such drastic changes to medical practice. Plaintiffs stressed that existing federal, state, and local laws already appropriately balance the conscience rights of health providers with their ethical duties to provide patient-centered care and do no harm. But in May 2019, the Department issued a final rule that largely discounted commenters' concerns and enshrined broad conscience-objection rights for health care providers. *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. Part 88) (the "Final Rule").

Such a seismic shift in approach to conscience objections—including a vastly expanded universe of who may object, and how, when, and to what—threatens immediate and irreparable harm to Plaintiffs as regulators, insurers, and most urgently as direct providers of care in various settings. In some of these settings, like emergency care, the risk of harm posed by the Final Rule is literally a life-or-death matter. In addition to being harmful, the regulation is unlawful. The Final Rule violates the Administrative Procedure Act because it exceeds the Department's statutory authority, is not in accordance with law, and is arbitrary and capricious. The Final Rule also violates the Spending Clause of the U.S. Constitution in several respects, as well as the constitutional principle of separation of powers. As set forth in detail below, Plaintiffs are likely to succeed on the merits of these claims, the balance of equities undoubtedly tips in Plaintiffs' favor, and an injunction is clearly in the public interest. Accordingly, Plaintiffs respectfully request that the Court grant provisional relief enjoining implementation of the Final Rule.

BACKGROUND

I. Statutory framework.

The Final Rule purports to implement nearly thirty federal statutory provisions regarding refusals to provide health care based on the religious or moral views of providers. 84 Fed. Reg. at 23,263-69 (§ 88.3). The most relevant of these relate to abortion and sterilization; assisted suicide; and counseling and referral.

1. The Final Rule purports to implement a number of statutes that principally concern objections to abortion and sterilization. *Id.* at 23,264-66 (§§ 88.3(a), (b), (c), (f)). These include: (1) the Church Amendments, which among other things prohibit government entities that receive certain federal funds from discriminating against physicians or health care personnel because

they performed or assisted in the performance of any sterilization procedure or abortion or refused to do so because of religious beliefs or moral convictions, 42 U.S.C. § 300a-7(c)(1); (2) the Coats-Snowe Amendment, which prohibits state and local governments that receive federal funds from discriminating against health care entities on the ground that they refuse to be trained or provide training in the performance of abortion, *id.* §§ 238n(a), (c)(2); and (3) the Weldon Amendment, an appropriations rider that provides that no funds appropriated in the Act may be made available to any state or local government if it discriminates against a health care entity that "does not provide, pay for, provide coverage of, or refer for abortions." *Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019*, Pub. L. No. 115-245, § 507(d)(1), 132 Stat. 2981, 3118 (2018). In addition, section 1303 of the Affordable Care Act permits states to exclude abortion coverage from qualified health plans; provides that health plans are not required to cover abortion services as part of their essential health benefits; and prohibits health plans from discriminating against providers because of their unwillingness to provide or refer for abortions. 42 U.S.C. §§ 18023(a)(1), (b)(1)(A), (b)(4).

2. The Final Rule purports to implement several statutes concerning objections to assisted suicide. 84 Fed. Reg. at 23,266-67 (§§ 88.3(e), (i)). Section 1553 of the Affordable Care Act ("ACA") proscribes state and local governments that receive federal funds under the ACA from discriminating against a health care entity 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." 42 U.S.C. § 18113(a). In addition, the Assisted Suicide Funding Restriction Act of 1997 provides that the advanced directives requirements applicable to state-administered

Medicaid programs do not require a provider, organization, or its employees "to inform or counsel any individual regarding any right to obtain an item or service furnished for the purpose of causing, or the purpose of assisting in causing, the death of the individual, such as by assisted suicide . . . ." 42 U.S.C. § 14406.

3. The Final Rule also purports to implement statutory provisions related to health care counseling or referral. 84 Fed. Reg. at 23,266-67 (§ 88.3(h)). As applicable to Plaintiffs, federal law provides that Medicaid managed care organizations are not required "to provide, reimburse for, or provide coverage of, a counseling or referral service if the organization objects to the provision of such service on moral or religious grounds," so long as this is communicated to prospective enrollees. 42 U.S.C. § 1396u-2(b)(3)(B).[1]

II. The challenged rulemaking.

A. Prior regulations implementing conscience objection statutes.

In 2008, the Department first promulgated implementing regulations with respect to the Church Amendments, the Coats-Snowe Amendment, and the Weldon Amendment. *See* 73 Fed. Reg. 78,072 (Dec. 19, 2008) (the "2008 Rule"). The 2008 Rule defined statutory terms (including "assist in the performance" and "health care entity"); required all recipients and sub-recipients of Department funds to submit certifications of compliance; created an enforcement mechanism; and designated the Department's Office for Civil Rights ("OCR") to receive and coordinate the investigation of complaints. *Id.* at 78,096-78,101.

[1] In addition to statutes in the three subject areas discussed above, the Final Rule states that it implements a range of disparate statutes that relate in some way to religious refusals to provide care. 84 Fed. Reg. at 23,267-69 (§§ 88.3(j) – 88.3(q)). Among other statutes, the ACA's individual mandate includes an exemption for certain individuals whose religious beliefs prohibit accepting the benefits of private or public insurance. *See* 26 U.S.C. § 5000A(d)(2)(A)(i); 42 U.S.C. §§ 18081(a)(4), (b)(5); *see also* 26 U.S.C. § 1402(g)(1). The Final Rule also states that it implements statutes involving the Department's grants and research conducted in consultation with the Department of Labor and related to occupational safety and health, *see* 29 U.S.C. § 669(a)(5); as well as statutes concerning early intervention and suicide assessments for youth, *see* 42 U.S.C. §§ 290bb-36(f), 5106i(a).

In January 2009, eight states and several reproductive health care organizations sued to challenge the 2008 Rule on the grounds that it exceeded the scope of the agency's authority, constituted arbitrary and capricious decision-making, and violated the Spending Clause. Two months later, the Department proposed rescinding the 2008 Rule, *see* 74 Fed. Reg. 10,207 (proposed Mar. 10, 2009); and the Department completed its rescission in a 2011 rulemaking, *see* 76 Fed. Reg. 9968 (Feb. 23, 2011) (the "2011 Rule").[2]

The 2011 Rule (1) rescinded all of the definitions in the 2008 Rule definitions because "they may have caused confusion regarding the scope of the federal health care provider conscience protection statutes," 76 Fed. Reg. at 9974; (2) removed the 2008 Rule's certification requirements because they were "unnecessary to ensure compliance with" the applicable laws and "created unnecessary additional financial and administrative burdens on health care entities," *id.*; and (3) authorized OCR to receive and coordinate the handling of complaints based on the Church, Coats-Snowe, and Weldon Amendments," *id.* at 9975-77.

B. The Department's 2018 notice of proposed rulemaking.

On May 4, 2017, the President signed an Executive Order entitled "Promoting Free Speech and Religious Liberty." Exec. Order No. 13,798, 82 Fed. Reg. 21,675 (May 8, 2017). Among other things, this Executive Order directed the Attorney General to issue "Religious Liberty Guidance . . . interpreting religious liberty protections in Federal law." *Id.* On October 6, 2017, the Attorney General issued a memorandum "to guide all administrative agencies and executive departments in the execution of federal law." Ex. 60 (Memorandum from the Attorney

[2] The district court stayed the lawsuits challenging the 2008 Rule after publication of the 2009 proposed rescission. *See* Order, *Connecticut v. United States*, No. 09-cv-54, Dkt. 103 (D. Conn. Apr. 27, 2009). The plaintiffs voluntarily dismissed their challenges after publication of the 2011 Rule. *See* Order on Notice of Voluntary Dismissal, *Connecticut v. United States*, No. 09-cv-54, Dkt. 149 (D. Conn. Apr. 7, 2011).

General for All Executive Departments and Agencies, *Federal Law Protections for Religious Liberty* 1 (Oct. 6, 2017)).[3] The Attorney General's guidance identified several statutory provisions that the Department purports to implement in the Final Rule as intended to "root out public and private discrimination based on religion." *Id.* at 9a, 16a-17a.

Pursuant to the executive order and the Attorney General's guidance, in January 2018, the Department published a Notice of Proposed Rulemaking regarding refusals to provide health care services based on religious or moral objections. *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*, 83 Fed. Reg. 3880, 3881, 3923 (proposed Jan. 26, 2018) (the "Proposed Rule"). The Proposed Rule described broad, unconditional rights for health care personnel to refuse to provide health care services for "religious, moral, ethical, or other reasons." *Id.* at 3923. The Proposed Rule intended to enforce these rights by withholding, denying, or terminating all federal health care funds provided by the Department in the event the Department determined that there "appear[ed] to be a failure or threatened failure to comply" with the Proposed Rule or related statutes. *Id.* at 3931.

HHS received thousands of comments on the proposal, *see* 84 Fed. Reg. at 23,180, including comments from nineteen States, the District of Columbia, and the City of New York opposing the Proposed Rule and identifying shortcomings that are the subject of this challenge.[4] The proposal was also opposed by nearly every leading health care organization in the United States. For example, the American Medical Association explained that the proposal would "undermine patients' access to medical care and information, impose barriers to physicians' and

[3] All references in this memorandum to "Ex. __" are to the exhibits to the accompanying declaration of Matthew Colangelo (Dkt. 43).

[4] Ex. 53 (Comment Letter from Attorneys General of New York, *et al.*); Ex. 56 (Comment Letter from California Dep't of Justice); Ex. 64 (Comment Letter from N.Y. City Comm'n on Human Rights, *et al.*).

health care institutions' ability to provide treatment, impede advances in biomedical research, and create confusion and uncertainty among physicians, other health care professionals, and health care institutions about their legal and ethical obligations to treat patients."[5]

C. The Final Rule.

On May 21, 2019, the Department published the Final Rule, with an effective date of July 22, 2019. 84 Fed. Reg. at 23,170; *see* 84 Fed. Reg. 26,580 (June 7, 2019) (corrected publication date). The Final Rule is to be codified in several new subsections of 45 C.F.R. Part 88, relevant portions of which are described below.

Section 88.2 codifies new definitions of various terms, including:

- The Final Rule defines "assist in the performance" to mean "to take an action that has a specific, reasonable, and articulable connection to furthering a procedure," which "may include counseling, referral, . . . or otherwise making arrangements for the procedure . . . depending on whether aid is provided by such actions." *Id.* at 23,263.

- The Final Rule defines "discriminate or discrimination" to provide, among other requirements, that employers will need a "persuasive justification" to ask an employee if they are willing to perform an essential job function to which they might morally object, and places limits on how often an employer may ask; must depend on an employee's willingness to accept an accommodation to avoid discrimination, regardless of the reasonableness of such accommodation; and cannot use alternate staff to provide objected-to medical services if doing so would require "any" additional action by objecting staff members or would exclude those staff from any "fields of practice." *Id.*

- For purposes of the Coats-Snowe Amendment, "health care entity" is defined to include not only individual physicians and participants in health care training programs, but also any other health care personnel, provider, or facility, including pharmacists, pharmacies, medical laboratories, and research facilities; as well as—for purposes of the Weldon Amendment and Section 1553 of the Affordable Care Act—health insurance issuers, health insurance plans, and plan sponsors or third-party administrators. *Id.* at 23,264.

- The Final Rule defines "referral or refer for" to mean "the provision of information in oral, written, or electronic form . . . where the purpose or reasonably foreseeable outcome of provision of the information is to assist a person in receiving funding or financing for, training in, obtaining, or performing a particular health care service, program, activity, or procedure." *Id.*

[5] Ex. 51 (Comment Letter from Am. Med. Ass'n 1-7) (the "AMA Comment").

Section 88.3 identifies the nearly thirty statutory provisions that the Final Rule purports to implement. *Id.* at 23,264-69. Section 88.4 imposes new requirements that all applicants for and recipients of financial assistance must provide written assurances and certifications of compliance with those statutes as a condition of the approval, renewal, extension, or "continued receipt" of any financial assistance from the Department. *Id.* at 23,269 (§§ 88.4(a), (b)(5)).

Section 88.6 requires all recipients and their sub-recipients to maintain records of their compliance with the covered statutes; cooperate with any OCR investigation or compliance review, including by providing OCR with access to its books, records, facilities, and "other sources of information"; and disclose any OCR findings of noncompliance (including by any sub-recipient) in future applications for federal funds. *Id.* at 23,270-71.

Section 88.7 sets out the Final Rule's enforcement scheme. It provides that OCR may commence a compliance review or complaint investigation of any recipient if the Department "suspect[s]," based on any source, noncompliance with the Final Rule or any of the underlying statutes. *Id.* at 23,271 (§§ 88.7(c), (d)). If the Department determines that "there is a failure to comply" with any provision of the Final Rule or the statutes it implements, the Department may refer the matter to the Department of Justice for enforcement, or the Department may itself withhold, deny, suspend, or terminate federal funds. *Id.* at 23,271-72 (§§ 88.7(h), (i)(3), (j)).

The process for the Department to follow to effect compliance is described by reference to three disparate administrative procedures, each identified by way of non-exclusive example.[6] The Final Rule states that determinations of noncompliance may "be resolved by informal means," but expressly authorizes the Department to terminate a recipient's federal funds even

[6] 84 Fed. Reg. at 23,272 (§ 88.7(i)(3)) ("[C]ompliance . . . may be effected . . . 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).").

during the pendency of good-faith voluntary compliance efforts. *Id.* at 23,271-72 (§ 88.7(i)(2)). If the Department believes a recipient has "fail[ed] or refuse[d] to furnish an assurance or certification" required by § 88.4, the Department may suspend all HHS funding during any efforts at resolution and even before a finding of noncompliance. *Id.* at 23,272 (§ 88.7(j)).[7]

ARGUMENT

To obtain a preliminary injunction, Plaintiffs must establish that they are likely to suffer irreparable harm in the absence of preliminary relief; they are likely to succeed on the merits; the balance of the equities tips in their favor; and an injunction is in the public interest. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). In addition, the Administrative Procedure Act ("APA") authorizes courts "to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings." 5 U.S.C. § 705. The standard for a stay under § 705 is the same as the standard for a preliminary injunction. *See Texas v. EPA*, 829 F.3d 405, 435 (5th Cir. 2016); *Bauer v. DeVos*, 325 F. Supp. 3d 74, 104-05 (D.D.C. 2018).

I. The balance of equities and public interest strongly favor a preliminary injunction in light of the irreparable harm that Plaintiffs will suffer.

As this Court has recognized, "[a] showing of irreparable harm 'is the single most important prerequisite for the issuance of a preliminary injunction.'" *XL Specialty Ins. Co. v. Level Glob. Inv'rs, L.P.*, 874 F. Supp. 2d 263, 270 (S.D.N.Y. 2012) (quoting *Faiveley Transport. Malmo AB v. Wabtec Corp.*, 559 F.3d 110, 118 (2d Cir. 2009)). Plaintiffs need only show a "*threat* of irreparable harm, not that irreparable harm already [has] occurred."[8] *Mullins v. City of*

[7] Three additional sections of the Final Rule provide that the Department does not construe federal law to preempt state or local laws that are "equally or more protective of religious freedom," 84 Fed. Reg. at 23,272 (§ 88.8); direct that the Rule be given the broadest possible construction of religious freedom "to the maximum extent permitted," *id.* (§ 88.9); and provide for severability of each provision where permitted by law, *id.* (§ 88.10).

[8] Judicial review of agency action under the APA is ordinarily "based on the full administrative record that was before the Secretary at the time he made his decision." *Citizens to Pres. Overton Park v. Volpe*, 401 U.S. 402, 420 (1971). The Court may consider evidence outside the administrative record in determining whether Plaintiffs have

New York, 626 F.3d 47, 55 (2d Cir. 2010).

Plaintiffs are likely to suffer irreparable harm because the Final Rule: (1) forces Plaintiffs to choose between immediately making significant changes to their existing practices and procedures under a potentially unlawful regulation, or risking the loss of federal funds; (2) harms Plaintiffs' health institutions and impairs their direct delivery of health care; and (3) interferes with Plaintiffs' administration of their laws. By contrast, the Department will suffer no comparable prejudice from an injunction. An injunction would simply preserve the status quo, under which the relevant federal statutes and existing regulatory regime will continue to apply to Plaintiffs and other regulated entities and thus provide meaningful conscience protections.

A. The Final Rule irreparably harms Plaintiffs through a "Hobson's choice": make substantial changes to comply with a harmful and potentially unlawful regulation, or risk losing critical funds necessary to protect the public health.

The Final Rule meaningfully alters the status quo established by Congress's carefully tailored conscience-protection statutes and will thus require significant changes by Plaintiffs and other health care providers. To compel these changes, the Final Rule includes broad compliance requirements and enforcement authority that would authorize the Department to withhold, deny, suspend, or terminate Plaintiffs' receipt of federal funds if the Department believes "there is a failure to comply" with the Final Rule or any statute it purports to implement. 84 Fed. Reg. at 23,269-72 (§§ 88.4, 88.6, 88.7).

Yet as described in Part II below, the Final Rule is unlawful in many ways. Plaintiffs are thus faced with the choice of either incurring extensive compliance costs and threatening patient health by reorienting their entire health care sectors around an unlawful regulation, or risking the imminent loss of billions of dollars in health care funds for their states and localities.

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established irreparable harm for purposes of this preliminary injunction motion. *See E. Bay Sanctuary Covenant v. Trump*, 354 F. Supp. 3d 1094, 1106 (N.D. Cal. 2018).

Placing Plaintiffs on the horns of this dilemma causes irreparable harm that warrants preliminary injunctive relief: "[A]ny of the courses of action [Plaintiffs] might take . . . — accepting the grant and changing [their] policies; accepting the grant without changing [their] policies at risk of sanction; or foregoing the funds—all cause[] [Plaintiffs] irreparable harm." *City of Phila. v. Sessions*, 309 F. Supp. 3d 289, 340 (E.D. Pa. 2018), *vacated in part on other grounds*, 916 F.3d 276 (3d Cir. 2019).[9]

1. The first course of action—coming into compliance with the Final Rule—would require Plaintiffs to change a wide range of policies and practices prior to the Final Rule's effective date.[10] For example, certain requirements of New York's Public Health Law are implicated by the Final Rule—including informed consent regarding end-of-life care—and New York's Department of Health will need to expend significant resources amending internal guidance and retraining its staff to know when these violations of state law are no longer enforceable in light of the Final Rule. *See* Ex. 48 (Zucker Decl.) ¶¶ 64-66, 181-84. Other Plaintiffs will face similar burdens.[11]

In addition, Plaintiffs must make additional and daunting policy changes to address the separate risk that they may face enforcement efforts by the Department based on the actions of

[9] *Accord City of Phila. v. Sessions*, 280 F. Supp. 3d 579, 657 (E.D. Pa. 2017); *Cty. of Santa Clara v. Trump*, 250 F. Supp. 3d 497, 537 (N.D. Cal. 2017); *City of Chicago v. Sessions*, 264 F. Supp. 3d 933, 950 (N.D. Ill. 2017). This line of decisions applies to the context of federal funding the "well established" principle that "'[w]hen an alleged deprivation of a constitutional right is involved . . . no further showing of injury is necessary' to obtain a preliminary injunction." *Airbnb, Inc. v. City of New York*, No. 18 Civ. 7712 (PAE), 2019 WL 91990, at *23 (S.D.N.Y. Jan. 3, 2019) (quoting *Mitchell v. Cuomo*, 748 F.2d 804, 806 (2d Cir. 1984)).

[10] Resources expended by Plaintiffs to come into compliance with the Final Rule prior to its effective date themselves constitute harm warranting injunctive relief. Plaintiffs cannot recover a monetary award for these lost resources, as money damages are not available under the APA, *County of Suffolk v. Sebelius*, 605 F.3d 135, 140-41 (2d Cir. 2010), and sovereign immunity precludes monetary recovery against the Department on Plaintiffs' constitutional claims, *see FDIC v. Meyer*, 510 U.S. 471, 475 (1994).

[11] *See, e.g.*, Ex. 1 (Adelman Decl.) ¶ 13 (restructuring New Jersey Medicaid billing systems); Ex. 13 (Daly Decl.) ¶ 21 (revising conscience objection policy at Newark's University Hospital); Ex. 46 (Wagaw Decl.) ¶ 18 (Chicago's drafting of new policy and procedure to investigate employee complaints involving religious objections); *see also* Ex. 5 (Allen Decl.) ¶¶ 22, 33; Ex. 22 (Hedges Decl.) ¶ 8; Ex. 26 (Kunkel Decl.) ¶ 17; Ex. 35 (Oliver Decl.) ¶¶ 10-11.

sub-recipients. New York passes HHS funds to nearly a thousand sub-contractors based on a model contract it modifies by recipient; it must now review the model, identify among executed contracts those likely to cover areas of objection, determine whether any contract provisions conflict with the Final Rule, and modify contracts accordingly. *Id.* ¶¶ 185-86. Similarly, New Jersey must take steps to ensure compliance of more than 120 sub-contractors providing group homes to developmentally disabled adults, as well as draft and disseminate guidance documents to its roughly 630 other funding recipients and sub-recipients. *See* Ex. 1 (Adelman Decl.) ¶¶ 10-11; Ex. 15 (Elnahal Decl.) ¶ 15. Other Plaintiffs face the same burden.[12]

Moreover, every grantee in the chain of federal funding would either need to review and alter its existing contracts with subsequent grantees, enact burdensome compliance monitoring procedures, or both. For example, Illinois's Department of Public Health sub-grants several million dollars in HHS funds to the Chicago Department of Public Health and Cook County Health and Hospitals System. Ex. 17 (Ezike Decl.) ¶¶ 8-9, 28; Ex. 46 (Wagaw Decl.) ¶ 7; Ex. 39 (Shannon Decl.) ¶ 9. Chicago and Cook County then sub-grant some of that HHS funding to various agencies. Ex. 46 (Wagaw Decl.) ¶ 9-10. Thus, Illinois would not only have to monitor Chicago and Cook County, but also all of Chicago and Cook County's sub-grantees—because any alleged violation by a sub-grantee would ripple up the funding chain to Illinois as a grantor. This monitoring will be enormously burdensome; and several Plaintiffs already are struggling to develop feasible methods of ensuring the compliance of their sub-contractors alone.[13]

[12] For example, the Illinois Department of Public Health will be required to reconfigure current grants to sub-grantees and revise its compliance monitoring in areas that include contraception, STI testing, pregnancy counseling, HIV/AIDS treatment, and pre-exposure prophylaxis. Ex. 17 (Ezike Decl.) ¶¶ 33-39, 49-51; *see also* Ex. 21 (Greenbaum Decl.) ¶ 77; Ex. 30 (Macomber Decl.) ¶ 14; Ex. 35 (Oliver Decl.) ¶ 12; Ex. 41 (Stevens Decl.) ¶ 6; Ex. 44 (Turnage Decl.) ¶¶ 13-14.

[13] Chicago's Department of Public Health—which is now developing a complaint policy and procedure for its workforce for religious or moral objections—is struggling to develop any reasonable way to monitor, enforce, and

2. The alternative to undertaking extensive efforts to change each Plaintiff's policies—namely, "accepting the grant without changing its policies at risk of sanction," *City of Phila.*, 309 F. Supp. 3d at 340—presents an equally imminent risk of irreparable harm. *Id.*; *see also Cty. of Santa Clara*, 250 F. Supp. 3d at 538. The Department's own recent actions make clear that this risk is not speculative: one Plaintiff, the State of Illinois, is now the subject of an investigation OCR commenced six months ago regarding allegations that it "has violated the conscience rights of health care providers or has discriminated against them on the basis of religion."[14] Ex. 17 (Ezike Decl.) ¶¶ 52-57 & Attach. B. Further, one of Illinois's sub-recipients of HHS funds, Winnebago County, is now the subject of a separate OCR investigation commenced less than three months ago regarding allegations that the County discriminated against a former employee. Ex. 32 (Martell Decl.) ¶¶ 9-15 & Attach. C. And any sanction would have a trickle-down effect: should OCR take action against Illinois based on alleged non-compliance, the City of Chicago and Cook County could in turn lose sub-grants they receive from Illinois.

The "risk of injury for non-compliance is not speculative" where the Department is already investigating certain Plaintiffs for purported non-compliance with grant conditions. *City of Phila.*, 280 F. Supp. 3d at 657. And the Final Rule states on its face that one of its central purposes is to facilitate enforcement actions by the Department against its federal funding recipients. *See* 84 Fed. Reg. at 23,178, 23,183, 23,263 (§ 88.1).

3. Finally, the third course of action available to Plaintiffs—foregoing federal health care

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train around the Final Rule as to its more than 150 contracts with 89 community-based subcontractors, which the City must rely upon for critical public health services. *See* Ex. 46 (Wagaw Decl.) ¶ 16; *see also* Ex. 9 (Brancifort Decl.) ¶¶ 9-11, 19, 22-24 (same challenges in Connecticut).

[14] Although OCR opened this investigation in December 2018, before the Final Rule was published, OCR demanded information from Illinois that extends beyond the State's compliance with the statutes regulated by the 2011 Rule then in effect, to include receipt of funds under any provision of the ACA (which was not regulated by the 2011 Rule). *See* Ex. 17 (Ezike Decl.) ¶¶ 52-57 & Attach. B. It is thus reasonable for Illinois and other Plaintiffs to conclude that the Final Rule only *increases* the risk and imminence of compliance efforts by the Department.

funds entirely—is no option at all. Plaintiffs rely upon billions in federal funds for a wide array of essential functions to promote and protect the health of their residents. These include:

- Medicare and Medicaid, administered through the State Plaintiffs, ensuring medical care for millions of low-income and elderly residents, *see* Ex. 1 (Adelman Decl.) ¶ 5; Ex. 5 (Allen Decl.) ¶ 8; Ex. 11 (Clark Decl.) ¶ 8; Ex. 20 (Forsaith Decl.) ¶¶ 7, 10; Ex. 33 (Miller Decl.) ¶¶ 14, 16-18; Ex. 38 (Rosen Decl.) ¶ 7; Ex. 44 (Turnage Decl.) ¶ 7; Ex. 47 (Zimmerman Decl.) ¶ 7; Ex. 48 (Zucker Decl.) ¶¶ 93-94;

- Maternal & Child Health Block Grants and other funds used to promote the health of women, infants, and children through SIDS and fetal alcohol syndrome prevention, lead and newborn hearing screenings, and pediatric vaccination, *see* Ex. 9 (Brancifort Decl.) ¶ 16; Ex. 15 (Elnahal Decl.) ¶ 9; Ex. 17 (Ezike Decl.) ¶¶ 25-29; Ex. 19 (Foley Decl.) ¶¶ 5-6; Ex. 20 (Forsaith Decl.) ¶ 8; Ex. 28 (Levine Decl.) ¶¶ 11-14;

- Funds to combat the opioid use epidemic and other substance use disorders, *see* Ex. 15 (Elnahal Decl.) ¶ 11; Ex. 20 (Forsaith Decl.) ¶¶ 7, 9; Ex. 28 (Levine Decl.) ¶ 28(vi); Ex. 40 (Sherych Decl.) ¶ 7; Ex. 44 (Turnage Decl.) ¶ 8;

- Family planning and contraception, *see* Ex. 2 (Alexander-Scott Decl.) ¶ 9; Ex. 10 (Charest Decl.) ¶¶ 3, 5; Ex. 17 (Ezike Decl.) ¶¶ 14-23; Ex. 35 (Oliver Decl.) ¶ 5; Ex. 37 (Rattay Decl.) ¶ 15; Ex. 42 (Swartz Decl.) ¶ 8;

- Health programs to treat and screen for arthritis, asthma, breast, cervical, and other cancers, and heart disease, *see* Ex. 2 (Alexander-Scott Decl.) ¶ 8; Ex. 9 (Brancifort Decl.) ¶ 15; Ex. 17 (Ezike Decl.) ¶¶ 14-23; Ex. 28 (Levine Decl.) ¶ 14;

- Medical services to residents with HIV, including medication to low-income residents and support services to assist with treatment compliance, *see* Ex. 5 (Allen Decl.) ¶ 8; Ex. 7 (Anderson Decl.) ¶ 8; Ex. 15 (Elnahal Decl.) ¶¶ 7-8; Ex. 17 (Ezike Decl.) ¶¶ 33-35;

- Funds for bioterrorism and Ebola preparedness, and other disaster response, *see* Ex. 28 (Levine Decl.) ¶¶ 14, 28(ii), 28(iv); Ex. 35 (Oliver Decl.) ¶ 7; Ex. 46 (Wagaw Decl.) ¶ 6;

- Student health services at university campuses, including vaccinations, HIV/STD prevention, contraception, and abortion referrals, *see* Ex. 24 (Hirata Decl.) ¶¶ 5-7; Ex. 34 (Nichols Decl.) ¶¶ 5-7; and

- Biomedical and health-related research, education, and training funds to universities, *see* Ex. 22 (Hedges Decl.) ¶ 6; Ex. 23 (Herbst Decl.) ¶¶ 13-14; Ex. 29 (Lucchesi Decl.) ¶ 7.

Irreparable harm is shown where Plaintiffs "currently must choose either to attempt to comply" with the Final Rule, "which they allege[] is unconstitutional . . . , or to defy [it] and risk losing hundreds of millions of dollars in federal grants." *Cty. of Santa Clara*, 250 F. Supp. 3d at 538.

B. The Final Rule harms Plaintiffs' health institutions and their direct delivery of health care.

The Final Rule also threatens irreparable harm to Plaintiffs' health institutions and their ability to deliver effective patient care by disrupting carefully-designed staffing and personnel practices in ways that will undermine effectiveness and threaten patient well-being, especially in emergency, rural, and end-of-life settings.

1. Many of the Plaintiffs directly operate (or fund through sub-grants) hospitals and health clinics that collectively serve millions of patients every year—from major metropolitan communities served by New York City Health + Hospitals ("NYC H+H"), the largest public health care system in the country, to the remote rural populations served by the State of Hawai'i's public hospital system, the Hawaii Health Systems Corporation. Ex. 5 (Allen Decl.) ¶ 4; Ex. 38 (Rosen Decl.) ¶¶ 6, 8; *see also* Ex. 25 (Hunter Decl.) ¶¶ 5-6; Ex. 39 (Shannon Decl.) ¶ 5; Ex. 45 (Vanden Hoek & Perna Decl.) ¶¶ 5-8.

Plaintiffs' health institutions are committed to providing outstanding and ethical patient care while accommodating the religious beliefs of their employees. To accomplish these objectives, and consistent with existing statutory conscience protections, many of Plaintiffs' institutions have developed and implemented policies that address employees' religious objections.[15] These policies are tailored to comply with applicable laws in their respective jurisdictions but share a number of common features. These include that: (1) an employee making an objection on religious or moral grounds must state it to the employer in writing, in advance of the objected-to activity; (2) an employee may not object in real time or abandon a

[15] *See, e.g.*, Ex. 5 (Allen Decl.) ¶¶ 10-19; Ex. 13 (Daly Decl.) ¶¶ 11-12; Ex. 16 (Eshghi Decl.) ¶¶ 9-10; Ex. 23 (Herbst Decl.) ¶¶ 15-22; Ex. 25 (Hunter Decl.) ¶¶ 11-15; Ex. 29 (Lucchesi Decl.) ¶¶ 8-12; Ex. 39 (Shannon Decl.) ¶ 11; Ex. 45 (Vanden Hoek & Perna Decl.) ¶¶ 12-13; *see also* Ex. 4 (Alfredo Decl.) ¶ 9.

patient in need; and (3) an employee could face discipline for failing to abide by these notice requirements.[16] *See, e.g.*, Ex. 5 (Allen Decl.) ¶¶ 10-19; Ex. 13 (Daly Decl.) ¶ 11; Ex. 16 (Eshghi Decl.) ¶¶ 9-10; Ex. 29 (Lucchesi Decl.) ¶¶ 9-10, 12. The notice required by Plaintiffs' institutions is essential to their staffing decisions and the effectiveness of their overall operations, because it allows them to accommodate employees' objections while ensuring that patient care is uninterrupted. *See* Ex. 4 (Alfredo Decl.) ¶ 10; Ex. 5 (Allen Decl.) ¶¶ 15-19; Ex. 25 (Hunter Decl.) ¶ 16; Ex. 29 (Lucchesi Decl.) ¶ 11.

2. The Final Rule upends the careful balances struck by Plaintiffs' institutions. In particular, the Final Rule's definitions of the terms "discrimination," "health care entity," and "assist in the performance" will—in the judgment of experienced leadership at Plaintiffs' institutions across the country—dramatically expand the scope and coverage of federal conscience protections, requiring extreme departures from existing practice and immediately threatening Plaintiffs' delivery of effective patient care.

The definition of "discrimination," as Plaintiffs' institutions understand it, sets the following parameters with regard to their employees:

- Plaintiffs may not inquire, prior to hiring an applicant, if a religious objection would prevent the applicant from performing core duties or responsibilities of the position sought, *see* 84 Fed. Reg. at 23,263 (definition of "Discriminate," at ¶ 5);
- Once an employee is hired, Plaintiffs may inquire about that employee's religious objections no more frequently than once per calendar year (absent an undefined "persuasive justification"), *id.* (Discriminate ¶ 5);
- An employee is free to refuse to provide care to a patient based on a religious or moral objection—even if the employee provides no advance notice and instead objects at the

[16] Plaintiffs' policies also incorporate, implicitly or explicitly, an evaluation of the feasibility of an employee's requested accommodation. This evaluation is essential both to operating a financially sustainable public hospital system and to providing seamless patient care at complex institutions with multiple professionals staffed to work together to meet the required standard of care. *See* Ex. 5 (Allen Decl.) ¶ 19; Ex. 38 (Rosen Decl.) ¶ 13, *see also* Ex. 4 (Alfredo Decl.) ¶¶ 6, 15; Ex. 8 (Boyle Decl.) ¶ 13; Ex. 31 (Madara Decl.) ¶ 10 (AMA Code of Medical Ethics demands balancing physician's beliefs with patient needs).

moment care is being sought by a patient—and in such a case, Plaintiffs' institutions would be at risk of noncompliance with the Final Rule if they disciplined, terminated, or took any adverse action against that employee, *see id.* (Discriminate ¶¶ 1-3, 5);

- Any steps Plaintiffs take to use alternate staff to provide objected-to medical services are impermissible if those steps exclude the objecting employee from a "field[] of practice" or require "any" additional action by that employee, *id.* (Discriminate ¶ 6); and

- Any accommodation Plaintiffs' institutions offer to an objecting employee must be voluntarily accepted, and in the event the employee rejects the accommodation, our institutions may not reassign the employee or replace her with another qualified employee no matter how reasonable the accommodation, *see id.* (Discriminate ¶ 4).

See generally Ex. 5 (Allen Decl. ¶¶ 20-22); Ex. 18 (Flotte Decl.) ¶¶ 16-17; Ex. 23 (Herbst Decl.) ¶¶ 23-26; Ex. 29 (Lucchesi Decl.) ¶¶ 13-16; Ex. 45 (Vanden Hoek & Perna Decl.) ¶¶ 16-18.

At the same time, the Final Rule's expansion of the term "health care entity," as well as its definition of "assist in the performance," vastly increases both the universe of Plaintiffs' employees who may object, and the services those employees may object to providing. *See* 84 Fed. Reg. at 23,263-64 (§ 88.2). The new definition of "health care entity" expands the coverage of the applicable statutes to include, among other categories, all "health care personnel . . . or any other health care provider or health care facility." *Id.* at 23,264. And in addition to skilled professionals reasonably understood to "assist in the performance" of a medical procedure, the Final Rule now extends to individuals who "otherwise make[] arrangements for the procedure . . . depending on whether aid is provided by such actions"—a sweeping definition that appears to include clerical employees like front desk receptionists, clerks who input insurance information, and transport aides who move a patient from one place to another. *Id.* at 23,263.

The Final Rule thus dramatically expands who can object and what they can object to, while curtailing Plaintiffs' ability to make alternate arrangements when objections arise. This is a tremendous departure from existing practice at Plaintiffs' institutions, and will wreak havoc on

Plaintiffs' ability to plan for effective patient care.[17] Several of Plaintiffs' institutions have begun discussions and attempts to make contingency plans for double- or triple-staffing departments; but given budget constraints and limits imposed by both collective bargaining agreements and privacy regulations, it is unclear if their institutions can feasibly manage the risk presented by the Final Rule at all, or at least without cutting other essential hospital functions.[18]

3. These disruptions will have particularly harmful consequences in the context of emergency medical services, rural health care settings, and end-of-life care.

Many of Plaintiffs' institutions provide emergency care. Staffing decisions are crucial in emergency settings (such as emergency room shifts) where a hospital's staffing may be limited and patient care could be compromised by the unexpected unavailability of a single employee. *See, e.g.*, Ex. 5 (Allen Decl.) ¶¶ 26-30; Ex. 13 (Daly Decl.) ¶ 12; Ex. 25 (Hunter Decl.) ¶ 16; Ex. 29 (Lucchesi Decl.) ¶¶ 11, 17-22; Ex. 39 (Shannon Decl.) ¶¶ 13-16; *see also* Ex. 31 (Madara Decl.) ¶¶ 16-21 (noting Final Rule's threat to patient safety).

In addition, because emergency care frequently includes areas of likely religious objection, the risk of disruption caused by the Final Rule is high. The Downstate Medical Center of the State University of New York ("SUNY Downstate") regularly treats women in its emergency room who are diagnosed with ectopic pregnancies—treatment for which some consider abortion. *See* Ex. 29 (Lucchesi Decl.) ¶¶ 10, 17-18. Twelve to sixteen individuals are

[17] *See, e.g.*, Ex. 5 (Allen Decl.) ¶¶ 19-22, 26-30; Ex. 16 (Eshghi Decl.) ¶¶ 13-14; Ex. 18 (Flotte Decl.) ¶ 18; Ex. 23 (Herbst Decl.) ¶¶ 23-29; Ex. 25 (Hunter Decl.) ¶¶ 17-22; Ex. 29 (Lucchesi Decl.) ¶¶ 13-16; Ex. 38 (Rosen Decl.) ¶¶ 11-16; Ex. 43 (Thomas Decl.) ¶¶ 9-11; Ex. 44 (Turnage Decl.) ¶ 12; Ex. 45 (Vanden Hoek & Perna Decl.) ¶¶ 19-25; *see also* Ex. 4 (Alfredo Decl.) ¶ 13; Ex. 31 (Madara Decl.) ¶ 13 (the Final Rule's "overly broad definitions" amount to a "reckless indifference to how medicine is practiced"); Ex. 36 (Prezant Decl.) ¶¶ 13-16.

[18] *See, e.g.*, Ex. 5 (Allen Decl.) ¶¶ 22-30; Ex. 13 (Daly Decl.) ¶¶ 14-16; Ex. 16 (Eshghi Decl.) ¶ 13; Ex. 18 (Flotte Decl.) ¶¶ 16-19; Ex. 23 (Herbst Decl.) ¶ 28; Ex. 29 (Lucchesi Decl.) ¶ 22; Ex. 38 (Rosen Decl.) ¶¶ 11-16; Ex. 39 (Shannon Decl.) ¶¶ 13-16, 25-26, 30; Ex. 43 (Thomas Decl.) ¶¶ 9-11; Ex. 45 (Vanden Hoek & Perna Decl.) ¶¶ 19-20; *see also* Ex. 14 (Dineen Decl.) ¶ 82; Ex. 21 (Greenbaum Decl.) ¶ 75.

involved in providing that care, with no extra staff to perform each function, and an objection by any of those staff would jeopardize patient safety. *Id.* ¶¶ 19-21. Similarly, a woman who arrives at an NYC H+H emergency room with a miscarriage—treatment for which some consider an abortion—would encounter at least fifteen individuals during her course of treatment. Ex. 5 (Allen Decl.) ¶¶ 26-29. Because NYC H+H operates under "enormous budgetary constraints and does not have additional staff to perform essential functions required for a patient experiencing an emergency," an objection by any of those staff would compromise patient care. *Id.* ¶ 27.

The Final Rule also presents extreme risks and unworkable situations in ambulatory emergency services. The Final Rule's definition of "assist in the performance" includes ambulatory Emergency Medical Technicians ("EMTs") and paramedics. *See* 84 Fed. Reg. at 23,263 (§ 88.2); *id.* at 23,188. A number of Plaintiffs' institutions operate vehicular and helicopter fleets or contribute to fleets for the emergency response systems in their jurisdictions. *See, e.g.*, Ex. 2 (Alexander-Scott Decl.) ¶ 18; Ex. 7 (Anderson Decl.) ¶¶ 10, 12. The sole responsibility of drivers, pilots, and EMTs is to keep a patient alive en route to a hospital, yet Plaintiffs face an impossible choice: either (1) require employees to aid all patients without exception, regardless of objection and in possible violation of the Final Rule, or (2) permit real-time objection and possibly compromise the safety of a patient in need of emergency aid and transportation.[19] *See* Ex. 2 (Alexander-Scott Decl.) ¶ 18; Ex. 7 (Anderson Decl.) ¶¶ 10, 12-13, 15-16.[20] Irreparable harm is established where the Final Rule "will directly compromise

[19] Double-staffing is not an option because vans and helicopters typically lack the physical space necessary to allow for backup personnel. *See* Ex. 4 (Alfredo Decl.) ¶ 12.

[20] Further, emergency response systems in some of Plaintiffs' jurisdictions draw upon many different employers in order to ensure a rapid response. In New York City, the Fire Department ("FDNY") manages calls to the 911 system and dispatches ambulances from both FDNY and private fleets. Ex. 36 (Prezant Decl.) ¶¶ 6-8. FDNY does not currently have a policy to address religious objections in the provision of emergency medical services, because its drivers and EMTs cannot make exceptions to their protocols for care consistent with their professional and ethical

providers' ability to deliver effective care and force them to obstruct and delay patients with pressing medical needs." *California v. Azar*, No. 19-cv-1184, 2019 WL 1877392, at *8-11 (N.D. Cal. Apr. 26, 2019).

Plaintiffs' health institutions in rural settings also face imminent harm to their provision of care. The Hawaii Health Systems Corporation, for example, services rural and remote geographic areas across Hawai'i. *See* Ex. 38 (Rosen Decl.) ¶ 8; Ex. 43 (Thomas Decl.) ¶ 9. Some of its hospitals have only one physician on duty; and due to a shortage of skilled health care workers and the long distances required to commute to rural providers, it is difficult for the Corporation to substitute employees rapidly in the event of a sudden staffing gap. *See* Ex. 38 (Rosen Decl.) ¶¶ 11-13; Ex. 43 (Thomas Decl.) ¶ 10. When the Final Rule takes effect, Hawai'i and other states with large rural areas will immediately face the risk that an employee may object to providing care without notice, undermining their ability to meet their ethical obligations and standard of care. *See* Ex. 7 (Anderson Decl.) ¶¶ 18-19; Ex. 38 (Rosen Decl.) ¶¶ 11-13; Ex. 43 (Thomas Decl.) ¶¶ 9-13.[21] Irreparable harm is established where the Final Rule "will compound an already severe crisis in physician and nurse practitioner availability." *California*, 2019 WL 1877392, at *10 (internal quotation marks omitted); *see also Oregon v. Azar*, No. 19-cv-317, 2019 WL 1897475, at *15 (D. Or. Apr. 29, 2019).[22]

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duties. *Id.* ¶ 9. When considering the number of private providers who also contribute ambulances to multi-party systems, it is unclear to Plaintiffs how any of them can operate a multi-party emergency response system in compliance with the Final Rule. *See id.* ¶¶ 12-17; *see also* Ex. 4 (Alfredo Decl.) ¶¶ 11-12.

[21] *See also* Ex. 6 (Andazola Decl.) ¶ 8 (doctor shortages in rural New Mexico); Ex. 30 (Macomber Decl.) ¶¶ 14-16 (single providers for regions of rural Michigan); Ex. 41 (Stevens Decl.) ¶ 7 (nurse shortages in rural Minnesota); *see generally* Ex. 3 (Alfero Decl.) ¶¶ 7-15 (describing challenges to providing care in rural New Mexico); Ex. 31 (Madara Decl.) ¶ 22 (noting unique vulnerability of providers who practice in small medical offices).

[22] The Final Rule's harm to public health in Plaintiffs' rural areas is not limited to the emergency setting. In many regions of Oregon, there are a limited number of potential providers for both primary and specialty care. *See* Ex. 12 (Coyner Decl.) ¶ 14. The state's Oregon Health Plan, a managed care structure, delivers care by contracting with Coordinated Care Organizations ("CCOs") that in turn contract with providers who, as Plaintiffs understand the Final Rule, would fall under the definition of "health care entity." *Id.* ¶¶ 10-13. Oregon's contract with its CCOs

The Final Rule also causes irreparable harm to Plaintiffs in the end-of-life care setting. As noted, the Final Rule requires Plaintiffs' institutions to prepare for an employee permissibly objecting to assisting in a medical procedure in real time, including the removal of life-sustaining treatment. For example, religious objections have occurred in SUNY Downstate's intensive care unit and emergency room in connection with procedures that involve removing life-sustaining treatment, like extubating a terminally-ill patient. *See* Ex. 29 (Lucchesi Decl.) ¶ 23. Under the notice regime SUNY Downstate has had in place for years, the hospital has planned and staffed to accommodate these doctors who provided advance notice. *See id.*

Following the Final Rule's effective date, SUNY Downstate and Plaintiffs' other institutions face the choice of either incurring the expense of double-staffing functions to avoid interruptions to end-of-life care, or risking harm to a patient or her loved ones if an employee objects to assisting in the removal of life support at the time the procedure is set to occur. An attending physician, nurse, or resident who objects to the removal of life support—when a Plaintiff lacks notice and has not staffed for a replacement—risks extending the life of a patient whose representatives have made the arduous decision to allow the patient to die, while inflicting dignitary harms upon loved ones present for a scheduled end-of-life procedure. *See id.* ¶ 24.

The Final Rule thus causes irreparable harm to Plaintiffs through the disruption of their staffing policies and other carefully-coordinated operational practices, with particular injury in the emergency, rural, and end-of-life settings. *See Mayor & City Council of Baltimore v. Azar*, No. 19-cv-1103, 2019 WL 2298808, at *12 (D. Md. May 30, 2019); *Oregon*, 2019 WL 1897475, at *15; *California*, 2019 WL 1877392, at *10-13. Further, even one incident involving the

requires them to find an alternate provider in the event a contracted provider refuses to provide care to a health plan member. *Id.* ¶ 14. In remote areas, the limited number of providers makes it difficult if not impossible to find such an alternate health provider, likely leading to disruptions of care, increased costs to the state, or both. *Id.* ¶¶ 14-16.

harms described above risks compromising the reputation of Plaintiffs' institutions and the trust they have worked to build with their communities. Ex. 29 (Lucchesi Decl.) ¶ 27; Ex. 46 (Wagaw Decl.) ¶ 19; *see also* Ex. 31 (Madara Decl.) ¶¶ 12(c), 23-25. A risk of reputational injury constitutes irreparable harm. *See City of Chicago*, 264 F. Supp. 3d at 950.

C. The Final Rule interferes with Plaintiffs' administration of their insurance laws and threatens the health of their residents.

The Final Rule also irreparably harms Plaintiffs by interfering with the administration of their insurance coverage laws, specifically with respect to coverage for time-sensitive medical procedures. A number of Plaintiffs require insurers to provide coverage for contraception (including emergency contraception) and medically necessary abortions. *See* Compl. ¶¶ 117(a)–117(o) (Dkt. 3); *see also* Ex. 27 (Lacewell Decl.) ¶¶ 5-6; Ex. 39 (Shannon Decl.) ¶ 11. These requirements reflect the view that access to legal methods of birth control results in healthier residents and promotes the public health of our states.[23] Ex. 27 (Lacewell Decl.) ¶ 7.

The Final Rule interferes with Plaintiffs' administration of these insurance laws. The Final Rule expands the Weldon Amendment's definition of the term "health care entity" to include a "plan sponsor," 84 Fed. Reg. at 23,264 (§ 88.2), which effectively allows *any* employer who sponsors an insurance plan to object to providing coverage for services like contraception and medically necessary abortion. Ex. 27 (Lacewell Decl.) ¶ 11. It is likely that, upon the effective date of the Final Rule, a significant number of employers will object to providing such coverage—a likelihood supported by enforcement actions announced last month by regulators in

[23] It is likely that some will improperly attempt to invoke the Final Rule to avoid state laws that require insurance coverage of contraception (including Vermont's, *see* Vt. Stat. Ann. tit. 8, § 4099c, and New York's, *see* N.Y. Ins. Law § 3221(1)(16) (eff. Jan. 1, 2020)), or that require emergency rooms to dispense emergency contraception to survivors of sexual assault (including New York's, *see* N.Y. Pub. Health Law § 2805-p), even though contraception is not abortion and thus not covered by provisions in the Final Rule referring to abortion. *See, e.g.*, *Real Alts., Inc. v. Sec'y Dep't of Health & Human Servs.*, 867 F.3d 338, 353-54 & n.15 (3d Cir. 2017); *see also* Ex. 27 (Lacewell Decl.) ¶ 12 (noting that some individuals view forms of contraception as abortion or equivalent to abortion).

Plaintiff New York. *See id.* ¶¶ 9-10, 12. This outcome would cause irreparable harm to Plaintiffs by diverting state funds as an alternative to insurer-provided contraceptives. *See* Ex. 42 (Swartz Decl.) ¶ 18; Ex. 48 (Zucker Decl.) ¶ 84; *see also California v. Health & Human Servs.*, 351 F. Supp. 3d 1267, 1297 (N.D. Cal. 2019) ("*HHS*").

Furthermore, in the likely event that plan sponsors object to providing coverage for abortion, New York's insurance regulator—the Department of Financial Services ("DFS")—will be compelled when the Final Rule takes effect to locate insurers willing to provide abortion and contraception coverage for affected employees to purchase, which will be difficult or impossible to achieve due to adverse selection market failure. *See* Ex. 27 (Lacewell Decl.) ¶ 16. The Final Rule thus inhibits DFS's enforcement of New York's regulation requiring insurance coverage for medically necessary abortions.[24] *Id.*

The Final Rule's interference with Plaintiffs' administration of their insurance laws will therefore cause irreparable harm that warrants preliminary injunctive relief. *See HHS*, 351 F. Supp. 3d at 1297; *see also Oregon*, 2019 WL 1897475, at *15.

D. The balance of equities and public interest favor preliminary injunctive relief.

To obtain preliminary relief, Plaintiffs must also show that the balance of the equities tips in their favor, and that an injunction is in the public interest. *Winter*, 555 U.S. at 20. When the

[24] In addition, likely objections by employers will place immediate burdens on state insurance regulators. For example, in response to anticipated objections, the New York State DFS is obligated to review riders submitted by insurers (at the request of plan sponsors) to alter coverage mid-policy year. *See* Ex. 27 (Lacewell Decl.) ¶ 13. DFS has historically refused to approve such mid-year changes, but the Final Rule appears to provide that such a denial would run afoul of the Final Rule, and DFS will be forced to alter its policy and permit riders to eliminate coverage. *See id.* ¶¶ 14-15. Separately, in areas where insurance coverage is provided on a managed care model, allowing providers to opt out of covered procedures will affect contracted payment rates. Oregon's Medicaid program is structured in this way, relying on fixed price contracts between the State/insurers, and insurers/providers. *See* Ex. 12 (Coyner Decl.) ¶¶ 10-12. Failure to provide covered services disrupts capitation contracts, and loss of providers increases costs and risks in coordinated care coverage for whole regions—changing the financial risk structure of Oregon's program, and leaving gaps in care for vulnerable residents on an entire plan basis. *Id.* ¶¶ 13-14.

federal government is a party, these factors merge. *Nken v. Holder*, 556 U.S. 418, 435 (2009).

The balance of the equities and public interest tip sharply in Plaintiffs' favor. If implemented, the Final Rule will cause Plaintiffs grave harm by forcing them either to undertake costly and time-consuming changes to their laws and policies (that already protect conscience rights), accept grant funds at risk of onerous sanctions, or forego federal health care funds entirely. By contrast, the Department will suffer no harm—an injunction would simply preserve the status quo, under which the relevant federal statutes will continue to apply, as the Department has itself long recognized. *See* 76 Fed. Reg. at 9970, 9975 ("[N]one of these statutory provisions require promulgation of regulations for their interpretation or implementation.").

In addition, the public interest is better served if Plaintiffs are not forced to choose between foregoing grant funds and implementing their carefully-balanced health care policies and laws. *Cf. City of Phila.*, 280 F. Supp. 3d at 658. Moreover, given Plaintiffs' likelihood of success on the merits, *see infra* Part II, "there is a substantial public interest in 'having government agencies abide by the federal laws that govern their existence and operations.'" *League of Women Voters v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016) (quoting *Washington v. Reno*, 35 F.3d 1093, 1103 (6th Cir. 1994)). By contrast, "[t]here is generally no public interest in the perpetuation of an unlawful agency action." *Id.* at 12.

II. Plaintiffs are likely to succeed on the merits of their claims.

A. The Final Rule violates the Administrative Procedure Act.

The APA provides that courts must "hold unlawful and set aside" agency action that is "in excess of statutory jurisdiction, authority, or limitations"; that is "not in accordance with law"; or that is "arbitrary, capricious, [or] an abuse of discretion." 5 U.S.C. §§ 706(2)(A), (C), (D). The APA requires this Court to conduct "plenary review of the Secretary's decision." *Citizens to Pres. Overton Park v. Volpe*, 401 U.S. 402, 420 (1971). Plaintiffs are likely to

succeed on the merits of their claims because the Final Rule exceeds the Department's statutory authority, is not in accordance with law, and is arbitrary and capricious.

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

The Final Rule violates the APA because it is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C). In determining whether agency action exceeds statutory authority, "the question . . . is always whether the agency has gone beyond what Congress has permitted it to do." *City of Arlington v. FCC*, 569 U.S. 290, 297-98 (2013). Here, the Final Rule has impermissibly expanded the reach of congressional enactments by redefining key terms far beyond what Congress has permitted.

1. Health care entity. Three statutes that the Final Rule implements (the Coats-Snowe Amendment, the Weldon Amendment, and Section 1553 of the ACA) include express statutory definitions of the term "health care entity." The Final Rule exceeds the Department's authority by expanding these statutory texts to include entirely different individuals and entities not identified in the text Congress enacted. *See, e.g.*, *City of Phila. v. Attorney Gen. of the United States*, 916 F.3d 276, 284-91 (3d Cir. 2019).

In the Coats-Snowe Amendment, Congress stated that "[t]he 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." 42 U.S.C. § 238n(c)(2). The Final Rule redefines this term to include entire categories of individuals and entities not identified in the statutory definition, defining "health care entity" to mean:

> [A]n 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.

84 Fed. Reg. at 23,264 (§ 88.2). The Final Rule thus extends Coats-Snowe's application from a statutorily narrow class that focuses on physicians and those training in the health professions, to an expansive regulatory definition that includes nearly the entire health sector—including all "health care personnel . . . or any other health care provider or health care facility." *Id.*

The Weldon Amendment provides 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." Pub. L. No. 115-245, § 507(d)(2), 132 Stat. at 3118. Section 1553 of the ACA uses the same definition. 42 U.S.C. § 18113(b). But the Final Rule expands the definition of "health care entity" for Weldon Amendment and Section 1553 purposes to include—in addition to many of the overbroad categories described above—entities that are entirely outside the health profession, including health plan sponsors (typically employers), plan issuers (such as insurance companies), and third-party administrators (that perform claims processing and administrative tasks). *See* 84 Fed. Reg. at 23,264. Congress could not have intended the statutes' text to include entire classes of entities distinct from those listed in the statutes. *See Wash. State Dep't of Soc. & Health Servs. v. Guardianship Estate of Keffeler*, 537 U.S. 371, 384-85 (2003).

2. Assist in the performance. The Final Rule defines the term "assist in the performance" to mean "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," which "may include counseling, referral, training, . . . or otherwise making arrangements for the procedure . . . , depending on whether aid is provided by such actions." 84 Fed. Reg. at 23,263 (45 C.F.R. § 88.2). One of the statutes that the Final Rule implements—the Church Amendments—includes

"assist in the performance" within the scope of protected conduct. *See* 42 U.S.C. § 300a-7(b). The statute does not expressly define this term, and the context, structure, and legislative history of the provision make clear that the Final Rule has expanded its meaning far beyond what Congress provided. *See Fin. Planning Ass'n v. SEC*, 482 F.3d 481, 487 (D.C. Cir. 2017).

First, the Department exceeded its statutory authority by interpreting "assist in the performance" to include several terms that Congress omitted from the relevant statutory provisions—42 U.S.C. § 300a-7(b), (c), and (d)—despite their specific inclusion elsewhere in the Church, Coats-Snowe, and Weldon Amendments. Specifically, while Congress referred to "counsel[ing]" in a separate Church Amendment provision, 42 U.S.C. § 300a-7(e); "training" in the Coats-Snowe Amendment, 42 U.S.C. § 238n(a); and "refer[rals]" in the Weldon Amendment, Pub. L. No. 115-245, § 507(d)(2), 132 Stat. at 3118, it did not include any of these terms in § 300a-7(b), (c), or (d), which prohibit discrimination only on the basis of a refusal to "perform" or "assist in the performance" of a particular procedure. Congress's use of these terms in other related statutes makes clear that Congress knew how to draft legislation that would cover these activities in the health care conscience context when it wanted to. The Department has no authority to define a statutory term in a manner that Congress chose to forego.

Second, the Department's definition of "assist in the performance" is contrary to the common meaning of the words "assist" and "performance" and therefore exceeds the plain meaning of the statutory texts. Merriam-Webster defines "performance" as "the execution of an action" and "assist" as "to give support or aid."[25] The relevant provisions of the Church Amendments prohibit discrimination on the ground of refusal to "perform or assist in the

[25] *Performance*, Merriam-Webster Dictionary, https://www.merriam-webster.com/dictionary/performance; *Assist*, Merriam-Webster Dictionary, https://www.merriam-webster.com/dictionary/assist.

performance of" a specified procedure such as abortion or sterilization. 42 U.S.C. § 300a-7(c); *see also id.* § 300a-7(b), (d). The statute therefore proscribes discrimination on the ground of refusal to execute a specified procedure, or to give support or aid in the execution of a particular procedure. Had Congress intended for the Church Amendments to apply to all ancillary conduct that "further[s] a procedure," *see* 84 Fed. Reg. at 23,263 (§ 88.2), it would have used that term. Instead, Congress used the term "performance," which necessarily limits the scope of the statute to the medical execution of the procedure or to conduct that provides support or aid to such medical execution.

Third, legislative history confirms that the Final Rule's definition of "assist in the performance" would extend the Church Amendments far beyond what Congress intended. As Senator Church explained, the Church Amendments were "meant to give protection to the physicians, to the nurses, to the hospitals themselves, if they are religious affiliated institutions. . . . There is no intention here to permit a frivolous objection from someone unconnected with the procedure to be the basis for a refusal to perform what would otherwise be a legal operation." 119 Cong. Rec. 9597 (Mar. 27, 1973) (statement of Sen. Church). But the Final Rule extends the reach of the Church Amendments beyond this tailored approach to cover not just individuals who perform a procedure, but instead to cover *anyone* taking *any* action with an "articulable connection" to a procedure—including the scheduler who keeps the calendar. 84 Fed. Reg. at 23,186-87. By defining "assist in the performance" so as to extend the Church Amendments in such a far-reaching manner, the Final Rule has exceeded the Department's statutory authority. *See ACA Int'l v. FCC*, 885 F.3d 687, 692, 697-99 (D.C. Cir. 2018).

3. Discriminate or discrimination. None of the statutes that are the subject of the Final Rule include a definition of the term "discrimination." The "ordinary meaning" of the term

"discriminates" is the "failure to treat all persons equally when no reasonable distinction can be found between those favored and those not favored." *CSX Transp., Inc. v. Ala. Dep't of Revenue*, 562 U.S. 277, 286 (2011) (quoting Black's Law Dictionary 534 (9th ed. 2009)). The Final Rule's lengthy and sweeping definition of "discrimination" exceeds the boundaries set in the statute by going beyond the ordinary meaning of that term. Specifically, the Final Rule imposes special restrictions on employers that compel favoring objecting employees at the expense of the safe and effective provision of health care services.

For example, the Final Rule provides that employers will need a "persuasive justification" to ask employees if they are willing to perform an essential job function to which they might object; cannot create an accommodation that excludes a staff member from her "field[] of practice"; and must depend on an employee's willingness to accept an accommodation to avoid discrimination, regardless of the reasonableness of such accommodation. 84 Fed. Reg. at 23,263 (§ 88.2). This definition appears to require that Plaintiffs' health care entities hire someone who cannot deliver health care services that are critical to the entity's mission, or risk sanction. Indeed, the Final Rule defines "discrimination" so broadly that it would in fact prohibit reasonable accommodations for religious practices and instead "command[] that . . . religious concerns automatically control over all secular interests at the workplace." *Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703, 709 (1985). This outcome—"impos[ing] on employers and employees an absolute duty to conform their business practices to the particular religious practices of the employee"—would likely violate the Establishment Clause. *Id.*

Where an administrative interpretation of a statute would raise serious constitutional questions, courts should construe the statute to avoid that problem where possible. *See Catskill Mountains Chapter of Trout Unlimited, Inc. v. EPA*, 846 F.3d 492, 517-18 (2d Cir. 2017). Here,

the Court should conclude that Congress did not intend this unconstitutional expansion of the term "discrimination" far beyond its ordinary meaning. *See New York v. U.S. Dep't of Justice*, 343 F. Supp. 3d 213, 227-38 (S.D.N.Y. 2018).

2. The Final Rule is not in accordance with law.

The APA provides that the Court shall "hold unlawful and set aside" agency action that is "not in accordance with law." 5 U.S.C. § 706(2)(A). The Final Rule is not in accordance with law in the four following respects.

a. The Final Rule violates the ACA Non-Interference Mandate.

In 2010, Congress acted to restrict the Department's ability to interfere with the provision of medical care by enacting Section 1554 of the Affordable Care Act—the ACA's "Non-Interference Mandate"—which directs that the Department:

> shall not promulgate any regulation that—
> (1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;
> (2) impedes timely access to health care services;
> (3) interferes with communications regarding a full range of treatment options between the patient and the provider;
> (4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions;
> (5) violates the principles of informed consent and the ethical standards of health care professionals; or
> (6) limits the availability of health care treatment for the full duration of a patient's medical needs.

42 U.S.C. § 18114. The Final Rule violates these proscriptions in multiple ways.

First, the Final Rule contravenes "the ethical standards of health care professionals," *id.* § 18114(5), by allowing health care providers to refuse to provide information regarding lawful medical services, including abortion and end-of-life care. The American Medical Association's Code of Ethics provides that medical professionals must "[p]resent relevant information accurately and sensitively, in keeping with the patient's preferences," and that "withholding

information without the patient's knowledge or consent is ethically unacceptable." AMA Code of Medical Ethics §§ 2.1.1(b), 2.1.3 (2016); *see also* Ex. 51 (AMA Comment 2). It further provides that patients have the right "[t]o receive information from their physicians and to have [the] opportunity to discuss the benefits, risks, and costs of appropriate treatment alternatives." AMA Code of Medical Ethics § 1.1.3(b). Rules of ethics that govern other health care professionals are to the same effect. *See, e.g.*, Ex. 52 (Comment Letter from Am. Nurses Ass'n 3-4) (quoting the Code of Ethics for Nurses).

The Final Rule would permit individual providers to violate these ethical standards by withholding relevant information and misrepresenting patient options. The Final Rule's broad definition of "assist in the performance" to include any actions that may provide "aid" in "furthering" a procedure—including *any* "provision of information" where an objected-to service is a "reasonably foreseeable outcome," 84 Fed. Reg. at 23,263-64—grants individuals a right to refuse to disclose ethically-required information about appropriate and medically-indicated services that goes far beyond what the statutes themselves provide. *See Oregon*, 2019 WL 1897475, at *12-14 (preliminarily enjoining a regulation that "appears to force medical providers to either drop out of the program or violate their codes of professional ethics," in violation of the ACA Non-Interference Mandate); *see also Mayor & City Council of Baltimore*, 2019 WL 2298808, at *8-9 (same); *California*, 2019 WL 1877392, at *23-26 (same).

Second, the Final Rule's creation of an overbroad right to withhold relevant information and misrepresent patient options violates the ACA Non-Interference Mandate by "creat[ing] . . . unreasonable barriers to the ability of individuals to obtain appropriate medical care," "imped[ing] timely access to health care services," "interfer[ing] with communications regarding a full range of treatment options between the patient and the provider," and "restrict[ing] the

ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions." 42 U.S.C. § 18114(1)–(4); *see California*, 2019 WL 1877392, at *24; *see also Mayor & City Council of Baltimore*, 2019 WL 2298808, at *8-9.

Third, the Final Rule further creates unreasonable barriers and impedes access to appropriate medical care in violation of the ACA Non-Interference Mandate, *see* 42 U.S.C. § 18114(1), (2), (6), by undermining Plaintiffs' ability to provide for the delivery of critical health care services in their institutions. As discussed in detail in Part I.B above, the Final Rule will interfere with the operations of Plaintiffs' health care systems and threaten the delivery of patient care—particularly in emergency, rural, and end-of-life care settings. *See supra* Part I.B. Because the Final Rule will "directly compromise providers' ability to deliver effective care," it violates the ACA Non-Interference mandate. *California*, 2019 WL 1877392, at *8-10, *22.

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

The Final Rule is also contrary to law because it conflicts with the Medicaid counseling and referral provisions it purports to implement. *See Friends of Richards-Gebaur Airport v. FAA*, 251 F.3d 1178, 1195 (8th Cir. 2001) ("[A]n agency implementing a statute may not ignore . . . a standard articulated in the statute."); *E. Bay Sanctuary Covenant v. Trump*, 349 F. Supp. 3d 838, 856-59 (N.D. Cal. 2018) (granting preliminary injunction where "the [r]ule flout[s] the explicit language of the statute").

The applicable statute provides that Medicaid managed care organizations are not required "to provide, reimburse for, or provide coverage of, a counseling or referral service if the organization objects to the provision of such service on moral or religious grounds," so long as any such policy is communicated to prospective enrollees. 42 U.S.C. § 1396u-2(b)(3)(B). The statute further provides, however, that with regard to informed consent, the counseling and

referral provision shall *not* "be construed to affect disclosure requirements under State law." *Id.*

Each of the Plaintiff States and the District of Columbia has enacted disclosure requirements that apply to precisely this issue. *See* Compl. ¶¶ 108(a)–108(t) (Dkt. 3). Yet the Final Rule includes no exception to or limit on a provider's counseling-or-referral refusal right to accord with these state-law requirements. *See* 84 Fed. Reg. at 23,266-67 (§ 88.3(h)(1)(ii), (h)(2)(ii)) (requiring "[a]ny State agency that administers a Medicaid program" to comply with the counseling or referral restriction with no exception for state-law disclosure requirements). And the Final Rule separately provides that it interprets federal law to impair the application of conflicting state laws unless those laws are "equally or more protective of religious freedom and moral convictions" than the Final Rule. *Id.* at 23,272 (45 C.F.R. § 88.8); *see also id.* at 23,223-26. The Final Rule thus obligates Plaintiffs to accommodate counseling or referral objections in their Medicaid programs even where those objections would violate state law.

c. The Final Rule violates the federal statutory guarantee of access to emergency medical care.

The Final Rule violates the Emergency Medical Treatment and Labor Act ("EMTALA"), 42 U.S.C. § 1395dd. EMTALA requires hospitals with an emergency room to provide medical screening and stabilizing treatment, or a medically beneficial transfer, to any individual experiencing an emergency medical condition. *Id.* § 1395dd(a)-(c).[26] The Final Rule creates significant obstacles to the effective delivery of emergency medical care, allowing the denial of emergency treatment in some circumstances. *See supra* Part I.B. For example, as the Department itself acknowledges, the Final Rule could permit a woman suffering an ectopic

[26] EMTALA defines the term "emergency medical condition" to include "a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy . . . ." 42 U.S.C. § 1395dd(e)(1)(A).

pregnancy to be denied emergency transportation on the ground that such activity could constitute "assisting in the performance" of an abortion. 84 Fed. Reg. at 23,188.[27] By reducing access to emergency care—including the contemplated denial of emergency treatment to a woman in the life-threatening situation of a ruptured ectopic pregnancy—the Final Rule violates EMTALA. 42 U.S.C. § 1395dd(a)-(c), (e)(1)(A).

In addition, by allowing religious refusals to impair the delivery of emergency medical services, the Department has also violated the underlying statutes the Final Rule purports to implement. The Weldon Amendment, for example, was not intended to extend to situations presenting the possibility of an emergency abortion; Representative Weldon himself explained that EMTALA requires critical-care health facilities to provide appropriate treatment to women in need of emergency abortions, the Weldon Amendment notwithstanding:

> The Hyde-Weldon amendment is simple. It prevents Federal funding when courts and other government agencies force or require physicians, clinics and hospitals and health insurers to participate in *elective* abortions. . . . It simply prohibits coercion *in nonlife-threatening situations*. . . . It ensures that in situations where a mother's life is in danger a health care provider must act to protect the mother's life. In fact, Congress passed [EMTALA] forbidding critical-care health facilities to abandon patients in medical emergencies, . . . —particularly pregnant women.

151 Cong. Rec. H176-77 (Jan. 25, 2005) (statement of Rep. Weldon) (emphases added).

Section 1303 of the ACA, which the Final Rule also purports to implement, is itself clear that it shall not be "construed to relieve any health care provider from providing emergency services as required by State or Federal law, including . . . EMTALA." 42 U.S.C. § 18023(d). The Final Rule's acknowledgment that it can relieve health care providers from providing emergency services likewise violates this statute.

[27] Plaintiffs confront this particular emergency every day. *See* Ex. 5 (Allen Decl.) ¶¶ 28-29; Ex. 15 (Elnahal Decl.) ¶ 21; Ex. 29 (Lucchesi Decl.) ¶ 18; Ex. 38 (Rosen Decl.) ¶ 17; Ex. 43 (Thomas Decl.) ¶ 12; Ex. 45 (Vanden Hoek & Perna Decl.) ¶ 22; Ex. 48 (Zucker Decl.) ¶ 79; *see generally* Ex. 36 (Prezant Decl.).

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

The Final Rule imposes an expansive new requirement on every recipient of federal funds to submit both a written assurance and a certification that the recipient will comply with the Final Rule and the underlying statutes it implements. 84 Fed. Reg. at 23,269 (§§ 88.4(a)(1), (2)); *see also id.* at 23,213-16. Because the Department has imposed these requirements without adhering to the statutory obligations it must follow before demanding information from states and local governments, these requirements are not in accordance with law.

Both the assurance and the certification codified at Section 88.4 of the Final Rule are new collections of information governed by the Paperwork Reduction Act ("PRA"), which was enacted by Congress to "minimize the paperwork burden for," among others, "State, local and tribal governments . . . resulting from the collection of information by or for the Federal Government." 44 U.S.C. § 3501(1). Under the PRA, agencies must submit any proposed collection of information to the Office of Management and Budget ("OMB") for review and approval. *Id.* § 3507(a).

The Department has acknowledged that the PRA applies to the assurance and certification, 83 Fed. Reg. at 3919-20, and represented that when issuing the Final Rule, it planned to "notif[y] the public that OMB has approved the final rule's information collection requirements under the [PRA]." *Id.* at 3923. But the Final Rule's information collection requirements have not been approved as required by law: the Department concedes in the Final Rule that it does not yet have lawful authority to collect this information. *See* 84 Fed. Reg. at 23,214 ("[T]he Department . . . is working to obtain [PRA] clearance for updates to the . . . form entitled *Assurance of Compliance*"); *id.* at 23,258-59 ("The Department is seeking PRA clearance to operationalize the certification of compliance requirement . . . .").

Because the Department has not complied with the PRA, the Department is prohibited from demanding the information that it has codified in the assurance and certification requirements of the Final Rule. *See* 44 U.S.C. § 3507(a). Yet the Final Rule imposes the assurance and certification requirements immediately upon the effective date. And under the Department's new enforcement authority, any "fail[ure] or refus[al] to furnish an assurance or certification" constitutes noncompliance that OCR can remedy not only through all of the enforcement provisions set out in § 88.7(i), but also by *immediately* suspending all federal health care funds, even during the compliance process. 84 Fed. Reg. at 23,272 (§ 88.7(j)).

This is a breathtaking overreach: as of the July 22 effective date, the Department could consider any of the Plaintiffs out of compliance with the Final Rule—and immediately suspend without any administrative process all health care assistance to an entire state, city, or county—for declining to submit assurance and certification documents that the Department has no legal authority to demand, and that have not even been finalized or approved as required by law. The assurance and certification requirements in the Final Rule are therefore not in accordance with law. *See NRDC v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 108-13 (2d Cir. 2018) (vacating the agency's decision for failure to comply with unambiguous statutory requirements).

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

Under the APA, the Court must "hold unlawful and set aside" agency action that is "arbitrary, capricious, [or] an abuse of discretion." 5 U.S.C. § 706(2)(A). Agency action is arbitrary and capricious if the agency "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or [made a decision that] is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

a. The Final Rule arbitrarily and unreasonably expands the scope of covered conduct by redefining statutory terms.

The Final Rule is arbitrary and capricious because the Department has unreasonably expanded the reach of the underlying statutes through new definitions of statutory terms, counter to the evidence before the agency that such expansion would dramatically undermine the safe and reliable provision of health care.

As discussed in Part II.A.1 above, the Final Rule defines key statutory terms in a manner that dramatically expands the scope and applicability of the underlying federal statutes. Taken together, the definitions of "assist in the performance," "discrimination," "health care entity," and "referral" so expand the universe of protected persons and prohibited conduct that they present an unworkable situation for Plaintiffs, both as direct providers of health care and as regulators and grantors of others who provide health care within Plaintiffs' jurisdictions.

For example, an ambulance driver in a private, sub-contracted fleet, a customer service representative at an insurance company's hotline, and a hospital pharmacist all share the right, under the Final Rule, not to be asked prior to hiring whether they can execute the core functions of their jobs without objection. Once hired, all three have no duty to voluntarily disclose to their employers any religious or moral objection to any aspect of their work. All three may object at any time to a task requested by their employers, without advance notice and regardless of the costs to patient health. And should their employers subsequently seek to accommodate an expressed objection, all three have the categorical right to reject the accommodation as not "effective"—and without any consequence to their employment. *See* Compl. ¶ 79 (Dkt. 3).

The administrative record is replete with evidence that the Final Rule's expansion of the underlying statutes in this way would disrupt Plaintiffs' effective delivery of health care services

to their residents.[28] Courts "ha[ve] not hesitated" to reverse agency decisions "when an agency ignores factual matters or fails to respond adequately to meritorious arguments raised in opposition to the agency's action." *Water Quality Ins. Syndicate v. United States*, 225 F. Supp. 3d 41, 68 (D.D.C. 2016); *see also League of Women Voters*, 838 F.3d at 9-12 (disregard for statutory requirement renders agency decision arbitrary).

In addition, the Final Rule is arbitrary because its full scope is vague and impossible to discern. The Final Rule defines "assist in the performance" to mean any action with any "articulable connection" to furthering a procedure, which "*may* include counseling, referral, . . . or otherwise making arrangements for the procedure . . . *depending on* whether aid is provided by such actions." 84 Fed. Reg. at 23,263 (§ 88.2) (emphasis added). Recipients of federal funds must guess which routine actions, procedures, or referrals at work "may" constitute "assistance" that requires additional steps to accommodate workers or protect patients, *id.* at 23,188. "Administrative action is arbitrary and capricious [if] it fails to articulate a comprehensible standard for assessing the applicability of a statutory category." *ACA Int'l*, 885 F.3d at 699 (internal quotation marks omitted)).

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

The Final Rule is also arbitrary and capricious because the Department relied on a flawed cost-benefit analysis, citing benefits the Final Rule would confer without any evidentiary basis, disregarding extensive costs detailed in the record, and declining entirely to quantify the costs of the Final Rule on critical concerns, including the impact on access to care. In relying on a cost-benefit analysis so inadequate and incomplete, the Department "offered an explanation for its

[28] *See, e.g.*, Ex. 53 (Comment Letter from Attorneys General of New York, *et al.*, 7-9, 13-15); Ex. 56 (Comment Letter from California Dep't of Justice 1, 6); Ex. 64 (Comment Letter from N.Y. City Comm'n on Human Rights, *et al.*, 1-4).

decision that runs counter to the evidence before the agency" and "entirely failed to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43.

In promulgating the Final Rule, the Department prepared and relied on a Regulatory Impact Analysis to identify the Final Rule's costs and benefits. *See* 84 Fed. Reg. at 23,226-27. As the Supreme Court recently recognized, "[a]gencies have long treated cost as a centrally relevant factor when deciding whether to regulate." *Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015). And "when an agency decides to rely on a cost-benefit analysis as part of its rulemaking, a serious flaw undermining that analysis can render the rule unreasonable." *Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1040 (D.C. Cir. 2012). Here, the analysis that the Department relied on in issuing the Final Rule is irreparably flawed in at least three respects.

1. First, the Department arbitrarily refused to quantify the costs of the Final Rule's impact on access to care—a critical problem raised in the rulemaking process. Commenters provided the Department with substantial evidence that the changes would drastically reduce access to health care, especially for vulnerable populations.[29] But the Department declined to assess the Final Rule's impact on access to health care services, concluding instead that the Final Rule should be implemented "without regard to whether data exists on the competing contentions about its effect on access to services." 84 Fed. Reg. at 23,182.

This is an astonishing determination: in the face of extensive and well-documented evidence in the administrative record that the Final Rule would hinder access to care, the

[29] *See, e.g.*, Ex. 49 (Comment Letter from Am. Acad. of Pediatrics 3-14); Ex. 50 (Comment Letter from Am. Coll. of Obstetricians & Gynecologists 2); Ex. 51 (AMA Comment 7); Ex. 52 (Comment Letter from Am. Nurses Ass'n 1-2, 5-7); Ex. 53 (Comment Letter from Attorneys General of New York, *et al.*, 18-20); Ex. 58 (Comment Letter from Inst. for Policy Integrity 5-8); Ex. 59 (Comment Letter from Lambda Legal Defense & Education Fund, Inc. 10-17); Ex. 61 (Comment Letter from Nat'l Council of Jewish Women 3-6); Ex. 62 (Comment Letter from Nat'l Immigration Law Ctr. 3-5); Ex. 63 (Comment Letter from Nat'l Women's Law Ctr. 10-13); Ex. 66 (Comment Letter from Planned Parenthood Fed'n of Am. 2-5) (the "Planned Parenthood Comment").

Department declined even to analyze those concerns, instead shrugging its shoulders and concluding that it should implement the Final Rule anyway.[30] The APA does not permit an agency to ignore so central an evidentiary question. *Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1198-1203 (9th Cir. 2008); *see also Am. Wild Horse Pres. Campaign v. Perdue*, 873 F.3d 914, 932 (D.C. Cir. 2017); *Kern v. U.S. Bureau of Land Mgmt.*, 284 F.3d 1062, 1072 (9th Cir. 2002).

2. Second, the agency purported to rely on benefits the Final Rule would confer that are entirely unsupported by the administrative record. For example, the Department identified as a benefit of the rule that faith-based health care providers would likely limit the scope of their medical practice if conscience rules were not in place. 84 Fed. Reg. at 23,246-47. As the sole support for this assertion, the Department cited a 2009 survey of members of five religious medical groups conducted by the Christian Medical Association regarding how the potential rescission of the 2008 Final Rule would affect faith-based professionals. *See id.* at 23,246-47 & n.316. But that rescission in fact took place in 2011—after the 2009 survey that the Department relies on—and the Department made no effort to determine whether the intervening eight-year period (from the rescission to the present) had *any* effect on the scope of practice of faith-based professionals.[31] *See Nat'l Fuel Gas Supply Corp. v. FERC*, 468 F.3d 831, 841 (D.C. Cir. 2006) (vacating agency action where agency lacked evidence to support key factual conclusion).

[30] The Department concluded that the Final Rule's impact on access to care is not quantifiable and essentially unknowable. 84 Fed. Reg. at 23,182. But apart from the many comments providing quantitative and qualitative evidence of the impact religious refusals have on access to care, *see generally* n.29 above, the administrative record further contains specific evidence describing numerous methodological approaches the Department could have used to estimate these impacts. *See, e.g.*, Ex. 58 (Comment Letter from Inst. for Policy Integrity).

[31] The Final Rule cites this same data source no fewer than eight times in support of its cost-benefit analysis. *See* 84 Fed. Reg. at 23,175, 23,181, 23,246-47, 23,249-50, 23,252-53. In preliminarily enjoining a different HHS rule issued this year that also relied on the same survey, the district court described the "myriad" "flaws" in relying on this poll. *California*, 2019 WL 1877392, at *34.

The Department also claimed that the Final Rule would "decrease . . . departures from the field," because "a certain proportion of decisions by currently practicing health providers to leave the profession are motivated by coercion or discrimination based on providers' religious beliefs or moral convictions." 84 Fed. Reg. at 23,247 & n.322. But the source the Department cites for that assertion—the same online survey conducted by the Christian Medical Association—contains no support for this conclusion. *See* Ex. 57 (Christian Med. Ass'n, Summary of Online Survey of Faith-Based Medical Professionals conducted April, 2009, at 2-5), *cited in* 84 Fed. Reg. at 23,247 n.322. An agency's decision is arbitrary and capricious where "there is no evidence of record . . . that [the agency] based [its] conclusion on any findings or data." *City of Los Angeles v. Sessions*, 293 F. Supp. 3d 1087, 1099-1100 (C.D. Cal. 2018).[32]

Furthermore, the Department relied heavily on its conclusion that the Final Rule would have the benefit of addressing the "significant need to amend the 2011 Rule to ensure knowledge of, compliance with, and enforcement of" the underlying statutes. 84 Fed. Reg. at 23,175; *see also id.* at 23,250. But the Final Rule cites no evidence that the rule will in fact generate these benefits. *See McDonnell Douglas Corp. v. U.S. Dep't of the Air Force*, 375 F.3d 1182, 1187 (D.C. Cir. 2004); *California*, 2019 WL 1877329, at *41 (enjoining HHS rule where HHS's claims that the rule would "[e]nhance[] compliance with statutory requirements" were based on "no evidence" and no "estimates of the expected magnitude of these supposed benefits").

3. Third, in addition to relying on unsupported benefits, the Final Rule understates the costs of compliance. For example, in estimating the number of covered entities, the Department

[32] Similarly, the Final Rule asserts that one of its benefits is to "provide[] a centralized office within the Department for individuals and institutions to file complaints," 84 Fed. Reg. at 23,250, but this office and function predate the Final Rule. *See* 73 Fed. Reg. at 78,101. Relying on a claimed benefit that already existed is arbitrary. *New England Coal. on Nuclear Pollution v. Nuclear Regulatory Comm'n*, 727 F.2d 1127, 1130-31 (D.C. Cir. 1984) (agency action is arbitrary when "the reason which the [agency] gave for its action . . . makes no sense").

determined that the Final Rule "*may* add [only] 65 to 130 new persons and entities" who were not already covered by the 2011 Rule, from a baseline estimate of between 392,000 and 613,000 entities—an increase of only approximately 0.02%. 84 Fed. Reg. at 23,233-35 & tbl.2. But this estimate ignores—among other factors—the Final Rule's dramatic expansion of the term "health care entity" to include all "health care personnel" and "any other health care provider or health care facility," as well as (for purposes of the Weldon Amendment and Section 1553 of the ACA) plan sponsors, plan issuers, and third-party administrators.[33] 84 Fed. Reg. at 23,264 (§ 88.2). The number of covered entities is thus far larger than the Department's estimate, and the accompanying compliance costs far higher. "Agency action based on a factual premise that is flatly contradicted by the agency's own record does not constitute reasoned administrative decisionmaking." *City of Kansas City, Mo. v. Dep't of Hous. & Urban Dev.*, 923 F.2d 188, 194 (D.C. Cir. 1991).

The Department's assessment of the compliance burden is fundamentally flawed in other ways. For example, the Final Rule estimated an average one-time burden of two hours for each covered entity or person to familiarize themselves with the Final Rule. 84 Fed. Reg. at 23,240. This estimate is both without any support and entirely fanciful,[34] thus dramatically understating the costs of compliance. *See California*, 2019 WL 1877392, at *32-34, *37-41 (concluding that an "inadequate" assessment of the costs of compliance renders a rule arbitrary).

Taken together, the Department's reliance on an analysis this deeply flawed bears the

[33] Concerns about this expansion of the Final Rule's coverage to large classes of previously un-covered entities are well-documented in the administrative record. *See, e.g.*, Ex. 54 (Comment Letter from BlueCross BlueShield Ass'n 1-3); Ex. 55 (Comment Letter from Calif. Dep't of Ins. 3-4); Ex. 65 (Comment Letter from N.Y. State Dep't of Fin. Servs. 1, 3-4); *see also* Ex. 51 (AMA Comment 4); Ex. 66 (Planned Parenthood Comment 9).

[34] The Final Rule is more than 113,000 words in length, has 400 footnotes, comprises over 100 pages in the Federal Register, and implements nearly 30 federal statutory provisions. Recipients face suspension or termination of federal financial assistance for noncompliance with any of its many provisions. The estimate of a one-time burden of two hours for familiarization costs with a regulation this broad and consequential is unreasonable on its face.

hallmarks of arbitrarily "put[ting] a thumb on the scale by [over]valuing the benefits and [under]valuing the costs," *Ctr. for Biological Diversity*, 538 F.3d at 1198, and "render[s] the rule unreasonable" in its entirety. *Nat'l Ass'n of Home Builders*, 682 F.3d at 1040.

c. The assurance and certification requirements are arbitrary and capricious.

As noted, the Final Rule codifies a new requirement on every recipient of federal funds to submit written assurances and certifications of compliance that contractually obligate the recipient to abide by the Final Rule's requirements. *See* 84 Fed. Reg. at 23,269 (45 C.F.R. § 88.4(a)); *see supra* Part II.A.2.d. Because the Final Rule does not even acknowledge the Department's own prior position that this precise collection of information is unnecessary and burdensome, these requirements are arbitrary and capricious.

The 2011 Rule rescinded a written certification requirement that had been codified by the 2008 Rule because, as the Department explained in its 2011 action, "the certification requirements in the 2008 Final Rule are unnecessary to ensure compliance with the federal health care provider conscience protection statutes, and . . . the certification requirements created unnecessary additional financial and administrative burdens on health care entities." 76 Fed. Reg. at 9974. But neither the description of the assurance and certification requirements in the Proposed Rule, nor the analysis and response to public comments in the Final Rule, acknowledge that the Department just a few years ago concluded that these requirements were unnecessary and burdensome.[35] *See* 84 Fed. Reg. at 23,213-16; 83 Fed. Reg. at 3896-97. Although an agency is not prohibited from changing its position through rulemaking, "the requirement that an agency provide reasoned explanation for its action . . . ordinarily demand[s] that it display

[35] The administrative record contains numerous comments opposing the assurance and certification requirements because they are unnecessary and burdensome. *See, e.g.*, Ex. 51 (AMA Comment 5).

awareness that it *is* changing position." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *see also R.F.M. v. Nielsen*, 365 F. Supp. 3d 350, 381 n.17 (S.D.N.Y. 2019) (same). The assurance and certification requirements are arbitrary for the Department's failure to do so.

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

Plaintiffs are also likely to succeed on the merits of their claim that the Final Rule violates constitutional separation of powers requirements.[36]

Because the Constitution vests the spending power in Congress, the Executive Branch "does not have unilateral authority to refuse to spend . . . funds" already appropriated by Congress "for a particular project or program." *In re Aiken Cty.*, 725 F.3d 255, 261 n.1 (D.C. Cir. 2013). Congress may delegate some discretion to the Executive Branch to decide how to spend appropriated funds, *see Clinton v. City of New York*, 524 U.S. 417, 488 (1998), but that discretion is cabined by the scope of the delegation, *City of Arlington*, 569 U.S. at 296.

Over the course of decades, Congress has enacted conditions on the receipt of federal funds that relate to religious or moral refusals to provide health care. These provisions are tailored to specific procedures, specific involvement in those procedures, and specific health care providers or entities. For example, the Coats-Snowe Amendment prohibits discrimination related to training in the performance of abortion in specifically-defined "health care entities," 42 U.S.C. § 238n(c)(2), while Section 1553 of the ACA prohibits discrimination against a *different* category of "health care entities" on the basis of any refusal to provide services that assist in any assisted suicide, 42 U.S.C. § 18113. In doing so, Congress has clearly attached specific conditions to the acceptance of specific sources of funds, and not others. *E.g.*, 42 U.S.C. § 300a-

[36] In reviewing Plaintiffs' likelihood of success on the merits of their constitutional claims, the Court's review is not limited to information in the administrative record. *See Saget v. Trump*, No. 19-cv-1599, 2019 WL 1568755, at *61 (E.D.N.Y. Apr. 11, 2019); *New York v. U.S. Dep't of Commerce*, 351 F. Supp. 3d 502, 667-69 (S.D.N.Y. 2019).

7(c) (identifying specific grants to which certain of the Church Amendments' protections apply).

Disregarding the careful and deliberate legislation that Congress has enacted, the Final Rule cobbles together a one-size-fits-all federal conscience scheme that purports to rely on dozens of disparate provisions of law and regulation. *See* 84 Fed. Reg. at 23,264-69 (§ 88.3). This new remedial scheme redefines key terms, grants the Department broad investigative and compliance authority, and allows the Department to terminate billions of dollars in federal funds to Plaintiffs. *Id.* at 23,263-64, 23,269-71 (§§ 88.2, 88.4, 88.6, 88.7). But the Department has no authority to rewrite the statutes Congress enacted in this way. Rather, "[t]he Constitution gives an 'unmistakable expression of a determination that legislation by the national Congress be a step-by-step, deliberate and deliberative process.'" *City & Cty. of San Francisco v. Sessions*, 372 F. Supp. 3d 928, 941 (N.D. Cal. 2019) (quoting *I.N.S. v. Chadha*, 462 U.S. 919, 959 (1983)).

Nor does the Department have the authority to refuse to spend funds Congress appropriated for a particular program. *In re Aiken Cty.*, 725 F.3d at 261 n.1 (citing *Train v. City of New York*, 420 U.S. 35, 42-45 (1975)). Accordingly, the Final Rule violates the constitutional separation of powers and exceeds the Department's discretion to attach conditions on the use of federal funds.

C. The Final Rule violates the Spending Clause.

Finally, Plaintiffs are likely to succeed on the merits of their claims because the Final Rule violates the Spending Clause.

The Constitution vests Congress with the spending power to "provide for the common Defence and general Welfare of the United States." U.S. Const. art. I, § 8, cl. 1. Through its spending power, Congress may "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). Such power "is of course not unlimited, but is instead subject to several general restrictions," including that any

conditions Congress sets on the receipt of federal funds (1) must be unambiguous and cannot be retroactively imposed, (2) must not be coercive, (3) must have a nexus between the funds at issue and the federal program's purpose, and (4) "may not be used to induce the States to engage in activities that would themselves be unconstitutional." *South Dakota v. Dole*, 483 U.S. 203, 207-08, 211 (1987) (citing *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 & n.13 (1981)). The Final Rule violates each of these limitations. An agency tasked with implementing a statute that imposes spending conditions is subject to the same limitations. *See Lau v. Nichols*, 414 U.S. 563, 569 (1974) (evaluating Spending Clause challenge to regulation implemented pursuant to Title VI of the Civil Rights Act of 1964).

1. The Final Rule attaches retroactive and ambiguous conditions to Plaintiffs' receipt of federal funds.

When an agency places conditions on federal funds, "it must do so unambiguously" so that states and local jurisdictions determining whether they agree to accept such funds may "exercise their choice knowingly, cognizant of the consequences of their participation." *Dole*, 483 U.S. at 203. In assessing whether an agency has provided the clear notice that the Spending Clause requires, a court must view the statute "from the perspective of a state official who is engaged in the process of deciding whether the State should accept [the] funds and the obligations that go with those funds," and "must ask whether such a state official would clearly understand that one of the obligations of the [covered statutory provisions] is the [purported] obligation." *Arlington Cent. Sch. Dist.*, 548 U.S. at 296.

Here, the Final Rule runs afoul of the Spending Clause's clear notice requirement by retroactively imposing conditions on the receipt of federal funds in at least four ways. Because these were not "unambiguous condition[s] that the states and local jurisdictions voluntarily and knowingly accepted at the time Congress appropriated these funds, [they] cannot be imposed

now." *Cty. of Santa Clara*, 250 F. Supp. 3d at 532.

First, as discussed in Parts II.A.1 and II.A.3.a above, the Final Rule includes new definitions for key terms in the underlying statutes that dramatically expand the scope of those statutes, significantly altering the conditions to which Plaintiffs initially agreed.

Second, the Final Rule imposes new, retroactive, and burdensome compliance requirements that apply immediately to all recipients of federal funds. *See* 84 Fed. Reg. at 23,269-70 (§ 88.4(a), (b)(5)). The Final Rule then leverages those retroactive certifications—which include the agreement to comply with the Final Rule, *see* 84 Fed. Reg. at 23,269 (§ 88.4(a))—to conscript Plaintiffs into cooperating with data collection requirements, compliance reviews, investigations, and "any . . . other part of OCR's enforcement process." *Id.* at 23,270-72 (§§ 88.6(b), (c), 88.7(c), (d)).

Third, the Final Rule's termination scheme disregards that Congress in the relevant statutes conditioned funding from specific sources with specific prohibitions, *compare*, *e.g.*, 42 U.S.C. § 300a-7(c)(1) (Church Amendment restrictions that apply to specific statutory funding sources), *with id.* § 300a-7(c)(2) (Church Amendment restrictions that apply only to "grant[s] or contract[s] for biomedical or behavioral research), and instead authorizes the Department to withhold, deny, suspend, or terminate *all* federal health care funds to Plaintiffs if the Department determines that Plaintiffs have failed to comply with the Final Rule. *See* Fed. Reg. at 23,271-72 (§ 88.7(i)).

Fourth, the Final Rule purports to identify conflicts with literally dozens of state and local laws on issues as wide-ranging as emergency care, patient abandonment, informed consent, the availability of lawful prescriptions, religious accommodations in the workplace, access to comprehensive reproductive health care, and insurance coverage for contraception and abortion.

See id. at 23,226; Compl. ¶¶ 103-118 (Dkt. 3). Plaintiffs did not knowingly agree to undercut these state and local laws when they accepted federal funds. *Cf. City & Cty. of San Francisco*, 372 F. Supp. 3d at 949-51.

The Final Rule separately violates the Spending Clause's clear notice requirement by failing to make clear what conduct the Final Rule prohibits or requires, what funding streams are at stake, and how recipients can avoid its penalties. As discussed above, the definitions of the Final Rule taken together require Plaintiffs to hypothesize whether routine work-related actions, procedures, and services—central to the provision of health care—would require onerous steps to accommodate workers or protect patients. *See supra* Part II.A.3.a. The Department's responses to the concern that the Proposed Rule generated—and the Final Rule codifies—further underscore the ambiguity of the Final Rule. For example, in considering whether the Final Rule's definition of "assist in the performance" would cover "driving a patient to a procedure," the Department states that it "would depend on the facts and circumstances of each case." 84 Fed. Reg. at 23,188. Similarly, in positing whether emergency transportation of an individual with an ectopic pregnancy would constitute assistance under the Final Rule, the Department notes that its determination "would depend on the facts and circumstances." *Id.* And in responding to concerns about the Final Rule's effect on HIV treatment, pre-exposure prophylaxis, and infertility treatment, the Department declines to definitively answer whether such procedures are implicated by the Final Rule, again noting only that "the Department would examine the facts and circumstances of [a] complaint to determine whether it falls within the scope of the statute in question and these regulations." *Id.* at 23,182.

The Department's repeated refrain that interpretations of the Final Rule central to Plaintiffs' knowing and voluntary acceptance of the federal funds they receive will depend on the

"facts and circumstances" of each case[37] highlights the constitutional infirmity of the Final Rule. These are not abstract concerns for Plaintiffs: their health care institutions and sub-grantees provide these services and confront these situations every day—including HIV treatment,[38] pre-exposure prophylaxis,[39] driving patients to procedures,[40] and emergency presentation of ectopic pregnancy.[41] The Department cannot dodge the Spending Clause's clear notice requirement by deferring determinations regarding what the Final Rule does and does not prohibit to its post-hoc interpretations. *See City & Cty. of San Francisco*, 372 F. Supp. 3d at 350-51.

In addition to leaving federal grant recipients guessing as to the scope and meaning of the Final Rule, the Department erodes the clear notice requirement of the Spending Clause by placing the impossible responsibility on federal fund recipients to reconcile the Final Rule with other conflicting federal and state laws with which Plaintiffs are obligated to comply. *See supra* Part II.A.2. For example, in response to comments expressing confusion as to how the Final Rule may be reconciled with EMTALA and federal anti-discrimination statutes, the Department merely notes that "OCR intends to read every law passed by Congress in harmony to the fullest extent possible so that there is maximum compliance with the terms of each law." 84 Fed. Reg. at 23,183. This unilluminating response underscores the ambiguity of the Final Rule, and makes it impossible for recipients of federal health care funds to decide whether to "accept [the] funds and the obligations that go with those funds." *Arlington Cent. Sch. Dist.*, 548 U.S. at 296.

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[37] *See* 84 Fed. Reg. at 23,182, 23,187–23,190, 23,192, 23,196, 23,201, 23,205, 23,223, 23,249, 23,252–53, 23,270.

[38] *See, e.g.*, Ex. 5 (Allen Decl.) ¶ 8 ; Ex. 7 (Anderson Decl.) ¶ 8; Ex. 15 (Elnahal Decl.) ¶ 8; Ex. 17 (Ezike Decl.) ¶¶ 33-35; Ex. 24 (Hirata Decl.) ¶ 5; Ex. 34 (Nichols Decl.) ¶ 5; Ex. 46 (Wagaw Decl.) ¶ 10; Ex. 48 (Zucker Decl.) ¶¶ 108-18, 186.

[39] *See, e.g.*, Ex. 17 (Ezike Decl.) ¶¶ 36-37; Ex. 39 (Shannon Decl.) ¶¶ 21-22.

[40] *See, e.g.*, Ex. 1 (Adelman Decl.) ¶ 11; *see generally* Ex. 36 (Prezant Decl.).

[41] *See, e.g.*, Ex. 5 (Allen Decl.) ¶¶ 28-29; Ex. 15 (Elnahal Decl.) ¶ 21; Ex. 25 (Hunter Decl.) ¶ 15; Ex. 29 (Lucchesi Decl.) ¶ 18; Ex. 38 (Rosen Decl.) ¶ 17; Ex. 43 (Thomas Decl.) ¶ 12; Ex. 45 (Vanden Hoek & Perna) Decl. ¶ 22; Ex. 48 (Zucker Decl.) ¶ 79.

Finally, even if Plaintiffs could discern what was expected of them in exchange for receiving federal health care funds, the Final Rule's enforcement scheme is unclear as to the funds Plaintiffs stand to lose and how the Department plans to make such determinations. Specifically, despite the Department's response to comments regarding the astonishing overbreadth of the threat to terminate all federal health care funds 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, the Final Rule's regulatory text contains no description at all of the funds that are at stake, *see id.* at 23,271-72 (§ 88.7(i)). And the process for the Department to follow in order to effect compliance with the Final Rule is described only by cursory reference to three disparate administrative procedures, each identified by way of non-exclusive example, providing insufficient notice to Plaintiffs of their rights and responsibilities in an administrative process that could cost Plaintiffs billions of dollars in health care resources. *See id.* at 23,272 (§ 88.7(i)(3)).

Because of the vagueness of the meaning, scope, and threatened penalties of the Final Rule, Plaintiffs cannot possibly "exercise their choice [to receive federal funds] knowingly, cognizant of the consequences of their participation." *Dole*, 483 U.S. at 207 (internal quotation marks omitted); *see also Cty. of Santa Clara*, 250 F. Supp. 3d at 532 (holding that the executive order at issue violated the Spending Clause because its "vague language [did] not make clear what conduct it proscribes or give jurisdictions a reasonable opportunity to avoid its penalties").

2. The Final Rule is unconstitutionally coercive.

Any federal effort to "coerce[] a State [or local government] to adopt a federal regulatory system as its own" is "contrary to our system of federalism." *Nat'l Fed'n of Indep. Bus. v. Sebelius ("NFIB")*, 567 U.S. 519, 577-78 (2012); *see also Dole*, 483 U.S. at 211. That is exactly what the Department has done here. Through the Final Rule, the Department has created a new

federal conscience regime by cobbling together dozens of disparate provisions throughout the United States Code, appropriations riders, and the Code of Federal Regulations, *see* 84 Fed. Reg. at 23,264-69 (§ 88.3); redefining key statutory terms to cover numerous new individuals and entities, *see id.* at 23,263-34 (§ 88.2); and fashioning a compliance scheme that confers broad authority on the Department while ignoring congressional efforts to tailor specific requirements to specific sources of funds, *see id.* at 23,269-72 (§§ 88.4, 88.6, 88.7). The Final Rule thus accomplishes "a shift in kind, not merely degree." *NFIB*, 567 U.S. at 583.

Most significantly, the Final Rule authorizes the Department to withhold, deny, suspend, or terminate billions of dollars in federal funds if the Department determines, in its view, that "there is a failure to comply" with the Final Rule by Plaintiffs or any of their sub-recipients. *Id.* at 23,271-72 (§ 88.7(i)). The amount of federal funding at risk, and the importance of that funding to Plaintiffs and the public health, *see supra* Parts I.A, I.B, leaves Plaintiffs with no meaningful choice but to acquiesce to the Final Rule. The "financial 'inducement' Congress has chosen . . . is a gun to the head" and, therefore, unconstitutionally coercive. *NFIB*, 567 U.S. at 581, 588*; see also Cty. of Santa Clara*, 250 F. Supp. 3d at 533.

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

The Final Rule further violates the Spending Clause's requirement that any conditions imposed on spending must be reasonably related to the purpose of the federal program, *see Dole*, 483 U.S. at 207-08, because—through the Weldon Amendment—the Rule appears to condition the receipt of billions of dollars in federal funds entirely unrelated to health care on compliance with the Department's rulemaking regarding health care conscience laws.

The Weldon Amendment provides that "[n]one 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." *Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019*, Pub. L. No. 115-245, § 507(d), 132 Stat. at 3118 (emphasis added). The appropriations law separately provides that "[e]xcept as expressly provided otherwise, any reference to 'this Act' contained in any division of this Act shall be treated as referring only to the provisions of that division." *Id.* § 3, 132 Stat. at 2981. The Weldon Amendment is contained in Division B of the appropriations law, which is the *Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2019*. *Id.* §§ 2, 507(d), 529, 132 Stat. at 2981, 3048, 3118, 3122. This Division thus includes congressional appropriations administered not only by HHS, but also by the Department of Labor and the Department of Education.

In implementing the Weldon Amendment and establishing an enforcement scheme for noncompliance, the Department has expressly *not* cabined its claimed reach only to HHS funds when it comes to "temporarily withholding" or "wholly or partly suspending" funds. *See* 84 Fed. Reg. at 23,272 (§§ 88(i)(3)(i), (iii)). In other words, the Department's implementation of the Weldon Amendment appears to place at risk—through "temporarily withholding" or "wholly or partly suspending"—all federal funds not just from HHS, but from the Labor Department and Education Department as well. These appropriations have nothing whatsoever to do with HHS's interest in health care conscience statutes.

By threatening Plaintiffs' receipt and continued use of congressionally-appropriated funds that are wholly unrelated to the provision of health care, the Final Rule violates the Spending Clause's relatedness requirement. *See, e.g.*, *City & Cty. of San Francisco*, 349 F.

Supp. 3d 924, 959-61 (N.D. Cal. 2018); *Cty. of Santa Clara*, 250 F. Supp. 3d at 532-33.

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

The Final Rule violates the Constitution's constraint that the spending power "may not be used to induce the States to engage in activities that would themselves be unconstitutional," *Dole*, 483 U.S. at 210, because it requires Plaintiffs to engage in conduct that would violate the Establishment Clause. *See Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 217-21 (2013) (enjoining application of a condition on federal funds because it violated the plaintiffs' First Amendment rights).

Laws violate the Establishment Clause when they "impose on employers and employees an absolute duty to conform their business practices to the particular religious practices of the employee." *Caldor*, 472 U.S. at 709. The Final Rule requires Plaintiffs to accommodate their employees' religious beliefs to the exclusion of all secular interests or the conflicting religious beliefs of other employees or patients, *see supra* Part II.A.1, and thereby substantially burdens third parties by, for example, impairing patients' access to medical care and imposing tremendous administrative costs on Plaintiffs' employers and other employees. *See supra* Parts I.B, I.C; *see also Cutter v. Wilkinson*, 544 U.S. 709, 721 (2005).

In addition, the Final Rule requires Plaintiffs to impose these same commands on the thousands of nongovernmental entities with whom Plaintiffs subcontract for the provision of health care to their residents. *See supra* Part I.A.1. Indeed, Plaintiffs' federal funding depends on it. *See* 84 Fed. Reg. at 23,270 (§ 88.6(a)); *see also id.* at 23,207. But Plaintiffs cannot constitutionally require employers to "adjust their affairs to the command of the State whenever [the Final Rule] is invoked by an employee." *Cf. Caldor*, 472 U.S. at 709.

III. Scope of provisional relief.

The Court should enjoin Defendants from implementing the Final Rule without geographic restriction or, in the alternative, postpone the effective date of the Final Rule.

1. The purpose of interim equitable relief "is not to conclusively determine the rights of the parties, but to balance the equities as the litigation moves forward," bearing in mind "'the overall public interest.'" *Trump v. Int'l Refugee Assistance Project*, 137 S. Ct. 2080, 2087 (2017) (quoting *Winter*, 555 U.S. at 26). Because the Final Rule violates the APA and is unconstitutional, *see supra* Part II, and because "[f]orcing federal agencies to comply with the law is undoubtedly in the public interest," *Cent. United Life, Inc. v. Burwell*, 128 F. Supp. 3d 321, 330 (D.D.C. 2015), *aff'd*, 827 F.3d 70 (D.C. Cir. 2016), enjoining implementation of the Final Rule without geographic limitation is the appropriate balance of the equities.

Plaintiffs recognize that some courts of appeals have cautioned that preliminary injunctive relief should not be overbroad. *See, e.g.*, *California v. Azar*, 911 F.3d 558, 582-84 (9th Cir. 2018). But as the Supreme Court has held, the "scope of injunctive relief is dictated by the extent of the violation established, not by the geographical extent of the plaintiff class." *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979). Here, Plaintiffs have demonstrated a likelihood of success on the merits of their claims and nationwide relief is the usual course in an APA action because "when a reviewing court determines that agency regulations are unlawful, the ordinary result is that the rules are vacated—not that their application to the individual petitioners is proscribed." *Harmon v. Thornburgh*, 878 F.2d 484, 495 n.21 (D.C. Cir. 1989); *see also NAACP v. Trump*, 315 F. Supp. 3d 457, 462-63 n.3 (D.D.C. 2018).

Plaintiffs' expansive geographic presence also minimizes any concerns about this Court's power to award relief without geographic limitation. Plaintiffs in this action are 23 states, cities, and counties located in ten of the twelve federal judicial circuits. This is not a case where a

single plaintiff seeks to leverage a localized dispute into national relief; it is instead a challenge by Plaintiffs with national scope to an unlawful regulation with significant national impact.

2. In the alternative, the Court should stay the effective date of the Final Rule pending adjudication of this case on the merits. The APA permits this Court to "postpone the effective date of an agency action" where "necessary to prevent irreparable injury . . . pending conclusion of the review proceedings." 5 U.S.C. § 705. Courts assessing requests for a stay under the APA apply the same four-factor test used to evaluate requests for preliminary injunctive relief. *Bauer*, 325 F. Supp. 3d at 104-05. Here, for the reasons discussed above, Plaintiffs have satisfied the showing required of a request for preliminary injunctive relief. The Court should therefore stay the effective date of the Final Rule pending resolution of this case on the merits, to avoid irreparable harm to Plaintiffs. *See, e.g.*, *Texas*, 829 F.3d at 435.

CONCLUSION

Plaintiffs respectfully request that the Court enjoin implementation of the Final Rule.

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Respectfully submitted,

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