September 6, 2019

ATTORNEY GENERAL RAOUL FILES MOTION TO BLOCK HEALTH CARE DISCRIMINATION RULE

Federal 'Refusal-of-Care' Rule Would Allow Businesses and Individuals to Refuse to Provide Health Care Based on Their Own Religious, Moral, Ethical Beliefs

Chicago — Attorney General Kwame Raoul, as part of a coalition of 26 public jurisdictions and health care providers, today filed a motion to prevent the implementation of a federal rule that would enable health care providers to arbitrarily deny patient care.

In a motion for summary judgment filed with the United States District Court for the Southern District of New York, Raoul and the coalition seek to block the federal refusal-of-care rule. The rule seeks to expand the ability of businesses and individuals to refuse to provide vital health care services on the basis of a business's or an employee's "religious beliefs or moral convictions."

"This rule allows providers to discriminate against marginalized populations that deserve access to quality health care, and nothing should stand in the way of someone's right to receive the medical care they need," Raoul said. "I am committed to fighting discrimination wherever it occurs and protecting the right of all individuals to exercise autonomy over their health care."

The Department of Health and Human Services (HHS) initially proposed the rule in January 2018 to expand the ability of businesses and individuals to refuse to provide necessary health care on the basis of their "religious beliefs or moral convictions." A coalition of attorneys general from around the nation, including Illinois, immediately submitted a comment letter to the administration urging that the rule be withdrawn. In May 2019 — after the rule was adopted — Raoul and the coalition filed a lawsuit against the administration arguing that the rule would fundamentally increase the number of reasons and ways Americans across the country could be denied essential health services. In June, Raoul and that same coalition sought a preliminary injunction to prevent implementation of the rule. In response to this preliminary injunction motion, HHS pushed back the rule's original implementation date of July 2019. Today the coalition is asking the court to hold that the refusal-of-care rule violates federal statutory law and the U.S. Constitution.

The lawsuit alleges that the final rule, if implemented, would undermine the delivery of health care by giving a wide range of health care institutions and individuals a right to refuse care, based on the provider's own personal views. The rule drastically expands the number of providers eligible to make such refusals, ranging from ambulance drivers to emergency room doctors to receptionists to customer service representatives at insurance companies. Additionally, the rule makes this right absolute and categorical, and no matter what reasonable steps a health provider or employer makes to accommodate the views of an objecting individual, the provider or employer is left with no recourse if that individual rejects a proposed accommodation.

Under the rule, a hospital could not inquire, prior to hiring a nurse, if that individual objected to administering a measles vaccination — even if this was a core duty of the job in the middle of an outbreak of the disease. A doctor could also refuse to assist a woman who arrived with a ruptured ectopic pregnancy. Businesses, including employers, would be able to object to providing insurance coverage for procedures they consider objectionable, and allow individual health care personnel to object to informing patients about their medical options or referring them to providers of those options. The devastating consequences of the rule would fall particularly hard on marginalized patients, including LGBTQ+ patients, who already confront discrimination in obtaining health care.

The lawsuit further alleges that the risk of noncompliance is the termination of billions of dollars in federal health care funding. If HHS determines, in its sole discretion, that states or cities have failed to comply with the final rule — through their own actions or the actions of thousands of sub-contractors relied upon to deliver health services — the federal government could terminate funding to those states and cities to the price tag of hundreds of billions of dollars. States and cities rely upon those funds for countless programs to promote the public health of their residents, including Medicaid, the Children’s Health Insurance Program, HIV/AIDS and STD prevention and education, and substance abuse and mental health treatment.

The lawsuit argues that this drastic expansion of refusal rights, and the draconian threat of termination of federal funds, violates the federal Administrative Procedure Act, as well as the Spending and Establishment Clauses and the separation of powers principles in the U.S. Constitution.

Joining Attorney General Raoul in filing the motion are the attorneys general of Colorado, Connecticut, Delaware, Hawaii, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, Oregon, Pennsylvania, Rhode Island, Vermont, Virginia, Wisconsin, and the District of Columbia; as well as the cities of New York and Chicago; and Cook County, Ill. Additionally, Planned Parenthood Federation of America and one of its affiliates, as well as the National Family Planning and Reproductive Health Association and Public Health Solutions, brought two separate lawsuits against the administration for implementation of this rule, which have now been consolidated into this lawsuit.

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) (lead) 19 Civ. 5433 (PAE) (consolidated) 19 Civ. 5435 (PAE) (consolidated)

MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' CROSS-MOTION FOR SUMMARY JUDGMENT, IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS OR FOR SUMMARY JUDGMENT, AND REPLY IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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Plaintiffs cite the following short form citations for motions, memoranda of law, and exhibits filed in these consolidated cases (all citations to docket entries are to the docket of the lead action, 19 Civ. 4676 (PAE), unless otherwise specified):

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Compl.	Plaintiffs' Complaint for Declaratory and Injunctive Relief, Dkt. 3 (filed May 21, 2019).
Defs.' Mem.	Defendants' Consolidated Memorandum of Law in Support of Defendants Motion to Dismiss or, in the Alternative, Motion for Summary Judgment, and in Opposition to Plaintiffs' Motions for Preliminary Injunction, Dkt. 148 (filed Aug. 14, 2019).
Defs.' Mot.	Defendants' Consolidated Motion to Dismiss or, in the Alternative, Motion for Summary Judgment, Dkt. 147 (filed Aug. 14, 2019).
Ex. __	Citations to Exhibits 1 to 4 and Exhibits 6 to 66 are to the exhibits to the Declaration of Matthew Colangelo, Dkt. 43 (filed June 14, 2019).
	Citations to Exhibit 5 are to the exhibit to Plaintiffs' Notice of Filing of Corrected Exhibit, Dkt. 44 (filed June 14, 2019).
	Citations to Exhibits 67 to 136 are to the excerpts from the administrative record and other evidence lodged with the Court as exhibits to the Declaration of Matthew Colangelo, Dkt. 180 (filed Sept. 5, 2019).
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INTRODUCTION

Plaintiffs filed this action to challenge a regulation issued by the U.S. Department of Health and Human Services that—ostensibly in the name of conscience-protection rights—would instead dramatically disrupt the country's entire health care sector by redefining the scope and application of nearly thirty federal statutes, and that would coerce Plaintiffs to carry out the federal government's current policy agenda by subjecting Plaintiffs to the unilateral termination of billions of dollars in federal funds under deeply unclear criteria.

1. Judicial review is warranted now. Defendants argue that Plaintiffs' constitutional claims may not proceed until after the regulation takes effect and the Department initiates a specific enforcement action for noncompliance. But this argument ignores the fact that the purpose and likely effect of the Final Rule is to compel Plaintiffs and others to comply with the Final Rule's unlawful and unreasonable expansion of federal funding statutes. That compliance obligation ripens on November 22, 2019, the effective date of the Final Rule; and, in the meantime, the Final Rule is already affecting Plaintiffs in significant ways, as the Department expected would occur. No further factual development is needed for the Court to discern the clear constitutional violations at issue, and Plaintiffs would be irremediably harmed by delay.

In the face of Plaintiffs' overwhelming showing of drastic and immediate injury—supported by sworn testimony from dozens of national leaders in their fields, with deep experience in medical practice, ethics, public health, epidemiology, health systems administration, and other specialties—Defendants have failed to offer any concrete evidence to the contrary, and instead wave aside Plaintiffs' sworn testimony by mischaracterizing it in broad strokes as "hypothetical" or "imagined." This dismissive approach is unpersuasive; Plaintiffs' challenges are ripe; and the motion to dismiss should be denied.

2. On the merits, the Final Rule is invalid under the Administrative Procedure Act

because it exceeds the Department's statutory authority, is not in accordance with law, and is arbitrary and capricious. Most notably, production of the administrative record following its court-ordered completion reveals that a central factual assertion the Department relied on to support this rulemaking—namely, the number of complaints of discrimination the agency has received in the past three years—is simply false: nearly 95% of the complaints of discrimination that the Department claims formed the basis for the Final Rule in fact *have nothing to do* with the federal refusal statutes. It is hard to find a clearer case of arbitrary agency action than when an agency falsely cites to evidence that it does not actually have to support its action.

Defendants argue that the rule clears APA review because Defendants "considered" the concerns identified in public comments, and that the rule "simply clarifies" the Department's enforcement process. But mere consideration of public comments does not establish a reasoned basis for agency action where that consideration was window-dressing; and counsel's assurances of regulatory modesty contrast starkly with the grand proclamations the federal government has spent two years delivering by Executive Order and in statements from senior officials—including the President and members of his cabinet—regarding the true intended scope and breadth of this rulemaking. The Final Rule should be vacated under the APA.

3. Plaintiffs are also entitled to relief on their constitutional claims. The Final Rule is a paradigmatic example of executive branch overreach that violates the Spending Clause proscription on gun-to-the-head coercion: it retroactively conditions hundreds of billions of dollars of critical federal health care funds on compliance with new and indeterminate policy pronouncements regarding how the federal health care refusal statutes should be broadened and redefined. And the rule violates the Establishment Clause because it impermissibly advances religious beliefs, effectively *requiring* Plaintiffs to hire employees who cannot deliver health

services critical to the entity's mission, and thus to conform their business practices to the employee's own religious practices.

Plaintiffs therefore respectfully request that the Court vacate and set aside the Final Rule.

ARGUMENT

I. Defendants' motion to dismiss should be denied.

Defendants move to dismiss Plaintiffs' Spending Clause and Establishment Clause claims for lack of subject-matter jurisdiction on the ground that Plaintiffs' claims are unripe until Defendants take specific enforcement action under the Final Rule. Defs.' Mem. 18-23. The motion should be denied because the Final Rule (1) requires Plaintiffs to adjust their conduct now, and (2) presents a risk of serious hardship to Plaintiffs absent adjudication of their claims.

A. Legal standard for assessing Defendants' motion to dismiss.

A complaint need only set forth "a short and plain statement of the grounds for the court's jurisdiction," and "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a). Under Rule 12(b)(1), Plaintiffs bear the burden of demonstrating that the Court has subject-matter jurisdiction. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). Plaintiffs may rely on the pleadings and any supporting affidavits, and the Court should "construe jurisdictional allegations liberally and take as true uncontroverted factual allegations." *Robinson v. Overseas Military Sales Corp.*, 21 F.3d 502, 507 (2d Cir. 1994).

B. Plaintiffs' constitutional challenges are ripe for judicial review.

1. Plaintiffs' claims are ripe because the Final Rule requires Plaintiffs to adjust their conduct immediately.

Defendants assert that Plaintiffs' constitutional claims are not yet ripe because "Plaintiffs have identified no specific enforcement action taken against them under the Rule." Defs.' Mem. 18. But this argument ignores both the explicit purpose and intended effect of the Final Rule,

which is to compel Plaintiffs' and others' *compliance* with Defendants' unlawfully and unreasonably expanded interpretation of federal funding statutes. *See, e.g.*, 84 Fed. Reg. at 23,179 ("Department is . . . required to ensure . . . the compliance of its funding recipients."); *id.* at 23,227-29 (the rule "incentivizes the desired behavior" by expanding enforcement in light of "[i]nadequate [existing] enforcement tools"); *id.* at 23,269-70 (requiring grantees to sign enforceable assurances and certifications of compliance). Defendants' threatened enforcement is merely a means of ensuring that compliance, not the object of the Final Rule. And "agency action is 'ripe' for review at once" when "as a practical matter [it] requires the plaintiff to adjust his conduct immediately." *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 891 (1990).

Plaintiffs' complaint alleges that once the Final Rule becomes effective, Plaintiffs will have no choice but to either acquiesce in the Final Rule's unconstitutional conditions, or risk losing billions of funds that the Final Rule plainly authorizes HHS to terminate or withhold. *See* Compl. ¶¶ 1-4, 80-88, 133-158; Pls.' PI Mem. 10-14; *see also infra* Parts III.B, IV.A. The immediate obligation to comply with the Final Rule—or risk losing billions in critical public health funds—is an immediate harm that this Court can and should address, and constitutes the very threat that the limitations on the spending power proscribe. *See Nat'l Fed'n of Indep. Business ("NFIB") v. Sebelius*, 567 U.S. 519, 580-81 (2012) (underscoring concerns with respect to the "nature of the threat" posed by the Medicaid provisions of the Affordable Care Act); *id.* at 581 (explaining that "[b]y financial inducement the Court meant the threat of losing . . . funds" (internal quotation marks omitted)). When Plaintiffs "ha[ve] no choice, the Federal Government can achieve its objectives without accountability," *id.* at 578, and Plaintiffs' well-pleaded allegations regarding the impact of HHS's fund-termination authority establish a real and imminent claim of unconstitutional government action. *See* Compl. ¶¶ 1-4, 80-88, 133-158.

Defendants also assert that the "scope of funding that may be at risk is unknown," Defs.' Mem. 20, but the Final Rule authorizes HHS to withhold or terminate billions of dollars in federal funding for even suspected violations of the Final Rule and its underlying statutes—as Defendants never contest, and as Plaintiffs clearly pled. *See* Compl. ¶¶ 1-4, 80-88, 133-158. In fact, *all* of Plaintiffs' federal health care funding is at risk, as Defendants elsewhere concede. Defs.' Mem. 4 ("Plaintiffs . . . have the straightforward remedy of no longer accepting the conditioned federal funds."). Plaintiffs are not required to gamble with that critical funding before this Court may adjudicate their constitutional claims. There is no risk of judicial entanglement in abstract disagreements here, *see Abbott Labs. v. Gardner*, 387 U.S. 136, 148 (1967)); and this Court need not wait until an enforcement action is taken under the Final Rule to conclude that Plaintiffs' claims are ripe for review, *see City of New York v. U.S. Dep't of Commerce*, 739 F. Supp. 761, 766 (E.D.N.Y. 1990).[1] The Final Rule standing alone seeks to compel changes in Plaintiffs' behavior or expose them to the risk of fund termination on the day it takes effect—with extremely disruptive consequences for Plaintiffs and the public health either way. Compl. ¶¶ 80-88, 133-158; Pls.' PI Mem. 13-14.

In any event, even assuming that ripeness depended on HHS's enforcement decisions, the likelihood of enforcement actions to terminate funds is sufficiently high to warrant adjudication of Plaintiffs' constitutional claims. It is hardly "hypothetical[]," Defs.' Mem. 20, that HHS plans to use the threat of funding termination to induce compliance with the Final Rule's new

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[1] The cases that Defendants cite with respect to the Weldon Amendment are either inapposite, or further support that Plaintiffs' claims are ripe for review. As Defendants themselves explain, *Nat'l Family Planning & Reproductive Health Ass'n, Inc. v. Gonzalez*, 468 F.3d 826 (D.C. Cir. 2006), dismissed the plaintiff's claims for lack of constitutional standing, which Defendants do not challenge in this case. In *California v. United States*, No. 05-cv-328, 2008 WL 744840 (N.D. Cal. Mar. 18, 2008), the Court made clear that when the federal government either determined that enforcing state law would violate the Weldon Amendment "or refuse[d] to provide an answer, thus leaving California in a difficult position of putting at risk billions of dollars in federal funds if it enforces its own statute, the case then would be ripe for a court to determine this matter." *Id.* at *6. This is exactly the "unfortunate situation" Plaintiffs confront here. *Id.*

requirements; HHS has said so itself, explicitly stating that one purpose in issuing the Final Rule is to address its "[i]nadequate enforcement tools to address unlawful discrimination and coercion." 84 Fed. Reg. at 23,228. Yet, there is no evidence at all in the administrative record that a single complaint of discrimination was unable to be remedied with the Department's existing tools. *See infra* Part II.C.1. This lack of evidence can only suggest that HHS intends to wield its new powers under the Final Rule to induce Plaintiffs to accept its new conditions.

Plaintiffs' Establishment Clause claim similarly presents "a concrete dispute between the parties." *Sharkey v. Quarantillo*, 541 F.3d 75, 89 (2d Cir. 2008); *see also Nat'l Org. for Marriage*, 714 F.3d at 689 (courts "assess pre-enforcement First Amendment claims . . . under somewhat relaxed standing and ripeness rules"). This claim turns on a straightforward legal analysis of the Final Rule's definition of "discrimination." That definition, at subsection (4), provides that an employer "shall not be regarded as having engaged in discrimination" against an objecting employee where the employer offers, and the employee "voluntarily accepts an effective accommodation." 84 Fed. Reg. at 23,263 (§ 88.2). Plaintiffs allege that this definition (as elaborated by the limited discussion in the rule's preamble, *see id.* at 23,190-92) violates the Establishment Clause because it permits an employee an unqualified right to refuse work for religious reasons, and accordingly requires employers like Plaintiffs to conform their business practices to the objecting employee's religious practices. *See* Compl. ¶¶ 73, 198-201. Although HHS disagrees on the merits that the Final Rule violates the Establishment Clause, *see* Defs.' Mem. 67-70, nowhere does the agency assert that the application of this definition is too "abstract" for the Court's review. *Abbott Labs.*, 387 U.S. at 148-49.

2. Plaintiffs face hardship absent the Court's consideration.

In addition, delaying review of these claims would cause immense and immediate harm to Plaintiffs and the public interest. *See id.* at 152-54; *see also New York v. U.S. Dep't of*

Commerce, 351 F. Supp. 3d 502, 626-27 (S.D.N.Y. 2019). Plaintiffs face hardship "where a regulation requires an immediate and significant change in the plaintiffs' conduct of their affairs with serious penalties attached to noncompliance." *Abbott Labs.*, 387 U.S. at 153; *see also Thomas v. City of New York*, 143 F.3d 31, 36 (2d Cir. 1998) (pre-enforcement challenge ripe where "plaintiffs must either incur great expense to comply with the requirements, or (if they choose to challenge the regulation through noncompliance) run the risk of incurring potentially even greater burdens").

This is exactly the situation Plaintiffs face. Plaintiffs' complaint alleges extensive, imminent, and potentially devastating injuries caused by the Final Rule. *See* Compl. ¶¶ 100-158. Plaintiffs' motion for preliminary injunction and supporting evidence further establish that the Final Rule will cause—and already has begun causing—these imminent harms. *See* Pls.' PI Mem. 10-22. Among these harms are significant administrative, policy, human resources, and other efforts Plaintiffs must undertake to come into compliance prior to the Final Rule's effective date, *id.* at 11-13 & nn.11-14, including efforts that have already begun. *See, e.g.*, Ex. 29 (Lucchesi Decl.) ¶ 22; Ex. 45 (Vanden Hoek & Perna Decl.) ¶¶ 19-20; Ex. 46 (Wagaw Decl.) ¶ 18. Indeed, HHS expressly states that one purpose of the Final Rule is to "institute proactive measures" by grantees like the Plaintiffs. 84 Fed. Reg. at 23,228. And Plaintiffs face "serious penalties attached to noncompliance," *Abbott Labs.*, 387 U.S. at 153, through the risk of losing billions of dollars in federal funds necessary to deliver health care to their residents. *See* Compl. ¶¶ 80-88, 133-158; Pls.' PI Mem. 13-14.

The fact that Plaintiffs must make immediate changes to the conduct of their affairs is not surprising, given the upheaval the Final Rule causes to their direct delivery of health care. As Plaintiffs alleged in their complaint and documented in the motion for preliminary injunction,

their hospitals have policies on accommodating religious objection, many of which track state laws and Title VII. *See* Compl. ¶¶ 112-114; Pls.' PI Mem. 15-16 & n.15. And as Plaintiffs also extensively documented, the Final Rule's definition of "discrimination" departs from the framework underlying their policies by, *inter alia*, allowing an employee to determine whether she has been discriminated against by tying such determination to whether she voluntarily accepts an employer's accommodation—a sea change that requires Plaintiffs' policies to be rewritten, eliminates Plaintiffs' ability to employ efficient and cost-conscious staffing arrangements, and imposes burdens on Plaintiffs' non-objecting staff. *See* Compl. ¶¶ 73-74, 79, 119-132; Pls.' PI Mem. 16-18 & nn.17-18.

Furthermore, changing their religious accommodation policies to permit objections in accordance with the Final Rule will require Plaintiffs to make staffing changes in emergency and rural settings, among others, and such changes threaten irreparable injury to the reputation of Plaintiffs' health institutions. *See* Compl. ¶¶ 119-132; Pls.' PI Mem. 18-22. Plaintiffs "deal in a sensitive industry, in which public confidence in their [services] is especially important," and "[t]o require them to challenge these regulations only as a defense to an action brought by the Government might harm them severely and unnecessarily." *Abbott Labs.*, 387 U.S. at 153; *cf. City of Chicago v. Sessions*, 264 F. Supp. 3d 933, 950 (N.D. Ill. 2017) (risk of reputational injury causes irreparable harm). Indeed, delaying judicial review until *after* Plaintiffs have been either forced to change their policies, stripped of billions of dollars in health care funds, or subjected to federal enforcement action "would result in extreme—possibly irremediable—hardship." *Dep't of Commerce v. U.S. House of Representatives*, 525 U.S. 316, 332 (1999).

Because Plaintiffs' constitutional claims are ripe for judicial review, Plaintiffs

respectfully request that the Court deny Defendants' motion to dismiss.[2]

II. The Final Rule violates the Administrative Procedure Act.

Plaintiffs are entitled to summary judgment on their claims that the Final Rule violates the Administrative Procedure Act ("APA") because "there is no genuine dispute as to any material fact and [Plaintiffs are] entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a).

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). Defendants assert that under the APA, the Final Rule is "presumed valid." Defs.' Mem. 17, 52. There is no support for this assertion; to the contrary, Congress intended for courts to conduct rigorous judicial review of agency action under the APA in order to maintain the balance of power between the branches of government: "[I]t would be a disservice to our form of government and to the administrative process itself if the courts should fail, so far as the terms of the [APA] warrant, to give effect to its remedial purposes." *Wong Yang Sung v. McGrath*, 339 U.S. 33, 41 (1950); *see also FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 537 (2009) (Kennedy, J., concurring) (in enacting the APA, "Congress confined agencies' discretion and subjected their decisions to judicial review").

Although it is correct that under the APA, "[a] reviewing court may not itself weigh the evidence or substitute its judgment for that of the agency," this standard does not support the claim of presumptive validity Defendants assert; instead, "within the prescribed narrow sphere,

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[2] Defendants also argue in general terms that all of Plaintiffs' claims should be dismissed for failure to state a claim, Defs.' Mem. 16, but do not appear to present a distinct argument on Rule 12(b)(6) grounds apart from their arguments on the merits. Defs.' Mem. 23-73. Under Rule 12(b)(6), Plaintiffs "need only allege 'enough facts to state a claim to relief that is plausible on its face.'" *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 45 n.12 (2011) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). For the reasons stated in Plaintiffs' opposition to Defendants' merits arguments in this memorandum, Plaintiffs easily clear the Rule 12(b)(6) threshold.

judicial inquiry must be searching and careful." *Islander E. Pipeline Co., LLC v. McCarthy*, 525 F.3d 141, 150-51 (2d Cir. 2008) (quotation marks and citation omitted). The Supreme Court has long made clear that the APA requires this Court to conduct "plenary review of the Secretary's decision," *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971), and that this review is to be "thorough, probing, [and] in-depth," *id.* at 415.

Here, there is no dispute of material fact that the Final Rule exceeds the Department's statutory authority, is not in accordance with law, and is arbitrary and capricious.

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

The APA requires this Court to set aside agency action that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C). For the reasons explained in the Provider Plaintiffs' summary judgment memorandum and Plaintiffs' preliminary injunction memorandum, the Final Rule exceeds the Department's statutory authority and violates the APA. *See* Provider SJ Mem., Part I; *see also* Pls.' PI Mem. 25-30.

B. The Final Rule violates the APA because it 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). For the reasons explained in the Provider Plaintiffs' summary judgment memorandum and Plaintiffs' preliminary injunction memorandum, the Final Rule is not in accordance with law because it violates the ACA's Non-Interference Mandate and impairs the federal statutory guarantee of access to emergency medical care. *See* Provider SJ Mem., Parts II.A, II.B, II.D; *see also* Pls.' PI Mem. 30-36.

In addition, the Final Rule conflicts with the Medicaid informed consent requirements and violates the Paperwork Reduction Act, as set out below.

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

The Final Rule conflicts with the Medicaid counseling and referral provision it purports to implement. *See* Pls.' PI Mem. 32-33. That statute provides that Medicaid managed care organizations will not be required to provide counseling or referral services if the organization objects on moral or religious grounds. 42 U.S.C. § 1396u-2(b)(3)(B). Congress, however, expressly cabined these refusal rights by providing that with regard to informed consent, the counseling and referral provision shall not "be construed to affect disclosure requirements under State law or under the Employee Retirement Income Security Act of 1974." *Id.* Because the Final Rule includes no exception for state-law disclosure requirements, 84 Fed. Reg. at 23,266-67 (§ 88.3(h)(1)(ii), (h)(2)(ii)), the Department's implementation of this provision exceeds its authority.

Defendants argue that the Final Rule "does not implicate any state disclosure requirements except to the extent they rely on [§ 1396u-2(b)(3)(B)] for authority," and that the Medicaid informed consent requirement "is simply not implicated here." Defs.' Mem. 49. But nothing in the Final Rule limits its reach in the way Defendants now propose; § 88.3(h)(1)(ii) provides that "[a]ny State agency that administers a Medicaid program is required to comply with," *inter alia*, sub-paragraph (h)(2)(ii); and that sub-paragraph in turn includes a blanket restriction on requiring an objecting Medicaid managed care organization to provide counseling or referral services, with no exception for state disclosure laws. 84 Fed. Reg. at 23,266-67. A regulation may be upheld only "on the basis articulated by the agency itself"—not on "counsel's post hoc rationalizations." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983).

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

Plaintiffs explained in their memorandum supporting a preliminary injunction that the assurance and certification requirements in the Final Rule, 84 Fed. Reg. at 23,269, are not in accordance with law because the Department failed to comply with the Paperwork Reduction Act ("PRA"). *See* Pls.' PI Mem. 35-36. Defendants' one-sentence response effectively concedes this point, arguing only that *after* the Final Rule was published, the Department belatedly sought to comply with its obligations and "fully expects approval prior to the Rule's revised effective date." Defs.' Mem. 51.

Defendants' response does not cure this legal infirmity. First, as of today, these data collection requirements still have not been approved; and Defendants cannot seriously be asking the Court to ignore a conceded APA violation because the Department "fully expects" that a non-party (the OMB Director) may take action in the future. *Cf. Bellevue Hosp. Ctr. v. Leavitt*, 443 F.3d 163, 179 (2d Cir. 2006) (agency decision was arbitrary where instead of complying with statutory requirement, "agency simply stated its intent to do better the next time").

Second, the Information Collection Request that the Department belatedly submitted to OMB seeks approval only for the assurance requirement, not the certification of compliance. *See* Information Collection Request, *Request for OMB Review and Approval*, at 5 (June 19, 2019), at https://www.reginfo.gov/public/do/DownloadDocument?objectID=92774800 ("Note that this information collection request does not include the related certification of compliance in section 88.4(b).").[3] Defendants' incomplete attempt at post-hoc compliance with its legal obligations renders the assurance and certification requirements invalid under the APA.

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[3] *See also* Information Collection Request—Agency Submission, https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201906-0945-003.

C. 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." *State Farm*, 463 U.S. at 43. Furthermore, agency changes to longstanding policies that have engendered reliance interests over time must "show that there are good reasons for the new policy," and provide a "detailed justification" for its new direction to survive arbitrary and capricious review. *Fox*, 556 U.S. at 515.

The Department's stated reasons for implementing the Final Rule are unsupported and inconsistent with the record evidence; the Department failed entirely to consider the record evidence of significant upheaval the Final Rule would cause; and despite that record evidence, the Department grossly failed to appropriately assess the costs and benefits of its rulemaking.

1. HHS has justified the Final Rule on the basis of asserted problems that do not in fact exist.

HHS's repeated refrain that the Final Rule is necessary to address confusion created by the 2011 Rule, and to adequately provide for enforcement of federal conscience protections, is unsupported by the record and therefore arbitrary and capricious. HHS fails to "acknowledge . . . record evidence directly contradicting its [stated rationales for the Final Rule]," *Islander E. Pipeline Co., LLC v. Conn. Dep't of Envtl. Prot.*, 482 F.3d 79, 102 (2d Cir. 2006), and does not satisfactorily provide a "rational connection between the facts found and the choice made," *State Farm*, 463 U.S. at 43 (internal quotation marks omitted).

First, HHS claims that the Final Rule is necessary to address confusion created by the

2011 Rule. *See* 84 Fed. Reg. at 23,175, 23,228. HHS claims that:

> The 2011 Rule created confusion over what is and is not required under Federal conscience and anti-discrimination laws and narrowed OCR's enforcement processes. Since November 2016, there has been a *significant increase* in complaints filed with OCR *alleging violations of the laws that were the subject of the 2011 Rule,* compared to the time period between the 2009 proposal to repeal the 2008 Rule and November 2016. The increase underscores the need for the Department to have the proper enforcement tools available to appropriately enforce all Federal conscience and anti-discrimination laws.

84 Fed. Reg. at 23,175 (emphasis added); *see also id.* at 23,229 (separately calculating the number of complaints, and stating that OCR received 34 complaints between November 2016 and January 2018, and 343 during fiscal year ("FY") 2018); *id.* at 23,183 ("This rule provides appropriate enforcement mechanisms *in response to a significant increase* in complaints alleging violations of Federal conscience and anti-discrimination laws." (emphasis added)).

But on review of the administrative record, this rationale proves false. Prior to the November 2016 election, evidence of confusion with respect to the underlying statutes and the current regulatory scheme is slim to non-existent: as HHS itself highlights, the Department only received ten complaints alleging violations of federal conscience protections between 2009 and November 2016. *See* 83 Fed. Reg. at 3886. Subsequently, HHS purportedly received 34 complaints between November 2016 and January 2018, and 343 complaints in FY 2018 when it issued the notice of proposed rulemaking. *See* 84 Fed. Reg. at 23,229.[4] However, the vast

[4] HHS misleadingly suggests that the 34 complaints received between November 2016 (after the election) and January 2018 are distinct from the 343 complaints received in FY 2018. The relevant fiscal year, however, is from October 1, 2017 to September 30, 2018. *See* https://www.usa.gov/budget. Accordingly, some of the 34 complaints overlap with the 343 complaints. Given this confusion, Plaintiffs requested that Defendants' counsel direct Plaintiffs to the bates numbers for the 34 complaints, but Defendants never provided that information. *See* Ex. 135 (Miller Decl.) ¶¶ 4-9.

From what Plaintiffs have been able to discern, the administrative record shows 358 unique complaint numbers for the period between the November 2016 election and the end of FY 2018 on the index provided by HHS. *See* Ex. 135 (Miller Decl.) ¶¶ 10-11 & Ex. 135-A. Twenty-two of those complaints are exact duplicates, *see* Ex. 135 (Miller Decl.) ¶ 12 & Ex. 135-B, leaving 336 unique complaints. Ex. 135 (Miller Decl.) ¶ 13. As Plaintiffs explain further, *infra*, the vast majority of these unique complaints are irrelevant to the underlying refusal statutes or the Final Rule.

majority of complaints received after November 2016 reflect a fundamental misunderstanding of what federal conscience laws require or protect.

Tellingly, Defendants now concede that "a large subset of" the complaints received by HHS after November 2016 "complain of conduct that is outside of the scope of the Federal Conscience Statutes and the [Final] Rule." Defs.' Mem. 53. And while the Final Rule expressly claims a "*significant* increase" in complaints alleging violations of "Federal conscience and anti-discrimination laws," 84 Fed. Reg. at 23,175 (emphasis added), Defendants now acknowledge, as they must, that only "*some*" of the complaints "do implicate the relevant statutes." Defs.' Mem. 53 (emphasis added).

These are startling admissions, yet still manage to understate matters. In response to comments that the Final Rule was unnecessary because of the number of complaints HHS had received, HHS made a specific empirical claim that "OCR received 343 complaints alleging conscience violations" in FY 2018. 84 Fed. Reg. at 23,229. Yet a review of the administrative record reveals that the vast majority of these complaints—approximately 79%—do *not* in fact allege conscience violations, and instead relate to vaccinations, *see* Ex. 135 (Miller Decl.) ¶ 15 & Ex. 135-F, which the Department expressly admits is beyond the scope of the Final Rule. *See, e.g.*, 84 Fed. Reg. at 23,183. Numerous other complaints have nothing to do with the topics the Final Rule purports to clarify,[5] and a few vehemently *oppose* issuance of the Final Rule.[6]

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[5] *See e.g.,* Ex. 123, AR 542627-36 (complaint filed because federal agencies forced complainant to remove social media ads for "divine cure for cancer"); Ex. 124, AR 543082-90 (parent alleging discrimination against a health care entity because parent did not want newborn to have a newborn screening test); Ex. 125, AR 543879-82 (allegations of identity theft and health care fraud); Ex. 126, AR 544035-43 (complainant upset about needing to purchase coverage for unneeded prescriptions); Ex. 128, AR 544235-43 (allegations of HIPAA violations when an entity posted medical records online); Ex. 131, AR 544753-62 (employee complains of suspension for refusing to meet with board of directors regarding unspecified grievances); *see also* Ex. 135 (Miller Decl.) ¶ 16 & Ex. 135-D.

[6] *See* Ex. 121, AR 542414-22 (explaining HHS's actions are "an appalling, unethical abuse of 'religious freedom' to impose archaic religious ideals on citizens in order to deny them civil liberties and health care"); Ex. 122, AR

Indeed, of the total number of complaints in the record received by HHS since November 2016, a mere *six percent* (21 complaints) allege conduct that is even arguably covered by the refusal statutes or Rule. *See* Miller Decl. ¶ 17 & Exs. 135-F, 135-G.[7]

The mismatch between the agency's stated explanation for the Final Rule and the actual facts in the administrative record cannot be overstated. HHS has woefully failed to substantiate its claim that "allegations and evidence of discrimination and coercion have existed since the 2008 Rule and increased over time." 84 Fed. Reg. at 23,175. It comes nowhere near supporting its assertion that there has been a "significant increase" in complaints related to the refusal statutes. *Id.* The agency's very specific claim of 343 complaints in FY 2018 that allege violations of these laws turns out to be patently false. "Suffice it to say, it is arbitrary and capricious for an agency to base its decision on a factual premise that the record plainly showed to be wrong." *NRDC v. Rauch*, 244 F. Supp. 3d 66, 96 (D.D.C. 2017) (citing *State Farm*, 463 U.S. at 43); *cf. Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2575 (2019) (invalidating agency action where "the evidence tells a story that does not match the explanation the Secretary gave for his decision"). That is exactly the case here, as Defendants now all but admit.[8] Far from supporting HHS's contention that the 2011 Rule needed clarification, the record shows that if anything, the Department's proposal to significantly alter the status quo has sown more confusion in the past year than in the previous seven years combined.

542449-57 ("The Current Administration has allowed religious Zealots to run health information agencies.").

[7] Plaintiffs do not concede that all of these complaints are legitimate. And while Plaintiffs do not always agree with HHS's interpretation of the scope of the refusal statutes, *see, e.g.*, 84 Fed. Reg. at 23,178-79 (discussing Weldon Amendment), for purposes of this brief Plaintiffs have erred on the side of including such complaints in this category.

[8] Defendants contend that the supposed increase in complaints was just one of "many metrics" the agency relied on, Defs.' Mem. 53, but Defendants have not here illuminated what those other metrics are, and they do not disagree that complaint volume was in fact a central reason the agency gave for promulgating the Final Rule. A rulemaking that relies a mischaracterization of the actual record evidence is arbitrary. *City of Phila. v. Sessions*, 280 F. Supp. 3d 579, 623-24 (E.D. Pa. 2017).

HHS's second justification for the Final Rule—"[i]nadequate enforcement tools to address unlawful discrimination and coercion," 84 Fed. Reg. at 23,228—also finds no support in the administrative record, and is again counter to the evidence. As explained above, the majority of complaints upon which HHS relies to promulgate the Final Rule do not require enforcement by the Department, or even fall within the scope of the Final Rule or the underlying statutes, as HHS concedes. Moreover, with respect to most of the complaints in the record, there is zero evidence that HHS investigated them at all, or needed more authority to do so.[9] The record further reveals that in the small number of instances where HHS investigated complaints, they were largely unfounded or otherwise satisfactorily resolved.[10] Indeed, HHS highlights the corrective actions health care providers and institutions took in response to OCR investigations. *See, e.g.*, 83 Fed. Reg. at 3,886 (explaining that after OCR conducted investigations of complaints, relevant entities revised policies, posted notices, trained personnel about statutory obligations, and made public announcements indicating changes to practices). Where, as here, the record evidence "directly contradicts the unsupported reasoning of the agency and the agency fails to support its pronouncements with data or evidence," courts will not defer to agency action. *Islander*, 482 F.3d at 103.

Effectively conceding that the Department's reliance on a supposed record of hundreds of conscience complaints is false, Defendants now point to only three complaints in the entire

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[9] There is no evidence in the administrative record pertaining to any investigation of the FY 2018 complaints, with the exception of one complaint. *See* Ex. 135 (Miller Decl.) ¶ 18 & Ex. 135-E. And with respect to complaints filed before November 2016, HHS concedes that nearly all have been resolved. *See* 83 Fed. Reg. at 3886. Further, HHS offers no explanation for why two pre-November 2016 complaints remain open, but in any event there is nothing on the face of these complaints to suggest it is because the Department lacks enforcement authority. *See* Ex. 132, AR 545712-16 (Aug. 15, 2014 complaint alleging complainant denied admission privileges because she performed abortions); Ex. 133, AR 545736-40 (Nov. 4, 2015 complaint alleging California's FACT Act violates federal law).

[10] *See, e.g.*, Ex. 120, AR 541967 (OCR closed matter because complaint failed to state a claim of discrimination); Ex. 119, AR 541805 (complaint withdrawn when grantee took actions to come into compliance); *see also* Ex. 135 (Miller Decl.) ¶ 18 & Ex. 135-E (listing record evidence of 14 resolved complaints).

administrative record that purportedly "implicate the relevant statutes." Defs.' Mem. 53. Even this thin showing undermines, rather than supports, the Department's stated reasons for the Final Rule. As noted below, two of the complaints concern issues or entities that are not subject to the underlying statutes; and as to all three, there is nothing in the administrative record to suggest these complaints were even investigated, let alone that they could plausibly form a basis for concluding that the Department needed greater enforcement authority.

Specifically, the first complaint Defendants cite is a 2018 letter from the American Association of Pro-Life Obstetricians and Gynecologists ("AAPLOG") to OCR complaining about a decade-old ethics committee opinion by the American College of Obstetricians and Gynecologists ("ACOG") that, according to AAPLOG, leaves ob-gyns "vulnerable to the possibility that his or her conscience-based refusal to participate in abortion could be considered unethical." Ex. 129, AR 544525. The letter fails to refer to a single example of this "discrimination" occurring in the more than ten years since the ethics committee opinion was published.[11] But even if it had, ACOG is a professional organization of doctors and is plainly not subject to any of the refusal statutes. It makes no sense, then, to point to this complaint as evidence of confusion over the scope of the refusal statutes, or of the inadequacy of existing enforcement mechanisms.

The second complaint Defendants cite provides even less support for HHS's stated rationales for the Final Rule. Ex. 127, AR 544188. This 2018 complaint, by an employee of the Washington State Department of Corrections, alleges discrimination based on a refusal to provide hormone therapy to incarcerated transgender persons. Because the objected-to conduct

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[11] Moreover, the administrative record includes a statement by ACOG explaining that the committee opinion will *not* be used to determine whether an ob-gyn was entitled to board certification. Ex. 129, AR 544516, at 544557-58; *see also id.* at AR 544555 (letter from American Board of Obstetrics & Gynecology to then-Secretary of HHS Michael O. Leavitt).

has nothing to do with abortion or sterilization procedures, the complaint, by definition, does not implicate the Church (b), (c)(1), (e), Coats-Snowe, or Weldon Amendments. The only refusal statute provisions that could even arguably be at issue here are Church (c)(2) or Church (d). Church (c)(2), however, concerns the rights of employees of entities that receive biomedical and behavioral research funds administered by HHS. *See* 42 U.S.C. § 300a-7(c)(2). However, federal law severely restricts HHS-funding of biomedical or behavioral research on incarcerated persons, subject to discrete and narrow exceptions. *See* 45 C.F.R. § 46.306(a)(2). Meanwhile, Church (d) only applies to a "health service program or research activity funded in whole or in part under a program administered by" HHS, 42 U.S.C. § 300a-7(d), and therefore, "does not encompass . . . medical treatments and services performed by health care providers [that] are not 'part of' a health service program receiving funding from HHS," 84 Fed. Reg. at 23,197. Defendants do not identify any HHS-funded program that provides gender-affirming health care to individuals incarcerated in state prisons and, as such, fail to explain how this complaint implicates any of the federal refusal statutes.[12]

This leaves a single complaint identified in HHS's brief that even arguably states a violation of the refusal statutes. *See* Ex. 130, AR 544612. That is far too thin a reed to rationally support the agency's express justification for the Final Rule: a "*significant increase* in complaints filed with OCR *alleging violations of the laws that were the subject of the 2011 Rule*," 84 Fed. Reg. at 23,175. Nor does the face of this complaint lend any support to HHS's second justification that it has inadequate enforcement tools at its disposal to address the issues it presents. 84 Fed. Reg. at 23,228. Indeed, the administrative record contains nothing with

[12] For example, federal law prohibits states from using federal Medicaid matching funds for health care services provided to adult and juvenile inmates of public institutions, except when the inmate is admitted to an off-site hospital or other qualifying facility for at least 24 hours. 42 U.S.C. § 1393d(a)(29)(A).

respect to HHS's assessment of the complaint, or any investigation thereof.

Defendants' own attempt to identify evidence to support HHS's stated reasons for the Final Rule reveals that HHS's decision is "unsupported by substantial evidence," and therefore arbitrary and capricious. *Genuine Parts Co. v. EPA*, 890 F.3d 304, 312 (D.C. Cir. 2018).

2. The Department failed to provide a reasoned explanation for its policy change.

In addition, to survive arbitrary and capricious review, an agency must provide a substantial justification when "its new policy rests upon factual findings that contradict those which underlay its prior policy; or when its prior policy has engendered serious reliance interests that must be taken into account." *Perez v. Mortgage Bankers Ass'n*, 135 S. Ct. 1199, 1209 (2015) (internal quotation marks omitted). The Final Rule implicates both concerns: the new policy rests on new factual findings based on substantially the same evidence the Department already considered in 2011 to reach the opposite conclusions; and Plaintiffs have relied on the prior policy as codified in the 2011 Rule, including the Department's previous view that existing "statutes strike a careful balance between the rights of patients to access needed health care, and the conscience rights of health care providers." 76 Fed. Reg. 9968, 9973 (Feb. 23, 2011).

In support of the Final Rule, the Department heavily relies on the same evidence that the agency considered in promulgating the 2011 Rule, which largely rescinded the 2008 Rule that had included many of the same onerous provisions found in the 2019 Final Rule.[13] *See, e.g.*, Pls.' PI Mem. 4-9. Yet in 2011, after considering this information, HHS found that (1) "the 2008 final rule attempting to clarify the Federal health care provider conscience statutes ha[d] instead led to greater confusion," 76 Fed. Reg. at 9969; (2) "the 2008 Final Rule may negatively affect

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[13] This evidence includes a 2009 survey, 2009 journal article, news reports in 2010, and comments the Department received in response to the proposed rescission of the 2008 Rule. *See, e.g.*, 84 Fed. Reg. at 23,175-76.

the ability of patients to access care if interpreted broadly," *id.* at 9974; and (3) the certification requirements imposed by the 2008 Rule "created unnecessary additional financial and administrative burdens on health care entities," *id.* The Department's reliance on the same evidence more than eight years later to reach precisely the opposite conclusions—with no explanation of why the Department's assessment of those facts in 2011 was incorrect—is arbitrary and capricious. *See Organized Vill. of Kake v. U.S. Dep't of Agric.*, 795 F.3d 956, 968 (9th Cir. 2015) (en banc) (holding an agency's decision arbitrary and capricious when "it made factual findings directly contrary to" its previous policy following a change in presidential administrations, and "expressly relied on those findings to justify the policy change"); *see also Fox*, 556 U.S. at 515-16; *Islander*, 482 F.3d at 103.

The Department claims that it did "acknowledge that it was changing its policy," Defs.' Mem. 52, but far more than an "acknowledgement" was required by the APA. The Department was required to provide "a reasoned explanation" for its dramatic change in course, which it failed to do. *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016). Instead, in responding to the many comments explaining that the Final Rule would jeopardize patient access to care[14]—one of the key findings underlying the 2011 Rule—the Department concluded "that finalizing the rule is appropriate *without regard to whether data exists* . . . about its effect on access to services." 84 Fed. Reg. at 23,182. But "[a]n agency cannot simply disregard contrary or inconvenient factual determinations that it made in the past, any more than it can ignore

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[14] *See, e.g.*, Ex. 87, AR 137920 (Comment, Attorneys General of New York, et al.) ("New York Comment"); Ex. 89, AR 138102 (Comment, Nat'l Family Planning & Reprod. Health Ass'n) ("NFPRHA Comment"); Ex. 99, AR 140484 (Comment, New York City Comm'n on Human Rights, et al.) ("NYC Comment"); Ex. 100, AR 147746 (Comment, Am. Civil Liberties Union) ("ACLU Comment"); Ex. 110, AR 149141 (Comment, Nat'l Women's Law Ctr.) ("NWLC Comment"); Ex. 113, AR 160751 (Comment, Planned Parenthood Fed. of Am.) ("PPFA Comment"); Ex. 117, AR 161476 (Comment, Lambda Legal) ("Lambda Comment").

inconvenient facts when it writes on a blank slate." *Fox*, 556 U.S. at 537 (Kennedy, J., concurring).

The Department's lack of reasoned explanation is particularly egregious given that the Final Rule's radical departure from long-established policy will upend strong reliance interests. Plaintiffs and many others have developed staffing patterns and scheduling practices, hired personnel, entered into collective bargaining agreements, signed contracts with subrecipients, and otherwise structured their operations around HHS's longstanding interpretation of the refusal statutes.[15] HHS acted arbitrarily in disregarding these strong reliance interests of Plaintiffs, their health care institutions, and the populations they serve. *See Encino Motorcars*, 136 S. Ct. at 2126; *see also Chamber of Commerce v. U.S. Dep't of Labor*, 885 F.3d 360, 387 (5th Cir. 2018) (vacating agency rule as arbitrary where it "transform[ed]" the "market . . . and . . . regulate[d] in a new way the thousands of people and organizations working in that market").

3. In promulgating the Final Rule, the Department entirely failed to consider important aspects of the problem.

The APA requires this Court to set aside Defendants' decision as arbitrary if Defendants "entirely failed to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43.

a. HHS failed to consider the Final Rule's radical disruption of health care delivery.

A failure to address serious harms presented to the agency—with widespread impact on a regulated industry—constitutes arbitrary decisionmaking. *See, e.g.*, *SecurityPoint Holdings, Inc. v. Transp. Sec. Admin.*, 769 F.3d 1184, 1188 (D.C. Cir. 2014) (vacating agency order where

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[15] *See, e.g.*, Ex. 72, AR 67173 (Comment, Wash. Dep't of Health) ("WA DOH Comment"); Ex. 76, AR 71138 (Comment, Ass'n of Am. Med. Colls.) ("AAMC Comment"); Ex. 86, AR 137905 (Comment, Calif. Dep't of Justice); Ex. 87, AR 137920 (New York Comment); Ex. 89, AR 138102 (NFPRHA Comment); Ex. 96, AR 140265 (Comment, BlueCross BlueShield Ass'n) ("BCBS Comment"); Ex. 97, AR 140350 (Comment, Calif. Dep't of Insurance) ("CA Insur. Comment"); Ex. 99, AR 140484 (NYC Comment); Ex. 100, AR 147746 (ACLU Comment); Ex. 101, AR 147824 (Comment, Greater New York Hospital Ass'n) ("GNYHA Comment"); Ex. 113, AR 160751 (PPFA Comment).

agency failed even to consider potential harms of its changes to an airport advertising program); *Stewart v. Azar*, 313 F. Supp. 3d 237, 263 (D.D.C. 2018) (vacating HHS Secretary's waiver of several requirements of expanded Medicaid because "[f]or starters, the Secretary never once mentions the estimated 95,000 people who would lose coverage, which gives the Court little reason to think that he seriously grappled with the bottom-line impact on healthcare."). Courts also consider agency action arbitrary and capricious when the agency "fail[s] to address the commenters' concerns." *Ass'n of Private Sector Colls. & Univs. v. Duncan*, 681 F.3d 427, 449 (D.C. Cir. 2012).

Here, as discussed in the Provider Plaintiffs' summary judgment memorandum and Plaintiffs' preliminary injunction memorandum, the Final Rule defines key statutory terms in a manner that dramatically expands the scope and applicability of the underlying federal statutes and that will have a widespread impact on the health care industry. *See* Provider SJ Mem., Part II.A; *see also* Pls.' PI Mem. 25-30, 37-38. The new definitions of "assist in the performance," "referral," and "discrimination" drastically expand the universe of individuals, entities, and conduct regulated by the refusal statutes, and radically disrupt Plaintiffs' and other providers' basic operations and ability to deliver care—including emergency care. Taken together, these definitions create a dangerous double bind for providers: "assist in the performance" and "referral" increase the number of prospective objectors from clinical staff to a potentially limitless group of workers, while "discrimination" prescribes unworkable limits on a provider's ability to learn about possible objections among this expanded group of workers, thereby limiting providers' ability to provide undisrupted patient care.[16]

[16] Pursuant to the Final Rule, an employee (1) may not be asked, pre-hire, whether she can execute core functions of her job without objection; (2) has no affirmative duty to disclose an objection to any aspect of her work; (3) may object at any time to any task, without advance notice to her employer and regardless of the effect on patient health;

The administrative record contains evidence that the Final Rule would do serious damage to Plaintiffs and other providers around the country in just this way. Major industry organizations and health provider systems, representing or employing millions of health care workers, raised the following operational concerns to HHS:

- Expanding the universe of potential objectors beyond clinicians to other workers, *e.g.*, janitorial, scheduling, or other administrative staff, "could significantly impact the smooth flow of health care operations for physicians, hospitals, and other health care institutions and could be unworkable in many circumstances." Ex. 91, AR 139590 (Comment, Am. Med. Ass'n) ("AMA Comment"); *see also* Ex. 72, AR 67174 (WA DOH Comment); Ex. 111, AR 151667 (Comment, California Med. Ass'n) ("CMA Comment").

- An employee's affirmative disclosure of an objection with meaningful advance notice to the employer is essential to the operations of hospitals and health providers, and its absence or restriction would disrupt business operations and jeopardize patient care. *See* Ex. 73, AR 67415 (Comment, Am. Hosp. Ass'n) ("AHA Comment"); Ex. 81, AR 134793 (Comment, San Francisco Dep't of Pub. Health) ("SFDPH Comment"); Ex. 84, AR 137611 (Comment, Ohio Hosp. Ass'n); Ex. 92, AR 139641-42 (Comment, Kaiser Permanente) ("Kaiser Comment"); Ex. 101, AR 147825-26 (GNYHA Comment); Ex. 102, AR 147872 (Comment, Massachusetts Health & Hosp. Ass'n);

- Confusion as to how an objecting employee's exercise of her right to refuse, pursuant to the expanded definitions of "assist in the performance" and "discrimination," affects existing collective bargaining agreements governing employees, and whether a health provider could legally administer the rule's requirements. *See* Ex. 81, AR 134793 (SFDPH Comment) (noting "problems with the fair administration of labor contracts between employees asserting conscience rights and those who do not"); Ex. 92, AR 139649 (Kaiser Comment); and

- The double bind of the definitions is especially destructive to "emergency departments, ambulance corps . . . and other urgent care settings" with extremely limited staffing, which cannot successfully plan for employee objections, consistent with the rule. Ex. 99, AR 140486 (NYC Comment) (noting the "very real financial impact on healthcare facilities, including government-run and subsidized clinics and hospital systems"); *see also* Ex. 106, AR 147982 (Comment, Am. Coll. of Emergency Physicians) ("ACEP Comment") (observing the rule requires "an impossible task that jeopardizes the ability to provide care, both for standard

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and (4) should an employer seek to accommodate an expressed objection, the employee has the categorical right to reject the accommodation as not "effective," with no consequence to her employment. *See* 84 Fed. Reg. at 23,263 (definition of "discrimination).

emergency room readiness and for emergency preparedness").

Despite this extensive evidence in the administrative record, the Department entirely failed to consider disruptions to the operations of health providers, including Plaintiffs. None is mentioned or discussed in the Final Rule. Contrary to the Department's argument, Defs.' Mem. 55, these examples are not "hypothetical"—they are documented disruptions presented directly to the agency through the administrative record by major health systems and industry organizations, concerning the drastic effect the Final Rule will have on the delivery of health care by their institutions and members.[17] The Department's failure to consider these consequences is arbitrary. *See Am. Wild Horse Pres. Campaign v. Perdue*, 873 F.3d 914, 932 (D.C. Cir. 2017) (agencies must "adequately analyze . . . the consequences" of their actions); *see also SecurityPoint Holdings*, 769 F.3d at 1188; *Stewart*, 313 F. Supp. 3d at 263.

Second, HHS claims that it satisfied its obligations under the APA because it "modified each definition in response to the comments it received." Defs.' Mem. 56. But those modifications utterly failed to address the concerns raised.[18] *See, e.g.*, *Duncan*, 681 F.3d at 449. This is true as to each definition, and the change to "discrimination" is illustrative. In finalizing the rule, HHS added subsections (4)-(6) to the definition as proposed, purportedly to address commenters' concerns about the Rule's interaction with Title VII. *See* 84 Fed. Reg. at 23,190-92, 23,263. Yet nowhere does the agency address concerns that advance notice of an objection is essential to provider operations and patient care. And HHS does not dispute that, consistent with the Final Rule's definition of "discrimination" (even as modified), an employee may object at

[17] Though HHS describes Plaintiffs' examples as "extreme," it appears to endorse just such an extreme scope with respect to the definition of "assist in the performance." Without in any way addressing the definition's operational consequences or burdens on providers, HHS appears to agree that, *e.g.*, an employee who schedules an abortion would assist in the performance of that procedure. *See* 84 Fed. Reg. at 23,186-87.

[18] Indeed, on this score HHS itself concedes that its modification of the definition of "referral" from the 2018 Proposed Rule to the 2019 Final Rule is "relatively minor." 84 Fed. Reg. at 23,199.

any time to performing even core job functions—without advance notice and irrespective of patient harm—with no consequence to her employment. Nor does HHS anywhere address the "double bind" or cumulative effect of its definitions upon health providers, though this was set out squarely before the agency. *See, e.g., WildEarth Guardians v. Salazar*, 741 F. Supp. 2d 89, 102-03 (D.D.C. 2010) (agency action is arbitrary where the agency failed to consider "cumulative effect" of factors individually considered). The Final Rule is arbitrary and capricious because of the Department's failure to consider the severe operational harms to providers that are extensively documented in the administrative record.

b. HHS failed to consider harms to public health and specific patient populations.

The Final Rule is arbitrary for the additional reason that the Department failed to consider, or to conduct a reasoned analysis regarding, the Final Rule's impact on reducing access to care for large numbers of people—*e.g.*, women, LGBTQ people, immigrants and refugees, people living with HIV/AIDS or disabilities—who already face barriers to access. HHS "does not dispute that people in such demographic categories face health care disparities of various forms," 84 Fed. Reg. at 23,251, and indeed such disparities and the harmful impacts of the Final Rule are documented in the administrative record through comments citing statistics, data, first-hand accounts from medical providers, and other evidence.[19]

Nor does the Final Rule account for the financial, physical, and mental harms—among other serious and wide-ranging negative effects—that patients who are denied care will suffer.

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[19] *See, e.g.*, Ex. 80, AR 134731-738 (Comment, Nat'l Ctr. for Lesbian Rights); Ex. 83, AR 135825-32 (Comment, Callen-Lorde Cmty. Health Ctr.); Ex. 108, AR 148073-74 (Comment, N.Y. State LGBT Health & Hum. Servs. Network); Ex. 109, AR 148096-107 (Comment, Nat'l Ctr. for Transgender Equality); Ex. 110, AR 149142-43, 149150-53 (NWLC Comment); Ex. 112, AR 160566-69 (Comment, GLMA: Health Professionals Advancing LGBT Equality) ("GLMA Comment"); Ex. 113, AR 160752-54 (PPFA Comment); Ex. 117, AR 161485-92 (Lambda Comment).

See, e.g., Provider Pls.' PI Mem. at 18-19. These harms include adverse health outcomes for patients who are denied information about or access to care; increased costs and burden related to the need to obtain care from other sources; and the harms of forgone medical assistance when patients fear refusal by a provider.[20] The failure to account for these documented harms is arbitrary. *See Humane Soc'y of U.S. v. Zinke*, 865 F.3d 585, 606 (D.C. Cir. 2017); *see also Stewart*, 313 F. Supp. 3d at 263.

In the face of this evidence, HHS makes three arguments. First, the agency argues that commenters failed to identify suitable data allowing for reliable quantification of the Final Rule's effects, Defs. Mem. 57-58, ignoring that it is the *Department's* burden to establish a "rational connection between the facts found and the choice made."[21] *Nat'l Treasury Emps. Union v. Horner*, 854 F.2d 490, 498 (D.C. Cir. 1988) (internal quotation marks omitted).

Second, HHS discounts the record evidence on this point as "anecdotal accounts . . . unfit for extrapolation," Defs. Mem 58, but this explanation is fatally inconsistent. The agency itself cites to anecdotal evidence in support of its belief that the Final Rule will increase the number of available providers, *see, e.g.*, 84 Fed. Reg. at 23,247, 23,252; and "[o]f course it would be arbitrary and capricious for the agency's decision making to be 'internally inconsistent.'" *NRDC v. U.S. Nuclear Regulatory Comm'n*, 879 F.3d 1202, 1214 (D.C. Cir. 2018). HHS also discounts the record support of harms to patients because the Department did not consider it "empirical

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[20] *See, e.g.,* Ex. 72, AR 67173 (WA DOH Comment); Ex. 73, AR 67413 (AHA Comment); Ex. 76, AR 71138 (AAMC Comment); Ex. 87, AR 137920 (New York Comment); Ex. 91, AR 139587 (AMA Comment); Ex. 94, AR 139749 (Comment, Am. Coll. of Obstetricians & Gynecologists) ("ACOG Comment"); Ex. 97, AR 140350 (CA Insur. Comment); Ex. 98, AR 140460 (Comment, Am. Acad. of Pediatrics); Ex. 99, AR 140484 (NYC Comment); Ex. 100, AR 147746 (ACLU Comment); Ex. 106, AR 147981 (ACEP Comment); Ex. 107, AR 148056 (Comment, Nat'l Immigration Law Ctr.); Ex. 110, AR 149141 (NWLC Comment); Ex. 113, AR 160751 (PPFA Comment); Ex. 116, AR 161178 (Comment, Inst. for Policy Integrity) ("IPI Comment").

[21] *See also infra* Part II.C.4 (concerning HHS's cost-benefit analysis); Provider PI Mem. 17-18.

evidence," 84 Fed. Reg. at 23,251; but here too, the Department has chosen to selectively credit non-empirical evidence that happens to support the Final Rule, including a summary of an outdated 2009 poll based on predictions about the effects of an entirely different rule (the 2011 Rule).[22] *See* Defs.' Mem. 54 ("There was nothing unreasonable, arbitrary, or capricious in HHS considering the poll among other non-empirical evidence."). Selective reliance on non-empirical evidence only when supportive—combined with the refusal to consider like evidence when it undermines the agency's position—is arbitrary. *See Water Quality Ins. Syndicate v. United States*, 225 F. Supp. 3d 41, 69 (D.D.C. 2016) (reversing agency decision that "cherry-pick[ed] evidence").

Third, HHS argues that the majority of comments on this topic "focused on *preexisting* discrimination in health care and did not attempt to answer the question of how the Rule itself would affect access to health care." Defs.' Mem. 58. As an initial matter, evidence of preexisting discrimination in health care is self-evidently germane to the agency's consideration of how a new health care policy will affect already-vulnerable populations. *Cf. Friends of Back Bay v. U.S. Army Corps. of Eng'rs*, 681 F.3d 581, 588 (4th Cir. 2012) ("A material misapprehension of the baseline conditions existing in advance of an agency action can lay the groundwork for an arbitrary and capricious decision."). In addition, among the handful of arguably pertinent complaints HHS cites to justify the specific need for the Final Rule, *see supra* Part II.C.1, is an objection that mirrors the very record evidence HHS discounts concerning the rule's impact on access to care. To the extent that HHS believes a complaint from a correctional employee—who objected to providing hormone therapy to a transgender inmate—warrants new

[22] Intervenors' argument that Plaintiffs "do not challenge the survey's methodology or results," CMDA Mem. 24, is curious given that the record includes no information regarding the poll's methodology. All that exists in the record is a two-page summary of the poll, Ex. 118, AR 537609-10; which makes HHS's reliance on it as part of its justification for the Final Rule all the more arbitrary.

HHS enforcement powers under the Final Rule, the underlying facts are similar to the record evidence before the agency concerning barriers to access for transgender patients and heightened discrimination since HHS first proposed the rule.[23] The agency's arguments about the evidence before them reflects either a complete failure to address these population-based patient harms or, at the least, the absence of a "reasoned analysis" and "satisfactory explanation of its action."[24] *State Farm*, 463 U.S. at 42-43; *see also Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015) ("[R]easonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions") (emphasis in original).

c. HHS failed to consider the Final Rule's interference with EMTALA.

The Final Rule is arbitrary and capricious because HHS failed to consider an important aspect of the problem that health care providers and entities repeatedly raised in response to the notice of proposed rulemaking—namely, how to reconcile the Final Rule with the Emergency Medical Treatment and Labor Act ("EMTALA").

Commenters stressed that it was critical for HHS to confirm that the Final Rule would not affect EMTALA's requirement that covered hospitals treat and care for patients in emergency situations.[25] As noted in the Provider Plaintiffs' summary judgment memorandum, the Final

[23] *See, e.g.*, Ex. 112, AR 160568 (GLMA Comment) ("Since the Department issued the proposed regulation, GLMA members have shared with us the ways they have seen religious objections used to the detriment of the healthcare of LGBT patients," citing multiple accounts of barriers to access); Ex. 117, AR 161490-91 (Lambda Comment) (citing instance of clinic doctor refusing to provide hormone replacement therapy to a transgender woman, based on a religious objection).

[24] This defense also fails because it is inconsistent with the Department's own reasoning in support of the Final Rule—in particular, HHS's reliance on the "preexisting" CMDA poll, which did not attempt to answer the question of how *this* Rule would affect access to care, or even whether the 2011 rescission of the 2008 rule actually led to the exodus of health care providers that the 2009 poll predicted.

[25] *See, e.g.*, Ex. 87, AR 137926-928 (New York Comment); Ex. 90, AR 139288 (Comment, Boston Med. Ctr.); Ex. 103, AR 147892 (Comment, Anne Arundel Med. Ctr.); Ex. 104, AR 147954 (The Disability Coalition); Ex. 113, AR 160755 (PPFA Comment); Ex. 114, AR 160821-22 (Comment, Ctr. for Reprod. Rights); Ex. 115, AR 161036-037 (Comment, Medicare Rights Ctr.).

Rule completely fails to address these significant and potentially life-threatening concerns. *See* Provider SJ Mem., Part II.B; *see also* Pls.' PI Mem. 33-34.

The Final Rule's four-sentence response to comments regarding EMTALA contains only curt and unreasoned factual statements (*e.g.*, "[t]his final rule . . . does not go into detail as to how its provisions may or may not interact with other statutes"), and generalities (*e.g.*, "[t]he Department intends to give all laws their fullest possible effect"), 84 Fed. Reg. at 23,183, that are insufficient to meet the APA's requirement of reasoned decisionmaking. *See Citizens for Responsibility & Ethics in Washington v. FEC*, 316 F. Supp. 3d 349, 411 n.48 (D.D.C. 2018). HHS fails to provide any non-conclusory explanation of its unsupported conclusion that EMTALA's requirement "does not conflict with Federal conscience and antidiscrimination laws." 84 Fed. Reg. at 23,183. Instead, the Department merely references the reasoning in the preamble of the 2008 Rule. *See id.* By "relying only on generalized conclusions," the Department's assessment is arbitrary and capricious. *AEP Tex. N. Co. v. Surface Transp. Bd.*, 609 F.3d 432, 441 (D.C. Cir. 2010).

d. HHS failed to consider the Final Rule's contravention of basic medical ethics.

HHS's adoption of the definitions discussed above is also arbitrary and capricious because the agency failed to consider, or at minimum failed to conduct a reasoned analysis of, how those definitions violate basic ethical canons of the health professions. *See, e.g.*, *Am. Acad. of Pediatrics v. Heckler*, 561 F. Supp. 395, 399-400 (D.D.C. 1983) (invalidating HHS regulation on arbitrary-and-capricious grounds where the administrative record showed no attempt to balance "the malpractice and disciplinary risks that may be imposed upon physicians and hospitals caught between the requirements of the regulation and established legal and ethical guidelines"). In particular, the definition of "discrimination" permits an employee to object

without notice—irrespective of her duty of care or the needs of a patient—and the definitions of "assist in the performance" and "referral" violate the fundamental concept of informed consent by permitting health care entities and providers to withhold basic information from patients—even in emergencies. *See* 84 Fed. Reg. at 23,263-64 (definitions).

The administrative record contains evidence from organizations tasked with developing codes of ethics within the health professions, *e.g.*, the American Medical Association ("AMA"), American Nurses Association, and the Association of American Medical Colleges. These groups and others unequivocally informed HHS that:

- Current codes and professional standards allow individuals to refuse to provide services to which they object, but such objections are not unlimited and "must be balanced against the fundamental obligations of the medical profession"—*i.e.*, the needs of the patient; *see* Ex. 91, AR 139588 (AMA Comment);[26]

- Physicians have a duty to provide medically indicated care in an emergency, irrespective of their moral or religious beliefs, and may not abandon a patient, *see id.*;[27] and

- Physicians and other health professionals have a duty to inform patients about all relevant options for treatment, including options to which they object, *see id.*;[28]

Despite notice from organizations that have codified the ethical standards of the health professions—in the case of the AMA, for over a century—HHS failed to consider how its

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[26] *See also* Ex. 70, AR 56915, at 56918 (Comment, Am. Nurses Ass'n) ("ANA Comment") (nurse's first duty is to the patient, citing Association's code of ethics and World Medical Association standards); Ex. 101, AR 147824-25 (GNYHA Comment) (principle that objections must not compromise "standards of professional care and the rights of patients" reflects "broad consensus in health care professions and health care ethics"); Ex. 106, AR 147981, at 147983 (ACEP Comment) (noting "one of the major, unacceptable flaws in the rule: it does not focus on the needs of patients or our responsibility as providers to treat them").

[27] *See also* Ex. 94, AR 139749, at 139750 (ACOG Comment) ("In an emergency in which referral is not possible or might negatively impact the patient's physical or mental health, providers have an obligation to provide medically indicated and requested care . . . . The Proposed Rule disregards these rigorous standards of care established by the medical community."); Ex. 105, AR 147963 (Comment, Ass'n of Women's Health, Obstetric and Neonatal Nurses) (discussing abandonment).

[28] *See also* Ex. 76, AR 71138, at 71141-42 (AAMC Comment) (noting rule's definition of "referral" is "incongruous with the standards of medical professionalism that are the core of a physician's education and the practice of medicine").

definitions contravene basic medical ethics. As a general matter, substantive references to "ethics" within the Final Rule overwhelmingly relate not to the patient, nor to what a health professional owes as a duty to that patient, but rather to the situation of the objector refusing to providing health care services—which the agency failed to "balance[] against the fundamental obligations of the medical profession." Ex. 91, AR 139588 (AMA Comment).[29] Specifically regarding the agency's expansive definition of "discrimination," HHS entirely failed to consider or address the Final Rule's implication for standards of professional ethics, by permitting an employee to object to a wide range of health care services at any time—without notice, even in emergency contexts—with no affirmative duty to disclose that objection or provide advance notice of any intent to object. *See supra* Part II.C.3.a.

Regarding the definitions of "referral" and "assist in the performance," the Final Rule's combination of these terms *itself* violates principles of medical ethics. The Final Rule identifies "referral" as an action that "may" constitute "assist[ance] in the performance" and thus form the basis of a protected objection. *See* 84 Fed. Reg. at 23,188-89. Yet this combination turns a basic principle on its head. As the AMA communicated to HHS, the provision of information about options for treatment is a method by which the health professions balance ethical duties, *i.e.*, allowing a practitioner to honor her own religious convictions about a health procedure, while simultaneously fulfilling her duty of care to a patient. *See* Ex. 91, AR 139587-88 (AMA Comment). AMA's Code directs physicians to "inform the patient about all relevant options for treatment, including options to which the physician morally objections," and should a physician decline to offer a referral, the physician should, at minimum, "offer impartial guidance to

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[29] *See, e.g.,* 84 Fed. Reg. at 23,171, 23,174-77, 23,181, 23,183, 23,189, 23,199-200, 23,204, 23,208, 23,246, 23,249-250.

patients about how to inform themselves regarding access to desired services."

Yet the Final Rule prevents this carefully calibrated balancing of ethical duties. Its definition of "referral" includes the "provision of information in oral, written, or electronic form" where "the purpose or reasonably foreseeable outcome . . . is to assist a person" in "obtaining . . . a particular health care service." 84 Fed. Reg. at 23,203. But if a patient "desires" a service—as stated in the AMA Code—it is a reasonably foreseeable outcome that the health service will result from a physician providing the patient guidance on how to inform herself on access—*e.g.*, from providing information resources. Thus, as HHS was well aware, the Final Rule's definition of "referral" expressly permits a doctor to object to her minimally required ethical duty under the AMA's Code. *See id.* at 23,253 (noting information the Final Rule "may allow" providers to abstain from providing).

Where HHS purports to address providers' duties to patients in the Final Rule—or the balancing of these duties described above—it does so in conclusory fashion. Referring generally to comments about the Final Rule and principles of informed consent, HHS pastes a near-verbatim answer into its discussions of both "assist in the performance" and "referral." The agency states that "medical ethics have long protected rights of conscience alongside the principles of informed consent" and, accordingly, it "does not believe that enforcement of conscience protections . . . violates or undermines the principles of informed consent." 84 Fed. Reg. at 23,200; *see also id.* at 23,189. Yet HHS sidesteps the fact that the Final Rule's definitions are precisely what undermine the method by which medical ethics harmonized those principles, as discussed above. HHS knew this, because the professional organizations that developed this method clearly stated it to the agency. HHS's "belief" reflects a complete failure to address the Final Rule's conflict with medical ethics or, at the least, the absence of a

"reasoned analysis" and "satisfactory explanation of its action." *State Farm*, 463 U.S. at 42-43.

e. HHS failed adequately to explain its departure from Title VII's framework for workplace religious accommodation.

The Final Rule is also arbitrary because, in departing without adequate rationale from the framework for religious accommodations in the workplace provided by Title VII of the Civil Rights Act of 1964, the Final Rule is not based on a "reasoned analysis" indicating that HHS "examine[d] the relevant data and articulate[d] a satisfactory explanation of its action." *State Farm*, 463 U.S. at 42-43. In failing to explain why existing remedies against discrimination are insufficient, the Department has not met its "duty to consider responsible alternatives to its chosen policy and to give a reasoned explanation for its rejection of such alternatives." *City of Brookings Mun. Tel. Co. v. FCC*, 822 F.2d 1153, 1169 & n.46 (D.C. Cir. 1987) (internal quotation marks omitted).

Title VII has long governed the assessment of claims for religious accommodations in the workplace, with a central focus on a balancing of all interests at stake. Existing employment discrimination law requires employers to accommodate employees' religious beliefs "unless an employer demonstrates that he is unable to reasonably accommodate to an employee's or prospective employee's religious observance or practice without undue hardship on the conduct of the employer's business." 42 U.S.C. § 2000e(j); *see also id.* § 2000e-2(a); 29 C.F.R. § 1605.2 (discussing reasonableness and undue hardship). This framework permits an employer simultaneously to consider the needs of the requesting employee, other employees, and its business and customers—in this context, patients in need of care.

Title VII thus protects individuals' religious beliefs while balancing employers' and employees' interests. The Final Rule departs from this framework uniquely in the context of the refusal-of-care statutes, but the Department has not explained why a departure from the Title VII

framework—to which Plaintiffs have long conformed their employment practices—is necessary. First, the definition of "discrimination," at subsection (5), prohibits an employer from inquiring, pre-hire, whether a prospective employee objects to performing or assisting in types of work, making it impossible for the employer to determine whether hiring that individual would pose an undue hardship on the business—*i.e.*, if the individual is unwilling to perform core job functions. *See* 84 Fed. Reg. at 23,263. Second, the definition, at subsection (4), provides that an employer does not discriminate when it offers and an objecting employee "voluntarily accepts an effective accommodation"—thus providing an employee a veto right over accommodation. *Id.* Under Title VII, an employee does not have this unilateral right to a religious accommodation of his or her choosing at the expense of all the other interests at play in the workplace.

Indeed, HHS concedes that it rejected "incorporating the additional concept of an 'undue hardship' exception for reasonable accommodations under Title VII." *Id.* at 23,191. But the agency dodges any reasoned explanation for this rejection, and instead merely asserts its belief that, because Congress "did not adopt an undue hardship exception" expressly within the various conscience protection statutes interpreted by the Final Rule, this reflects a legislative intent "to take a different approach."[30] *Id.* However, Congress's "silence in this regard can be likened to the dog that did not bark," and should not be interpreted as an intent to depart from Title VII's established framework for religious discrimination claims. *Miller v. Clinton*, 687 F.3d 1332, 1350 (D.C. Cir. 2012) (internal quotation marks omitted) (rejecting claim that silence in Basic Authorities Act altered provisions of Age Discrimination in Employment Act); *see also* Provider

[30] HHS argues that this purported legislative intent is "consistent with the fact that Title VII's comprehensive regulation of American employers applies in far more contexts, and is more . . . potentially burdensome . . . than the more targeted conscience statutes that are the subject of this rule," *id.*, apparently overlooking the fact that the agency's inclusion of "plan sponsor" in the definition of "health care entity" sweeps within the Final Rule's ambit virtually any employer that offers health insurance to its employees. *See* 84 Fed. Reg. at 23,195.

SJ Mem., Parts II.A.1, IV.

HHS's reliance on this congressional silence likewise does not constitute a reasoned analysis or satisfactory explanation for departing from a legislative policy that has set the standard for workplace religious accommodation for decades. *See City of Brookings Mun. Tel. Co.*, 822 F.2d at 1169 & n.46 ("[T]he failure of an agency to consider obvious alternatives has led uniformly to reversal."); *Action on Smoking & Health v. Civil Aeronautics Bd.*, 699 F.2d 1209, 1216, 1218 (D.C. Cir. 1983) (agency's decision failed to give sufficient consideration to narrower alternatives). To the contrary, "[a]nother shadow is cast when agency action, not clearly mandated by the agency's statute, begins to encroach on congressional policies expressed elsewhere." *Cape May Greene, Inc. v. Warren*, 698 F.2d 179, 190 (3d Cir. 1983) (holding EPA action arbitrary and contrary to law for "failure to give sufficient weight to congressional admonition in the Coastal Zone Management Act"). HHS's failure to explain why Title VII's framework is insufficient to address the harms the refusal-of-care statutes seek to prevent is arbitrary and capricious.

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

The Final Rule should be vacated as arbitrary and capricious for the independent reason that the Department relied on a cost-benefit analysis so flawed that it cannot be viewed as anything other than an effort to "put a thumb on the scale" by overvaluing the benefits and undervaluing the costs. *Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin.*, 538 F.3d 1172, 1198 (9th Cir. 2008); *see* Pls.' PI Mem. 38-43; Provider PI Mem. 23-24; Br. of the Inst. for Policy Integrity as *Amicus Curiae* 4-24, Dkt. 52-1 (filed June 21, 2019).

The Department casts this detailed presentation of the many flaws in its quantitative and qualitative analysis as nothing more than Plaintiffs' preference "to impose their own standard of

research on the agency before it can act." Defs.' Mem. 57. Not so: the "consideration of costs is an essential component of reasoned decisionmaking under the Administrative Procedure Act," *Mingo Logan Coal Co. v. EPA*, 829 F.3d 710, 732-33 (D.C. Cir. 2016); and agency action is invalid where it "fail[s] to adequately account" for relevant costs and benefits. *Council of Parent Attorneys & Advocates, Inc. v. DeVos*, 365 F. Supp. 3d 28, 53-55 (D.D.C. 2019).

For example, Plaintiffs identified the agency's significant mistake in underestimating the number of covered persons and entities, *see* Pls.' PI Mem. 41-42: the agency concluded that the Final Rule may increase the number of regulated entities by only about 0.02%, *see* 84 Fed. Reg. at 23,233-35 & tbl.2, even though the Final Rule's definition of "health care entity" both expands *and was intended to expand* the number of regulated persons and entities considerably. *See id.* at 23,194-96, 23,264 (§ 88.2). This is a significant miscalculation that results in a failure to present the true costs of the Department's policy choice. Yet Defendants' only response is that "New York provides no alternative evidence of its own" regarding the number of covered entities. Defs.' Mem. 59-60. But the administrative record that was before the agency when it was developing the Final Rule did provide the agency ample evidence of the expanded universe of regulated entities the rule's definitions would encompass.[31] And it is the agency's obligation to account for those costs, and show that it "examine[d] the relevant data" and can "articulate . . . a rational connection between the facts found and the choice made." *State Farm*, 463 U.S. at 43; *Council of Parent Attorneys & Advocates*, 365 F. Supp. 3d at 54-55.

The Department finally seeks to excuse its inadequate cost-benefit analysis by protesting that "[m]any of these questions . . . are difficult to answer." Defs.' Mem. 60. But "[a]n agency

[31] *E.g.*, Ex. 68, AR 52459 (Comment, N.Y. Dep't of Fin. Servs.); Ex. 91, AR 139587 (AMA Comment); Ex. 96, AR 140265 (BCBS Comment); Ex. 97, AR 140350 (CA Insur. Comment); Ex. 113, AR 160751 (PPFA Comment); Ex. 116, AR 161178 (IPI Comment).

may not avoid an obligation to analyze . . . consequences that foreseeably arise from [its action] merely by saying that the consequences are unclear . . . ." *Kern v. U.S. Bureau of Land Mgmt.*, 284 F.3d 1062, 1072 (9th Cir. 2002). The Department's "conclusory statements" regarding the costs and benefits of the Final Rule do not constitute reasoned decisionmaking. *Getty v. Fed. Savs. & Loan Ins. Corp.*, 805 F.2d 1050, 1057 (D.C. Cir. 1986).

III. The Final Rule is unconstitutional.

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

The Constitution vests the spending power in Congress. U.S. Const. art. I, § 8, cl. 1. The Executive Branch "does not have unilateral authority to refuse to spend . . . funds" already appropriated by Congress. *In re Aiken Cty.*, 725 F.3d 255, 261 n.1 (D.C. Cir. 2013).

In the context of the refusal statutes, Congress has chosen to tailor the conditions it has placed on the receipt of federal funds to specific procedures, involvement in those procedures, and health care providers or entities. *See* Pls.' PI Mem. 44-45. Defendants' wholesale refusal to address this argument is telling, especially because Defendants cannot dispute that the text of the Final Rule allows HHS to withhold all of the federal funding that Plaintiffs receive from the Department based on any perceived violation of any of the underlying statutes that it purports to implement. *See* Fed. Reg. at 23,272 (§ 88.7(i)(3)(i)-(iii)).

Although 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), this discretion is cabined by the scope of the delegation, *City of Arlington v. FCC*, 569 U.S. 290, 296 (2013). When Congress provides agencies with broad authority to withhold funds, it does so clearly. *See* Providers' SJ Mem., Part I. Defendants cannot find support in any of the underlying statutes for HHS's claim of broad power to terminate all federal funding. For example, the Weldon Amendment—on which Defendants rely—does not even mention HHS, let alone

expressly grant the Department this authority. Defs.' Mem. 71. Simply put, "Congress does not hide elephants in mouseholes." *Cyan, Inc. v. Beaver Cty. Emps. Ret. Fund*, 138 S. Ct. 1061, 1071-72 (2018) (internal quotation marks omitted).

B. The Final Rule violates the Spending Clause.

The Final Rule violates the Spending Clause because it (1) attaches retroactive and ambiguous conditions to Plaintiffs' receipt of federal funds; (2) is coercive; (3) lacks a nexus between the funds at issue and the Final Rule's purpose; and (4) induces Plaintiffs to engage in unconstitutional violations of the Establishment Clause. Pls.' PI Mem. 45-53; *see South Dakota v. Dole*, 483 U.S. 203, 207-08, 211 (1987).

Defendants' assertion that Plaintiffs' "real objection is to the underlying substantive law," Defs.' Mem. 60-61, is incorrect—Plaintiffs argue that the Final Rule substantially departs from the underlying statutes that it purports to implement by, among other things, redefining and dramatically expanding key definitions within those statutes, and threatening the termination of all HHS funds for a perceived violation of a new regime that HHS creates out of whole cloth. Plaintiffs' challenge is not to Congress's authority to enact the underlying statutes that Plaintiffs have complied with for years; it is instead to HHS's legislative fiat to create a new federal conscience regime in violation of the Spending Clause.

1. Plaintiffs did not knowingly accept the new and confusing conditions imposed by the Final Rule.

The Final Rule violates the Spending Clause's requirement to provide clear notice to Plaintiffs by retroactively and ambiguously imposing conditions on the receipt of federal funds. Pls.' PI Mem. 46-50. *See Dole*, 483 U.S. at 203 (explaining that when conditions are placed on federal funds it must be done "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").

"States cannot knowingly accept conditions of which they are 'unaware' or which they are 'unable to ascertain.'" *Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 296 (2006) (quoting *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981)). The Final Rule violates both of these principles. First, as Plaintiffs explained in detail in their opening brief, the Final Rule contorts the underlying statutes that it purports to implement to such a degree that Plaintiffs were not and could not have been aware of the new conditions when agreeing to accept the relevant funding. Specifically, the Final Rule (1) includes new definitions of key terms in the underlying statutes that dramatically expand the scope of those statutes; (2) imposes new, retroactive, and burdensome compliance requirements that apply immediately to all recipients of federal funds; (3) disregards that Congress in the relevant statutes conditioned funding from specific sources with specific prohibitions; and (4) purports to conflict with literally dozens of state and local laws on a variety of substantial issues related to health and patient care. Pls.' PI Mem. 47-48.

Defendants fail to address the import of any of these new conditions, and instead claim confusion as to the meaning of "retroactive." Defs.' Mem. 63. But as the Supreme Court has explained, "though Congress's power to legislate under the spending power is broad, it does not include surprising participating States with post-acceptance or retroactive conditions." *NFIB*, 567 U.S. at 584 (alterations and internal quotation marks omitted); *see also Mayhew v. Burwell*, 772 F.3d 80, 88 (1st Cir. 2014) ("[T]he anti-retroactivity rule . . . provides that Congress may not surprise states . . . with post-acceptance or retroactive conditions." (alterations and internal quotation marks omitted)). This is exactly what the Final Rule does. Pls.' PI Mem. 47-48. Indeed, Plaintiffs "could hardly anticipate that" HHS would claim authority to patch together

thirty statutes on a variety of topics scattered throughout the United States Code and appropriations riders to "transform" the landscape of health care provision and regulation "so dramatically." *NFIB*, 567 U.S. at 584; *see also Cty. of Santa Clara v. Trump*, 250 F. Supp. 3d 497, 532 (N.D. Cal. 2017) (where conditions are 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").

Second, the Final Rule is ambiguous in that it fails to make clear what conduct it prohibits or requires, what funding streams are at stake, and how recipients can avoid its penalties. *See* Pls.' PI Mem. 48-50. Rather than attempt to defend or clarify *any* of the Final Rule's opaque requirements, Defendants merely state, without support or explanation, that the Final Rule is "necessarily clearer and less ambiguous than the statutes." Defs.' Mem. 62. Defendants are wrong. For example, in sharp contrast to the underlying statutes, the Final Rule expands the scope and applicability of federal conscience protections in a way that significantly disrupts health care and creates an unworkable morass of potentially-life threatening situations for Plaintiffs. *See* Pls.' PI Mem. 15-30; Provider SJ Mem., Part II.A. Moreover, again in contrast to the underlying statutes, Plaintiffs have the impossible task of reconciling the Final Rule's requirements with conflicting provisions of other laws like EMTALA and Section 1554 of the ACA. *See* Provider SJ Mem., Parts II.A, II.B, II.D. And unlike the underlying statutes—which clearly identify the funds at stake for violations of the statutes—Plaintiffs stand to lose all HHS funds for any perceived misstep under the Final Rule.

Defendants' nearly singular reliance on the Ninth Circuit's decision in *Mayweathers v. Newland*, 314 F.3d 1062 (9th Cir. 2002) is misplaced. Defs.' Mem. 62-63. First, Plaintiffs take no issue with the fact that Congress may exercise its Spending Clause power to foster religious

freedom and deter religious-based discrimination. *Id.* at 62. As *Mayweathers* makes clear, however, in advancing these interests the limitations to the Spending Clause power—the same limitations that the Final Rule violates here—apply. *See Mayweathers*, 314 F.3d at 1066. Second, unlike the plaintiffs in *Mayweathers*, Plaintiffs here do not challenge Congress's "express conditional language" as "perhaps unpredictable." *Id.* at 1067. Instead, Plaintiffs challenge Defendants' contortion of clear and well-settled statutory conditions because they are unworkable, nonsensical, and contrary to both the statutes HHS purports to interpret and others on which Plaintiffs rely and with which they must comply.

HHS falls "well short of providing clear notice to [Plaintiffs] that they, by accepting funds . . . would indeed be obligated to comply" with Defendants' radical departure from congressional intent and the status quo. *Pennhurst*, 451 U.S. at 25. For these reasons, Plaintiffs could not have "exercise[d] their choice" to accept funds "knowingly, cognizant of the consequences of their participation." *Dole*, 483 U.S. at 203 (internal quotation marks omitted).

2. The Final Rule creates a new program and coerces Plaintiffs to comply.

The Final Rule also violates the Spending Clause because far from "creat[ing] incentives for [Plaintiffs] to act in accordance with federal policies," its "financial inducement . . . is a gun to the head." *NFIB*, 567 U.S. at 577, 581 (internal quotation marks omitted); *see* Pls.' PI Mem. 50-51.

Defendants' attempts to distinguish *NFIB* fall flat. First, as Plaintiffs explained in their opening brief, the Final Rule creates an entirely new regime that accomplishes "a shift in kind, not merely degree." *NFIB*, 567 U.S. at 583; *see* Pls.' PI Mem. 51. Defendants' only response is to once again point to the fact that the underlying statutes have been in effect for decades. Defs.' Mem. 65. This is no answer at all. *See NFIB*, 567 U.S. at 541 (noting Medicaid's enactment in

1965, and analyzing whether its expansion was coercive). Instead, the relevant inquiry is whether the challenged provisions have expanded those in the original statute to such a degree as to create a new program. *Id.* at 583. The Final Rule does just that: it weaves together disparate and distinct anti-discrimination prohibitions, 84 Fed. Reg. at 23,264-69 (§ 88.3); redefines terms to include newly covered individuals, entities, and procedures, *id.* at 23,263-64, (§ 88.2); and creates a compliance and enforcement scheme that substantially alters Congress's efforts to tailor specific requirements to specific sources of funds, *id.* at 23,269-72 (§§ 88.4, 88.6, 88.7). *See NFIB*, 567 U.S. at 583 (expansion of the original program "for four particular categories of" individuals beyond those categories was a shift in kind).

Second, Defendants are wrong that "it is far from clear that noncompliance with the conscience statutes and the [Final Rule] would impact all of the funding sources that New York identifies." Defs.' Mem. 64. The Final Rule's enforcement scheme plainly threatens billions of dollars in funding that Plaintiffs receive for a failure or suspected failure to comply with its provisions and those of the underlying statutes. Specifically, the Final Rule's enforcement scheme allows the Department to initiate a compliance review or a complaint investigation of Plaintiffs if it "suspect[s]" noncompliance. 84 Fed. Reg. 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 compliance process for the Department to follow is described by citations to three disparate administrative procedures. *Id.* at 23,272 (§ 88.7(i)(3)). And no matter Defendants' assurance that "HHS will always begin by trying to resolve a potential violation . . . through informal means," Defs.' Mem. 64, the Department is expressly

authorized to terminate a recipient's federal funds even *during* the pendency of good-faith voluntary compliance efforts. *Id.* at 23,271-72 (§ 88.7(i)(2)). Moreover, 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)). Accordingly, Plaintiffs stand to lose "not merely a relatively small percentage of its existing [HHS funding], but *all* of it." *NFIB*, 567 U.S. at 581 (internal quotation marks omitted).

Plaintiff States collectively received approximately $192 billion in federal funding from HHS in fiscal year 2018 based on publicly available information from the Department's Tracking Accountability in Government Grants System ("TAGGS").[32] This funding is critical to a wide range of essential programs and services that Plaintiffs use to promote the health and well-being of their residents, including: (1) Medicaid and the Children's Health Insurance Program;[33] (2) services to promote the health of women, infants, and children;[34] (3) family planning and contraception;[35] (6) treatment of substance use disorders;[36] (7) treatment and screening for arthritis, asthma, and other cancers, and heart disease;[37] (8) medical services to

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[32] *See* Ex. 136 (TAGGS Recipient Search). Plaintiffs generated this number by filtering "Fiscal Year" to "2018," "Recipient Class" to "State Government," and "State" to each State Plaintiff represented in this lawsuit. The Court may take judicial notice of this publicly available material, *see Force v. Facebook, Inc.*, No. 18-397, 2019 WL 3432818, at *3 n.5 (2d Cir. July 31, 2019), and Defendants also rely on data from TAGGS to justify the Final Rule, *see, e.g.*, 84 Fed. Reg. at 23,232 & n.182, 23,235-36 & n.224.

[33] *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.

[34] *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;

[35] *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.

[36] *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.

[37] *See* Ex. 2 (Alexander-Scott Decl.) ¶ 8; Ex. 9 (Brancifort Decl.) ¶ 15; Ex. 17 (Ezike Decl.) ¶¶ 14-23; Ex. 28

residents with HIV;[38] (9) funds for bioterrorism and Ebola preparedness, and other disaster response;[39] (10) student health services;[40] and (11) biomedical and health-related research, education, and training funds to universities.[41] Plaintiffs simply cannot gamble away some or all of this funding by hoping the Department will exercise with restraint its expansive authority under the Final Rule to withhold these funds in full. *Cf. United States v. Stevens*, 559 U.S. 460, 480 (2010) ("We would not uphold an unconstitutional statute merely because the Government promised to use it responsibly.").

Finally, Defendants' protest that Plaintiffs cannot succeed on a "facial challenge by identifying a handful of implausible and speculative circumstances" that "*might* have a coercive effect," Defs.' Mem. 66, fail for the same reason. The Final Rule's provisions and the authority that they provide to HHS are real, and they are currently set to take effect in only a few months. Nor do Plaintiffs take comfort in Defendants' note that HHS has never terminated substantial funding before. *Id.* Far from offering any reassurances that it will exercise restraint, HHS has made clear that it issued the Final Rule precisely *because* of "[i]nadequate enforcement tools to address unlawful discrimination and coercion," 84 Fed. Reg. at 23,228, without offering any explanation for why the tools it had—including informal resolution of complaints—were inadequate. *See supra* Part II.C.1. Accordingly, any nod to past HHS practice is irrelevant.

More fundamentally, Defendants' argument misunderstands the Spending Clause's constraint on the agency's rulemaking authority. The constitutional prohibition on coercion does

(Levine Decl.) ¶ 14.

[38] *See* Ex. 5 (Allen Decl.) ¶ 8; Ex. 7 (Anderson Decl.) ¶ 8; Ex. 15 (Elnahal Decl.) ¶¶ 7-8; Ex. 17 (Ezike Decl.) ¶¶ 33-35.

[39] *See* Ex. 28 (Levine Decl.) ¶¶ 14, 28(ii), 28(iv); Ex. 35 (Oliver Decl.) ¶ 7; Ex. 46 (Wagaw Decl.) ¶ 6.

[40] HIV/STD prevention, contraception, and abortion referrals, *see* Ex. 24 (Hirata Decl.) ¶¶ 5-7; Ex. 34 (Nichols Decl.) ¶¶ 5-7.

[41] *See* Ex. 22 (Hedges Decl.) ¶ 6; Ex. 23 (Herbst Decl.) ¶¶ 13-14; Ex. 29 (Lucchesi Decl.) ¶ 7.

not spring into effect only after the devastating consequences Plaintiffs confront because of the Final Rule—*i.e.*, the termination of substantial amounts of federal health care funds—come to fruition. Instead, it is the *threat* of terminating those funds that the limitations on the spending power proscribe. *See NFIB*, 567 U.S. at 580 (underscoring concerns with respect to the "nature of the threat" posed by the Medicaid provisions of the Affordable Care Act); *see also id.* (explaining that "[b]y financial inducement the Court meant the *threat* of losing . . . funds" (emphasis added)). This threat in the form of "economic dragooning" leaves Plaintiffs with "no real option but to acquiesce" in the Final Rule's new regime. *Id.* at 582.

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

As Plaintiffs explained, through the Weldon Amendment, the Final Rule appears to condition the receipt of billions of dollars of federal funds that are entirely unrelated to health care on compliance with its provisions. Pls.' PI Mem. 51-52. This violates the Spending Clause's requirement that any conditions imposed on spending must be related "to the federal interest in . . . [the] program[]." *Dole*, 483 U.S. at 207 (internal quotation marks omitted); *see also City & Cty. of San Francisco v. Sessions*, 349 F. Supp. 3d 924, 959-61 (N.D. Cal. 2018).

Defendants do not even attempt to dispute that by its terms, the Final Rule threatens federal funds not only from HHS but from the Department of Labor and the Department of Education as well. Nor do they defend that these funds have anything at all to do with the federal conscience statutes. Instead, Defendants' only response is an unsupported suggestion that Plaintiffs have an evidentiary burden to show Labor or Education funds "will actually be at risk." Defs.' Mem. 67. To the extent that Defendants suggest that HHS can constitutionally force Plaintiffs to choose whether to acquiesce to the Final Rule's provisions or take the risk that

HHS will terminate the Labor Department and Education Department funds the Final Rule authorizes it to do, this argument fails. *See supra* Part III.B.2.

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

For the reasons explained in the Provider Plaintiffs' summary judgment memorandum and Plaintiffs' preliminary injunction memorandum, the Final Rule requires Plaintiffs to engage in conduct that would violate the Establishment Clause, thus violating the Spending Clause's prohibition on unconstitutional conditions. *See* Provider SJ Mem., Part II.E; Pls.' PI Mem. 53.

C. The Final Rule violates the Establishment Clause.

For the reasons explained in the Provider Plaintiffs' summary judgment memorandum and Plaintiffs' preliminary injunction memorandum, the Final Rule is unconstitutional because it impermissibly advances religious beliefs in violation of the Establishment Clause. *See* Provider SJ Mem., Part II.E; *see also* Pls.' PI Mem. 29-30, 53.

IV. Plaintiffs are entitled to a preliminary injunction before the effective date of the Final Rule.

For the reasons set out herein (as well as in the Provider Plaintiffs' summary judgment memorandum and Plaintiffs' preliminary injunction memorandum), Plaintiffs are entitled to summary judgment that the Final Rule is invalid and should be set aside. The Court recognized, however, that the scale of the administrative record or other factors "may prevent a reliable final determination on the merits" before the Final Rule's current effective date of November 22, 2019. Dkt. 121. Plaintiffs request that in the event the Court determines not to enter final judgment on the merits before November 22, the Court should in the alternative grant Plaintiffs' request for provisional relief, and enjoin Defendants from implementing the Final Rule pending ultimate resolution of the merits. Plaintiffs are entitled to a preliminary injunction because they will suffer irreparable harm absent provisional relief; they are likely to succeed on the merits;

and the balance of equities and public interest favor a preliminary injunction.[42]

A. The Final Rule irreparably harms Plaintiffs.

1. Plaintiffs are irreparably harmed by "the Hobson's choice" of "whether to suffer this injury or else decline much-needed grant funds." *New York v. U.S. Dep't of Justice*, 343 F. Supp. 3d 213, 244 (S.D.N.Y. 2018); *see* Pls' PI Mem. 9-14. Defendants argue that the efforts Plaintiffs must undertake to comply with the Final Rule are merely "ordinary compliance costs [that] are typically insufficient to constitute irreparable harm." Defs.' Mem. 75 (quoting *Freedom Holdings, Inc. v. Spitzer*, 408 F.3d 112, 115 (2d Cir. 2005)); *see also* CMDA Mem. 5. But Plaintiffs have documented why compliance-related harms are unique here: in addition to the time, administrative burdens, and money that cannot be recouped, any changes Plaintiffs make to their policies and procedures before the Final Rule's effective date could have irreversible effects on the health of Plaintiffs' residents.[43]

Defendants also argue—citing no authority—that this forced choice fails to establish irreparable injury because "a long chain of events" would have to take place before fund termination could occur. Defs.' Mem. 75. Defendants' argument misses the point: the "long chain of events" they describe entail efforts to modify Plaintiffs' practices to comply with the Final Rule through measures short of fund termination, *see id.*; it is this precise compulsion—being forced to choose between changing policies to comply with an illegal regulation, or risking the loss of billions of dollars in health care funds—that causes irreparable harm to Plaintiffs. Courts have agreed, over objections identical to those Defendants raise here. *See, e.g.*, *New*

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[42] *See Winter v. NRDC*, 555 U.S. 7, 20 (2008). For the same reasons, Plaintiffs are entitled, in the alternative, to a stay under § 705 of the APA. *See Texas v. EPA*, 829 F.3d 405, 435 (5th Cir. 2016).

[43] *See* Pls.' PI Mem. 11-13 (noting changes that may be required to New York State's guidance to physicians and nurse practitioners concerning statutorily-mandated provision of information to terminally ill patients about palliative and end of life care) (citing, *e.g.*, Ex. 48 (Zucker Decl.)).

York, 343 F. Supp. 3d at 244; *City of Phila. v. Sessions*, 309 F. Supp. 3d 289, 340-42 (E.D. Pa. 2018) (citing *City of Phila.*, 280 F. Supp. 3d at 655-57); *City of Chicago*, 264 F. Supp. 3d at 950; *Cty. of Santa Clara*, 250 F. Supp. 3d at 536-38. The risk of loss need not be tomorrow or absolutely assured; rather, irreparable harm is established where a plaintiff receives federal funds "knowing that the [plaintiff] *may be later deemed out of compliance with*" federal conditions on those funds. *City of Phila.*, 280 F. Supp. 3d at 656 (emphasis added); *see* Pls.' PI Mem. 11 n.9.

2. Plaintiffs are also harmed by the damage the Final Rule will cause to their health institutions and direct delivery of health care. Defendants contend that Plaintiffs' evidentiary showing is "purely speculative and based on a misunderstanding of what the Federal Conscience Statutes and the Rule actually require." Defs.' Mem. 74. But the grave operational harms identified in the dozens of declarations from Plaintiffs' health providers and other fact witnesses are concrete and specific, not speculative. *See* Pls.' PI Mem. 15-22.[44] Instead of addressing Plaintiffs' evidence, HHS merely restates snippets of the Final Rule—for example, tautologically arguing that an objecting employee could not cause a staffing problem because Plaintiffs are allowed to accommodate the employee by moving her, as long as she voluntarily accepts the move, but is under no obligation to do so, no matter how reasonable. Defs.' Mem. 74.

HHS similarly argues that a need for advance notice of an objection poses no problem for Plaintiffs as health providers, because they may require an employee to inform them of an

[44] These declarants include national leaders in their respective fields whose written testimony is supported by detailed and specific evidence. *See* Exs. 1-48. Defendants have not contested a single paragraph from this written testimony, and have conceded that they will not seek to cross-examine a single witness at the preliminary injunction hearing in this matter. *See* Paragraphs 3(K) and 5(C)(i) of this Court's Individual Rules and Practices. Intervenors separately quibble at the margins with the likelihood that a particular physician will object to treating a woman with an ectopic pregnancy, or Plaintiffs' lack of identifying a specific ambulance driver or helicopter pilot who has made a religious objection in the past. CMDA Mem. 5-6, 9. These arguments again miss the point detailed by declarants from numerous hospital systems: they have policies in place requiring sufficient advance notice of religious objections to *avoid* crises that arise when objections are made at the time a patient needs treatment, and it is precisely these policies that the Final Rule limits and undermines to the point of inoperability. *See* Pls.' PI Mem. 15-22.

objection—leaving out the fact that the Final Rule permits this to happen only once a year (barring an undefined "persuasive justification"), and places no duty upon the employee to inform the employer of any change in the employee's religious views over the course of that year. But HHS remains silent as to how such a rule could safely be implemented in sensitive emergency or medical transit settings, or in rural settings with personnel shortages, though Plaintiffs documented their imminent injuries in just these settings. *See* Pls.' PI Mem. 18-20.[45]

3. Finally, the Final Rule irreparably injures Plaintiffs as regulators and insurers. *See* Pls.' PI Mem. 22-23. These injuries alone support injunctive relief, because "a state's inability to implement its laws constitutes irreparable harm." *New York*, 351 F. Supp. 3d at 675-76 (citing *Abbott v. Perez*, 138 S. Ct. 2305, 2324 n.17 (2018)). Defendants' and Intervenors' oppositions to preliminary injunction did not contest or respond at all to this showing of irreparable harm, Defs.' Mem. 73-76, CMDA Mem. 5-10, thereby conceding these injuries. *See, e.g.*, *Rodriguez v. Carson*, No. 17-cv-4344, 2019 WL 3817301, at *4 (S.D.N.Y. Aug. 14, 2019) (holding that a party's failure to raise an issue in an opposition brief waives the issue).

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

Plaintiffs have also established the required merits showing to entitle them to preliminary relief. In the Second Circuit, Plaintiffs may obtain a preliminary injunction by showing irreparable harm and either a likelihood of success on the merits or "sufficiently serious questions going to the merits to make them a fair ground for litigation . . . ." *Citigroup Glob. Mkts., Inc. v. VCG Special Opportunities Master Fund Ltd.*, 598 F.3d 30, 35 (2d Cir. 2010) (quoting *Jackson Dairy, Inc. v. H.P. Hood & Sons, Inc.*, 596 F.2d 70, 72 (2d Cir. 1979)).

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[45] HHS later argues that Plaintiffs assert harms against third parties, citing to a discussion of Plaintiffs' direct delivery of health care. *See* Defs.' Mem. 76. As discussed, Plaintiffs directly provide care as operators of health institutions, and administer insurance laws as health regulators; both such functions are impeded by the Final Rule.

For the reasons already briefed, Plaintiffs are likely to succeed on the merits of their claims that the Final Rule violates the APA and the Constitution. *See supra* Parts II, III; *see also* Pls.' PI Mem. 24-53; Provider SJ Mem., Parts I, II, III. In addition, given the overwhelming evidence that the "balance of hardships tip[s] decidedly" in Plaintiffs' favor—as discussed above and as Defendants hardly contest—this Court may also apply the "serious questions" standard and conclude that if nothing else, Plaintiffs have presented "a fair ground for litigation" on the merits. Under either standard, Plaintiffs readily clear the showing required for preliminary relief.

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

As to the final factors for a preliminary injunction, "there is a substantial public interest 'in having governmental 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)). Defendants argue that the federal government suffers irreparable injury if it is "enjoined by a court from effectuating statutes enacted by representatives of its people." Defs.' Mem. 76 (quoting *Maryland v. King*, 133 S. Ct. 1, 3 (2012)). But as Defendants point out repeatedly, Plaintiffs have not challenged the underlying refusal statutes, *see* Defs.' Mem. 1, 3, 61, 65-68, so there is no risk those statutes will be enjoined. Nor can the Department support its claim of injury where it asserts continuing investigative and enforcement authority under the refusal statutes independent of the Final Rule. *See* Defs.' Mem. 80; *see also* 76 Fed. Reg. at 9975 (acknowledgment in the 2011 Final Rule that "none of these statutory provisions require promulgation of regulations for their interpretation or implementation").

Intervenors claim that an injunction would cause their members distinct injury because they object to procedures on religious grounds, *see* CMDA Mem. 10-12, yet they fail to (1)

address that the refusal statutes will not be enjoined by this action, or (2) allege any instance of discrimination a member has faced, other than the general results of a survey cited in the Final Rule's preamble, the flaws of which have been addressed previously.[46] *See* Pls.' PI Mem. 40-41.

The Court should therefore grant Plaintiffs' motion for preliminary injunction.

V. Plaintiffs are entitled to vacatur of the Final Rule as well as declaratory and injunctive relief to remedy Defendants' violations of the APA and the Constitution.

A. The Court should vacate the Final Rule.

The APA mandates that the Court "shall" "hold unlawful and set aside agency action" that is arbitrary and capricious, contrary to law, or in excess of the agency's statutory authority. 5 U.S.C. § 706(2)(A), (C). When a regulation is not promulgated in accordance with the APA, challengers are "entitled to relief under that statute, which normally will be a vacatur of the agency's [decision]." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1084 (D.C. Cir. 2001).

Vacatur is the appropriate remedy under the APA both when an agency acts contrary to law, *e.g.*, *NRDC v. EPA*, 489 F.3d 1250, 1261 (D.C. Cir. 2007) (vacating rule that "conflicts with the plain meaning of the statute"), and when an agency action is arbitrary and capricious, *e.g.*, *Camp v. Pitts,* 411 U.S. 138, 143 (1973) ("If [the agency's] finding is not sustainable on the administrative record made, then the [agency's] decision must be vacated . . . ."). Vacatur

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[46] Intervenors now attempt to shoehorn in the results of a new survey that post-dates the Final Rule, is not part of the administrative record, and cannot, therefore, be used to uphold the Final Rule. *See* CMDA Mem. 10-12; Norman Decl., Dkt. 153. The Court should also disregard this new evidence in light of Intervenors' failure to comply with Rule 56(c)(4), which requires a declaration to "set out facts that would be admissible in evidence." The Norman Declaration fails to do so because either: (1) it is opinion testimony that fails to meet the standard for such testimony, *see* Fed. R. Evid. 702, and Intervenors failed to fulfill the disclosure requirements of Rule 26, *see* Fed. R.Civ. P. 26(a)(2); or, alternatively, (2) it is opinion testimony by a lay witness, only admissible if it is "rationally based on the witness's perception," and "not based on scientific, technical, or other specialized knowledge within the scope of Rule 702." Fed. R. Evid. 701(a), (c). The Norman Declaration fails both requirements, and especially 701(c), because public opinion polling and survey methodology are clearly "scientific, technical, or other specialized knowledge within the scope of Rule 702." *See, e.g.*, *United States v. Garcia*, 413 F.3d 201, 215 (2d Cir. 2005) (if the purported lay opinion "rests in any way upon scientific, technical, or other specialized knowledge, its admissibility must be determined by reference to Rule 702, not Rule 701") (quoting 4 Weinstein's Federal Evidence § 701.03[1]).

reflects the sound principle that an agency action that violates the APA "'cannot be afforded the force and effect of law,' and is therefore void." *Air India v. Brien*, No. 00-cv-1707, 2002 WL 34923740, at *14 (E.D.N.Y. Feb. 14, 2002) (quoting *Chrysler Corp. v. Brown*, 441 U.S. 281, 313 (1979)). Because the Final Rule violates both the APA and the Constitution, the Court should order the typical relief mandated by the APA and vacate the Final Rule. 5 U.S.C. § 706(2).

Contrary to Defendants' contention, nationwide relief is the usual course in an APA action because when "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 Pennsylvania v. President of the United States*, 930 F.3d 543, 575 (3d Cir. 2019) ("[O]ur APA case law suggests that, at the merits stage, courts invalidate—without qualification—unlawful administrative rules as a matter of course . . . . Congress determined that rule-vacatur was not unnecessarily burdensome on agencies when it provided vacatur as a standard remedy for APA violations.").

An order vacating the Final Rule under the APA thus inherently has nationwide application, and Defendants' concerns about nationwide injunctive relief are misplaced. *See NAACP v. Trump*, 315 F. Supp. 3d 457, 474 n.13 (D.D.C. 2018). Nationwide relief is further required here to provide a complete remedy to the Plaintiffs in these consolidated cases, who collectively operate health centers nationwide. *See* Pls.' PI Mem. 54-55; Provider PI Mem. 51.

B. In the alternative, the Court should order provisional relief under Rule 65(a) or 5 U.S.C. § 705.

Alternatively, if this case is not resolved on the merits by the Final Rule's effective date, the Court should grant Plaintiffs' request for interim equitable relief as the public interest requires, or stay the effective date of the Final Rule pending resolution on the merits, per 5 U.S.C. § 705. *See* Pls. PI Mem. 54-55.

Whether the Court proceeds to enter a preliminary injunction, or to postpone the effective date of the Final Rule pending judicial review, any relief granted would properly apply nationwide, as noted in Part V.A. The scope of preliminary injunctive relief "is dictated by the extent of the violation established." *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979). Plaintiffs have demonstrated a likelihood of success on the merits, and the usual nationwide relief granted in APA actions applies here. *See Harmon*, 878 F.2d at 495 n.21; *NAACP*, 315 F. Supp. 3d at 474 n.13. This is especially true in light of "the equities of [this] case." *California v. Azar*, 911 F.3d 558, 584 (9th Cir. 2018). Together, Plaintiffs are twenty-three state and local governments and two nationwide organizations operating hundreds of health centers in all fifty states, the District of Columbia, and the U.S. territories. Far from a case where "the record is not sufficiently developed on the nationwide impact of the [agency action]," *City & Cty. of San Francisco v. Trump*, 897 F.3d 1225, 1245 (9th Cir. 2018), Plaintiffs have described irreparable harms that are geographically expansive in scope. *See supra* Part IV.A; *see also* Pls.' PI Mem. 10-23. An injunction without geographic limitation is necessary to provide Plaintiffs with complete relief.

C. The Court should vacate and enjoin the Final Rule in its entirety because the challenged portions of the regulation are not severable from the remainder.

The Court should likewise reject Defendants' skeletal suggestion to vacate or enjoin only part, but not all, of the Final Rule. Defs.' Mem. 79-80. "Whether the offending portion of a regulation is severable depends on the intent of the agency *and* upon whether the remainder of the regulation could function sensibly without the stricken provision." *MD/DC/DE Broad. Ass'n v. FCC*, 236 F.3d 13, 22 (D.C. Cir. 2000) (citation omitted). Defendants' cursory explanation that the Final Rule covers a wide variety of statutory provisions and defines several terms that "can operate independently of one another" does not establish that the Final Rule would function if unspecified pieces of it were severed. Defs.' Mem. 79-80. Nor have Defendants explained

how the Court "might craft a limited stay." *Texas*, 829 F.3d at 435.

To the contrary, the Final Rule's provisions are co-dependent, which hinders the regulation's ability to function sensibly without all component parts. Several sections cross-reference and rely on one another. *See, e.g.*, 84 Fed. Reg. at 23,264-69 (mandating compliance with §§ 88.4, 88.6); *id.* at 23,269-70 (assurance/certification compliance requirements dependent on funds to which § 88.3 applies, and failure to submit assurances/certifications are subject to enforcement under § 88.7). And the Department makes clear that compliance with certain provisions of the Final Rule will inform its execution of its powers pursuant to other sections. *Id.* at 23,216 ("OCR will consider the posting of notices [described in § 88.5] as non-dispositive evidence of compliance . . . ."). At minimum, if the Court vacates parts of the Final Rule but believes others may be severable, Plaintiffs request the opportunity to brief the issue after receiving the benefit of the Court's judgment regarding which parts of the rule are invalid.

D. The Court should reject Defendants' request for an advisory opinion on the lawfulness of undisclosed investigations.

Finally, the Court should reject Defendants' invitation to opine on ongoing unspecified investigations not before the Court. Plaintiffs have challenged the Final Rule, not the underlying statutes on which the Department purportedly relies for its activities. Any type of declaratory relief concerning unidentified investigations not at issue in this litigation is without basis. *See* U.S. Const. art. III, § 2, cl. 1.

CONCLUSION

Plaintiffs respectfully request that the Court vacate and set aside the Final Rule, or in the alternative, enter a preliminary injunction pending resolution of Plaintiffs' claims on the merits.

DATED: September 5, 2019

Respectfully submitted,

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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

Plaintiffs,

v.

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

Defendants.

CIVIL ACTION NO.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INTRODUCTION

1. This lawsuit challenges a U.S. Department of Health and Human Services regulation that – in an unprecedented and unlawful expansion of nearly thirty federal statutory

provisions – would compel the Plaintiff States and local jurisdictions to grant to individual health providers the categorical right to deny lawful and medically necessary treatment, services, and information to patients, based on the provider's own personal views. *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*, 84 Fed. Reg. 23,170 (May 21, 2019) (the "Final Rule"). This change to put providers above patients comes at a dangerous price: it will undermine the Plaintiffs' ability to administer their health care systems and deliver patient care effectively and efficiently.

2. In violation of clear constitutional and statutory limits, the Final Rule seeks to coerce the Plaintiffs to comply with the Department's overbroad application of federal law by subjecting the Plaintiffs to termination, withholding, or denial of potentially all federal health care funds if the Department determines, in its sole discretion, that the Plaintiffs, their agencies, or any of their sub-recipients have failed to comply with the Final Rule or any of the related statutory provisions. 84 Fed. Reg. at 23,271-72 (to be codified at 45 C.F.R. § 88.7). For the Plaintiffs, this financial exposure could amount to hundreds of billions of dollars each year.

3. The requirements that Defendants seek to impose through this Final Rule are invalid. The Final Rule far exceeds in scope and substance the underlying federal health care statutes it purports to implement; conflicts with federal statutes regarding access to health care, informed consent, the provision of emergency medical services, and religious accommodations; violates constitutional safeguards that assign the spending power to Congress and prohibit the Executive Branch from coercing states to implement preferred federal policies; and violates the Establishment Clause by imposing a categorical requirement that Plaintiffs accommodate the religious objections of their employees, whatever the cost.

4. The Final Rule harms Plaintiffs by undermining Plaintiffs' carefully-balanced health care policies and laws; imposing severe constraints on the operation of Plaintiffs' health care institutions that will dramatically undermine their effectiveness and burden their operations; and threatening Plaintiffs' right to billions of dollars in federal health care funds needed to assure the health and safety of Plaintiffs' residents and communities.

5. Plaintiffs' health care institutions operate to protect the health and welfare of their residents, yet the Final Rule undermines their efficient delivery of care and creates irrational, untenable, and potentially cruel situations. For example, the Final Rule would prohibit Plaintiffs' institutions from inquiring, pre-hire, whether a candidate for a nursing position had a religious objection to administering a measles vaccination, regardless of whether such a duty was a core element of the position needed during an outbreak of the disease. Or if a woman arrives at the emergency room of one of Plaintiffs' institutions presenting with a ruptured ectopic pregnancy, the Final Rule would permit a wide swath of employees – from receptionists to nurses to doctors to pharmacists to anesthesiologists – to refuse to assist that patient in real time, and without any advance notice, no matter the intense medical risk to the patient. And despite existing efforts of Plaintiffs' institutions to balance the beliefs of their staff with their mission to provide patient care, the Final Rule would similarly permit a doctor or medical resident – again, without notice – to refuse to remove a feeding tube from a comatose patient at the moment the procedure is set to occur, even if the patient's loved ones were present to witness the objection.

6. Communities of color and other vulnerable populations will bear a disproportionate burden of the harms caused by the Final Rule. Patients reliant on federal funding for the provision of health care are disproportionately non-white compared to the overall

population. And women and LGBTQI individuals who are already stigmatized in obtaining access to health care will be further hindered in obtaining the lawful medical services they need.

7. Plaintiffs the State of New York, the City of New York, the State of Colorado, the State of Connecticut, the State of Delaware, the District of Columbia, the State of Hawai'i, the State of Illinois, the State of Maryland, the Commonwealth of Massachusetts, the State of Michigan, the State of Minnesota, the State of Nevada, the State of New Jersey, the State of New Mexico, the State of Oregon, the Commonwealth of Pennsylvania, the State of Rhode Island, the State of Vermont, the Commonwealth of Virginia, the State of Wisconsin, the City of Chicago, and the County of Cook therefore bring this action to vacate the Final Rule and enjoin its implementation because it exceeds and is contrary to Defendants' statutory jurisdiction, authority, and limitations in violation of the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2)(C); is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law under the APA, 5 U.S.C. § 706(2)(A); is unconstitutionally vague and coercive in violation of the Spending Clause, U.S. Const. art. I, sec. 8, cl. 1; violates the constitutional separation of powers; and violates the Establishment Clause of the First Amendment to the U.S. Constitution.

JURISDICTION AND VENUE

8. The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 2201(a). Jurisdiction is also proper under the judicial review provisions of the Administrative Procedure Act, 5 U.S.C. § 702.

9. Declaratory and injunctive relief is sought consistent with 5 U.S.C. §§ 705 and 706, and as authorized in 28 U.S.C. §§ 2201 and 2202.

10. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b)(2) and (e)(1). Defendants are United States agencies or officers sued in their official capacities. Plaintiffs the State of New York and the City of New York are residents of this judicial district, and a

substantial part of the events or omissions giving rise to this Complaint occurred and are continuing to occur within the Southern District of New York.

PARTIES

11. Plaintiff the State of New York, represented by and through its Attorney General, is a sovereign state of the United States of America. The Attorney General is New York State's chief law enforcement officer and is authorized to pursue this action pursuant to N.Y. Executive Law § 63.

12. Plaintiff the City of New York is a municipal corporation organized pursuant to the laws of the State of New York. New York City is a political subdivision of the State and derives its powers through the New York State Constitution, New York State laws, and the New York City Charter. New York City is the largest city in the United States by population.

13. Plaintiff the State of Colorado is a sovereign state of the United States of America. The State of Colorado brings this action by and through its Attorney General, Philip J. Weiser. The Attorney General has authority to represent the state, its departments, and its agencies, and "shall appear for the state and prosecute and defend all actions and proceedings, civil and criminal, in which the state is a party." Colo. Rev. Stat. § 24-31-101.

14. Plaintiff the State of Connecticut, acting by and through its Attorney General, William Tong, brings this action as the chief civil legal officer of the State, and at the request of Governor Ned Lamont. Attorney General Tong is empowered to bring this action on behalf of the State of Connecticut and the Governor under Conn. Gen. Stat. § 3-124 et seq.

15. Plaintiff the State of Delaware is represented by and through its Attorney General Kathleen Jennings, and is a sovereign state of the United States of America. Attorney General Jennings is Delaware's chief law enforcement officer, *see* Del. Const., art. III, and is authorized to pursue this action under 29 Del. Code § 2504.

16. Plaintiff the District of Columbia (the "District") is a municipal corporation empowered to sue and be sued, and is the local government for the territory constituting the permanent seat of the federal government. The District brings this case through the Attorney General for the District of Columbia, who is the chief legal officer for the District and possesses all powers afforded the Attorney General by the common and statutory law of the District. The Attorney General is responsible for upholding the public interest and has the authority to file civil actions in order to protect the public interest. D.C. Code § 1-301.81.

17. Plaintiff the State of Hawai'i, represented by and through its Attorney General, is a sovereign state of the United States of America. The Attorney General is the State of Hawai'i's chief law enforcement officer and is authorized to pursue this action pursuant to Hawai'i Revised Statutes §§ 26-7 and 28-1.

18. Plaintiff the State of Illinois, represented by and through its Attorney General, Kwame Raoul, is a sovereign state of the United States of America. The Attorney General is the chief legal officer of the State, Ill. Const. 1970, art. V, § 15, and is authorized to pursue this action under 15 ILCS 205/4.

19. Plaintiff the State of Maryland is a sovereign state of the United States of America. Maryland is represented by and through its chief legal officer, Attorney General Brian E. Frosh. Under the Constitution of Maryland, and as directed by the Maryland General Assembly, the Attorney General has the authority to file suit to challenge action by the federal government that threatens the public interest and welfare of Maryland residents. Md. Const. art. V, § 3(a)(2); 2017 Md. Laws, J. Res. 1.

20. Plaintiff the Commonwealth of Massachusetts, represented by and through its Attorney General, is a sovereign state of the United States of America. The Attorney General is authorized to pursue this action under Mass. Gen. Laws ch. 12, §§ 3 and 10.

21. Plaintiff the State of Michigan, represented by and through its Attorney General, is a sovereign state of the United States of America. The Attorney General is the State of Michigan's chief law enforcement officer and is authorized to pursue this action pursuant to Mich. Comp. Laws § 14.28.

22. Plaintiff the State of Minnesota, represented by and through its Attorney General, is a sovereign state of the United States of America. The Attorney General is Minnesota's chief legal officer and is authorized to pursue this action on behalf of the State. Minn. Stat. § 8.01.

23. Plaintiff the State of Nevada, represented by and through its Attorney General, is a sovereign state of the United States of America. Attorney General Aaron D. Ford is the chief legal officer of the State of Nevada and has the authority to commence actions in federal court to protect the interests of Nevada. Nev. Rev. Stat. § 228.170. Governor Stephen F. Sisolak is the chief executive officer of the State of Nevada. The Governor is responsible for overseeing the operations of the State and ensuring that its laws are faithfully executed. Nev. Const., art. 5, § 1.

24. Plaintiff the State of New Jersey, represented by and through its Attorney General, is a sovereign state of the United States of America. The Attorney General is New Jersey's chief legal officer and is authorized to pursue this action on behalf of the State. *See* N.J. Stat. Ann. § 52:17A-4(e), (g).

25. Plaintiff the State of New Mexico, represented by and through its Attorney General Hector Balderas, is a sovereign state of the United States of America. The Attorney

General is authorized to bring an action on behalf of New Mexico in any court when, in his judgment, the interests of the State so require, N.M. Stat. Ann. § 8-5-2.

26. Plaintiff the State of Oregon, acting by and through the Attorney General of Oregon, Ellen F. Rosenblum, is a sovereign state of the United States of America. The Attorney General is the chief law officer of Oregon and is empowered to bring this action on behalf of the State of Oregon, the Governor, and the affected state agencies under Or. Rev. Stat. §§ 180.060, 180.210, and 180.220.

27. Plaintiff the Commonwealth of Pennsylvania is a sovereign state of the United States of America. This action is brought on behalf of the Commonwealth by Attorney General Josh Shapiro, the "chief law officer of the Commonwealth." Pa. Const. art. IV, § 4.1. Attorney General Shapiro brings this action on behalf of the Commonwealth pursuant to his statutory authority under 71 Pa. Stat. § 732-204.

28. Plaintiff the State of Rhode Island has the authority to initiate this action by and through its Attorney General, Peter F. Neronha. The Attorney General is a constitutional officer of the State, is vested with all of its common law powers, and has broad discretion to bring actions for the benefit of the State. *See* R.I. Const. art. 9, § 12; R. I. Gen. Laws § 42-9-6; *see also State v. Lead Indus. Ass'n, Inc.*, 951 A.2d 428, 470-74 (R.I. 2008).

29. Plaintiff the State of Vermont, represented by and through its Attorney General, Thomas J. Donovan, is a sovereign state in the United States of America. The Attorney General is the state's chief law enforcement officer and is authorized to pursue this action pursuant to Vt. Stat. Ann. tit. 3, §§ 152 and 157.

30. Plaintiff the Commonwealth of Virginia brings this action by and through its Attorney General, Mark R. Herring. The Attorney General has the authority to represent the

Commonwealth, its departments, and its agencies in "all civil litigation in which any of them are interested." Va. Code Ann. § 2.2-507(A).

31. Plaintiff the State of Wisconsin, represented by and through its Attorney General, Joshua L. Kaul, is a sovereign state of the United States of America. The Attorney General appears in this action at the request of the Governor to represent the interests of the State of Wisconsin pursuant to Wis. Stat. § 165.25(1m).

32. Plaintiff the City of Chicago is a municipal corporation and home-rule unit organized and existing under the constitution and laws of the State of Illinois. Chicago is the third largest city in the United States by population.

33. Plaintiff the County of Cook, Illinois ("Cook County"), is the second most populous county in the United States, with a populace of over five million people. Cook County is represented by its State's Attorney, Kimberly M. Foxx, whose powers and duties include commencing and prosecuting all actions, civil and criminal, in which Cook County or its citizens might be concerned. 55 ILCS 5/3-9005. It is governed by its Board of Commissioners and Chief Elected Officer, Toni Preckwinkle (the "County Board"). The County Board serves as the Board of Public Health for Cook County, owning and operating Cook County Health & Hospitals System ("CCH").

34. Plaintiffs are aggrieved by Defendants' actions and have standing to bring this action because the Final Rule harms their sovereign, quasi-sovereign, economic, and proprietary interests and will continue to cause injury unless and until the Final Rule is vacated.

35. Defendant United States Department of Health and Human Services ("HHS" or "the Department") is a cabinet agency within the executive branch of the United States

government, and is an agency within the meaning of 5 U.S.C. § 552(f). HHS promulgated the Final Rule and is responsible for its enforcement.

36. Defendant Alex M. Azar II is the Secretary of HHS and is sued in his official capacity.

37. Defendant the United States of America is sued as allowed by 5 U.S.C. § 702.

ALLEGATIONS

I. Federal statutory background.

38. In the Final Rule, HHS claims to interpret and implement nearly thirty federal statutory provisions concerning refusals to provide health care services due to religious objections, several of which concern behavior by state and local governments. 84 Fed. Reg. at 23,170-74, 23,263-69 (to be codified at 45 C.F.R. § 88.3). The most relevant of these statutes relate to abortion and sterilization; assisted suicide, euthanasia, and mercy killing; and counseling and referral, as described below.

A. Federal statutes related to abortion and sterilization.

39. The Final Rule states that it implements a number of statutes that principally concern objections to abortion and sterilization. 84 Fed. Reg. at 23,264-66 (to be codified at 45 C.F.R. §§ 88.3(a), (b), (c), (f)).

40. The Church Amendments, codified at 42 U.S.C. § 300a-7, 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).

41. The Church Amendments also prohibit the use of federal funds to require any individual to perform or assist in the performance of any sterilization procedure or abortion, if contrary to that individual's religious beliefs or moral convictions. *Id.* § 300a-7(b)(1).

42. The Coats-Snowe Amendment, codified at 42 U.S.C. § 238n, prohibits state and local governments that receive federal funds from discriminating against "health care entities," defined to include physicians and participants in a health profession training program, on the ground that they refuse to be trained or provide training in the performance of abortion. 42 U.S.C. §§ 238n(a), (c)(2).

43. The Weldon Amendment is an appropriations rider that has been included in each HHS appropriations statute enacted since 2004. *E.g.*, 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. 2981, 3118 (Sept. 28, 2018). The Weldon Amendment provides that none of the funds appropriated in the Act may be made available to any state or local government if it discriminates against any institutional or individual health care entity "on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions." *Id.* § 507(d)(1), 132 Stat. at 3118.

44. Section 1303 of the Affordable Care Act ("ACA") 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).

B. Federal statutes related to assisted suicide.

45. The Final Rule also states that it implements several statutes concerning objections to assisted suicide, euthanasia, or mercy killing. 84 Fed. Reg. at 23,266-67 (to be codified at 45 C.F.R. §§ 88.3(e), (i)).

46. Section 1553 of the ACA proscribes state and local governments that receive federal funding 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).

47. In addition, the Assisted Suicide Funding Restriction Act of 1997 provides that the advanced directives requirements applicable to state-administered Medicaid programs, codified at 42 U.S.C. § 1396a(w), 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, euthanasia, or mercy killing . . . ." 42 U.S.C. § 14406.

C. Federal statutes related to counseling and referral.

48. The Department states in the Final Rule that it is implementing a number of federal statutory provisions related to health care counseling or referral. 84 Fed. Reg. at 23,266-67 (to be codified at 45 C.F.R. § 88.3(h)).

49. As applicable to the Plaintiffs, the statute related to state-administered Medicaid programs, 42 U.S.C. § 1396u-2(b)(3)(B), 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 policy is communicated to prospective enrollees. *Id.*

D. Other statutes that the Final Rule purports to implement.

50. The Final Rule states that it implements a range of disparate additional statutes that relate in some way to religious refusals to provide care. 84 Fed. Reg. at 23,267-69 (to be codified at 45 C.F.R. §§ 88.3(j) – 88.3(q)).

51. The ACA's individual mandate, 26 U.S.C. § 5000A, includes an exemption for individuals whose religious beliefs prohibit accepting the benefits of private or public insurance. 26 U.S.C. § 5000A(d)(2)(A)(i); *see* 26 U.S.C. § 1402(g)(1).

52. Seven statutory provisions concern specific exemptions from various requirements for "religious nonmedical health care providers." *See* 42 U.S.C. § 1320a-1(h) (exemption from limitation on use for capital expenditures); *id.* § 1320c-11 (exemption from requirements for quality improvement organizations); *id.* §§ 1395i-5, 1395x(e), 1395x(y)(1) (eligibility for nonmedical Medicare services); *id.* § 1396a(a) (exemption from Medicaid requirements for medical criteria and standards); *id.* § 1397j-1(b) (exemption from requirements to Elder Justice Block Grants to states).

53. 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).

II. The "Protecting Statutory Conscience Rights in Health Care; Delegations of Authority" rule.

54. 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.*

55. On October 6, 2017, as directed by Executive Order 13,798, the Attorney General issued a memorandum "to guide all administrative agencies and executive departments in the execution of federal law." Memorandum from the Attorney General to All Executive Departments and Agencies, *Federal Law Protections for Religious Liberty* 1 (Oct. 6, 2017), at https://www.justice.gov/opa/press-release/file/1001891/download.

56. The Attorney General's religious liberty guidance identified several statutory provisions that the Department purports to implement in the Final Rule – including the Church Amendments, the Coats-Snowe Amendment, and the Weldon Amendment – as intended to "root out public and private discrimination based on religion." *Federal Law Protections for Religious Liberty* 8a, 16a-17a.

A. The 2018 proposed rulemaking.

57. Pursuant to Executive Order 13,798 and the Attorney General's religious liberty guidance, in January 2018, HHS published in the Federal Register a Notice of Proposed Rulemaking regarding refusals to provide health care services based on religious, moral, ethical, or other objections. *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority*, 83 Fed. Reg. 3880, 3881, 3923 (proposed Jan. 26, 2018) (the "Proposed Rule") ("Pursuant to the President's Executive Order and Executive Branch policy, and in keeping with the Attorney General's religious liberty guidance, HHS proposes this rule to enhance the awareness and enforcement of Federal health care conscience and associated anti-discrimination laws, to further conscience and religious freedom, and to protect the rights of individuals and entities to abstain from certain activities related to health care services without discrimination or retaliation.").

58. The Proposed Rule described broad and unconditional rights for health care personnel to refuse to provide health care services on the basis of "religious, moral, ethical, or other reasons." *Id.* at 3923.

59. The Proposed Rule intended to enforce these refusal 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.

60. In assessing the likely costs of the Proposed Rule, the Department failed to include or account for the substantial monetary and nonmonetary costs of the health consequences and patient burdens resulting from increased likelihood of denials of medical services and care.

61. HHS received over 72,000 comments on the Proposed Rule. *See* Final Rule, 84 Fed. Reg. at 23,180 & n.41.

62. Nineteen States and the District of Columbia commented in opposition to the Proposed Rule and identified the shortcomings that are the subject of this challenge.[1]

63. Plaintiff the City of New York also commented on the Proposed Rule, explaining that the proposal would harm patients, result in discrimination against vulnerable populations, and impose costly administrative burdens on the City's health care system.[2]

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[1] *See* Comment Letter from the Attorneys General of New York, *et al.* (Mar. 27, 2018), at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70188; *see also* Comment Letter from N.Y. State Dep't of Fin. Servs. (Mar. 21, 2018), at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-51681; Comment Letter from the Attorney General of California (Mar. 27, 2018), at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70182.

[2] *See* Comment Letter from N.Y. City Dep't of Health & Mental Hygiene, *et al.* (Mar. 27, 2018), at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71028.

64. Prominent professional health care organizations and health care providers also submitted comments opposing the Proposed Rule, including the American Medical Association, the Association of American Medical Colleges, Planned Parenthood Federation of America, the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, and the American Academy of Physician Assistants.[3]

B. The Final Rule.

65. President Trump announced the Final Rule at a White House event on May 2, 2019. The President proclaimed that the Final Rule provided "new protections of conscience rights for physicians, pharmacists, nurses, teachers, students, and faith-based charities."[4]

66. Following President Trump's White House event, the Department released the Final Rule on May 2, 2019, and published it in the Federal Register on May 21, 2019. 84 Fed. Reg. at 23,170, 23-272.

67. The Final Rule is scheduled to take effect on July 22, 2019. 84 Fed. Reg. at 23,170.

68. The Final Rule states that its purpose is to "provide for the implementation and enforcement of the Federal conscience and anti-discrimination laws" identified in the Rule, in order to "protect the rights of individuals, entities, and health care entities to refuse to perform, assist in the performance of, or undergo certain health care services or research activities to

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[3] *See, e.g.*, Comment Letter from Am. Med. Ass'n (Mar. 27, 2018), at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70564; Comment Letter from Ass'n of Am. Med. Colleges (Mar. 26, 2018), at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-67592; Comment Letter from Planned Parenthood Fed'n of Am. (Mar. 27, 2018), at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71810; Comment Letter from Am. Coll. of Obstetricians & Gynecologists (Mar. 27, 2018), at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-70647; Comment Letter from Am. Acad. of Pediatrics (Mar. 27, 2018), at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-71048; Comment Letter from Am. Acad. of Physician Assistants (Mar. 26, 2018), at https://www.regulations.gov/document?D=HHS-OCR-2018-0002-65085.

[4] President Donald J. Trump, Remarks at the National Day of Prayer Service (May 2, 2019), at https://www.whitehouse.gov/briefings-statements/remarks-president-trump-national-day-prayer-service/.

which they may object for religious, moral, ethical, or other reasons." 84 Fed. Reg. at 23,263 (to be codified at 45 C.F.R. § 88.1).

69. To effectuate this purpose, the Department purports to rely on nearly thirty different statutory provisions, none of which provide HHS with explicit authority to issue legislative rules implementing or interpreting provisions concerning refusals to provide health care services due to religious or moral objections.

70. As described below, the Department has attempted to accomplish this purpose by (1) redefining key statutory terms far beyond their plain text, in order to cover a broader range of conduct and entities than Congress enacted; (2) assigning to itself an extraordinarily broad and coercive enforcement power that would allow the Department to terminate billions of dollars in federal health care funds to the Plaintiffs if the Department decides that Plaintiffs have failed to comply with the Final Rule or any of the nearly thirty statutes it implements; and (3) ignoring or expressly claiming to abrogate contrary federal law, including patient protections in the Affordable Care Act, the Emergency Medical Treatment and Labor Act, and Title VII of the Civil Rights Act of 1964.

1. The Final Rule's definitions of statutory terms.

71. 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." 84 Fed. Reg. at 23,263 (to be codified at 45 C.F.R. § 88.2).

72. Under this definition, simply scheduling a medical appointment would constitute "assistance," *id.* at 23,186-87; and recipients of federal funds would be required to guess which routine procedures or referrals – such as driving an individual with an ectopic pregnancy to the

hospital – “may” constitute “assistance” that requires additional steps to accommodate workers or protect patients, *id.* at 23,188. The Final Rule does not identify a statutory basis for adopting a definition this broad and vague.

73. The Final Rule contains a lengthy definition of “discriminate or discrimination” that, among other requirements, provides 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; cannot create an accommodation that excludes a staff member from their “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 (to be codified at 45 C.F.R. § 88.2).

74. This definition of “discrimination” would appear to require that Plaintiffs’ health care entities hire someone who cannot deliver health care services that are critical to the health care entity’s mission, or risk sanction. The Final Rule’s definition of “discrimination” also would prohibit Plaintiffs’ health care entities from transferring an employee to another area of a health care entity or a different shift even if the employee’s beliefs categorically preclude the employee from performing the essential functions of the initial position.

75. In addition, the Final Rule defines “health care entity” to extend far beyond physicians and health care professionals, including as well any “health care personnel,” pharmacists, pharmacies, medical laboratories, and research facilities; and, for purposes of the Weldon Amendment, also including health insurance issuers, health insurance plans, and plan sponsors or third-party administrators. 84 Fed. Reg. at 23,264 (to be codified at 45 C.F.R. § 88.2).

76. This definition is far broader than the definition of "health care entity" contained in both the Coats-Snowe Amendment, *see* 42 U.S.C. § 238n(c)(2); and the Weldon Amendment, *see* Pub. L. No. 115-245, § 507(d)(2), 132 Stat. at 3118.

77. The Final Rule's definition of "health care entity" would expand the applicable statutes far beyond their plain meaning, to permit objections by human resources analysts, customer service representatives, data entry clerks, and numerous others who believe that analyzing benefits, answering a benefits-related question, or entering a particular pre-authorization for an objected-to procedure, for example, is inconsistent with their personal beliefs.

78. 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." 84 Fed. Reg. at 23,264 (to be codified at 45 C.F.R. § 88.2).

79. When read together, the Final Rule's definitions present an unreasonable and 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. 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.

2. The Final Rule's funding termination scheme.

80. The Final Rule authorizes the Department to withhold, deny, suspend, or terminate billions of dollars in federal health care funds to the Plaintiffs if the Department determines that in its view "there is a failure to comply" with any provision of the Final Rule or the statutes it implements. *See* 84 Fed. Reg. at 23,271-72 (to be codified at 45 C.F.R. § 88.7(i)).

81. 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 during the pendency of good-faith voluntary compliance efforts. *Id.* at 23,271-72 (to be codified at 45 C.F.R. § 88.7(i)(2)).

82. The Final Rule's enforcement scheme disregards that Congress in the relevant statutes conditioned funding from specific sources to specific and disparate requirements and 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).

83. The Department responded to comments during the rulemaking process regarding the astonishing overbreadth of the fund-termination threat by asserting in the preamble to the Final Rule 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." *Id.* at 23,223. But the final regulatory text contains no description at all of the funds a recipient stands to lose if the Department determines that the recipient has not complied with the Final Rule. *See id.* at 23,271-72 (to be codified at 45 C.F.R. § 88.7(i)). Forcing Plaintiffs to guess which federal

funds are at risk – from among the nearly thirty statutes Defendants are claiming to implement with the Final Rule – is not consistent with constitutional and statutory requirements regarding separation of powers or grantmaking conditions that may attach to the use of federal funds.

84. In addition, the Department's implementation of the Weldon Amendment in particular would place at risk not only Plaintiffs' receipt of all federal funds from HHS, but also Plaintiffs' receipt of *all* federal funds from the Department of Labor and Department of Education as well, including funds entirely unrelated to health care. *See* Departments of Labor, HHS, Education, and Related Agencies Appropriations Act, Pub. L. No. 115-245, §§ 3, 507(d), 132 Stat. at 2981, 3118, 3122; 84 Fed. Reg. at 23,172, 23,265-66, 23,272 (to be codified at 45 C.F.R. §§ 88.3(c), 88.7(i)(3)(i), (iii)). The Department cited no statutory support for its purported authority to create a regulatory enforcement mechanism to terminate funds originating from the Department of Labor and the Department of Education.

85. The Final Rule also appears to give the Department authority to terminate congressionally-appropriated funding in its discretion. *See* 84 Fed. Reg. at 23,271-72 (to be codified at 45 C.F.R. § 88.7).

86. 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* 84 Fed. Reg. at 23,272 (to be codified at 45 C.F.R. § 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).").

87. The Final Rule authorizes the Department to commence a compliance review or investigation of any of the Plaintiffs if the Department "suspect[s]," based on any source, noncompliance with the Final Rule or any of the underlying statutes. 84 Fed. Reg. at 23,271 (to be codified at 45 C.F.R. §§ 88.7(c), (d)).

88. The Department also claims the right in any investigation to require the Plaintiffs to waive any rights to doctor or patient privacy or confidentiality. *Id.* at 23,270-71 (to be codified at 45 C.F.R. § 88.6(c)).

3. The Final Rule's interaction with federal law.

89. The Final Rule either ignores or expressly disclaims compliance with contrary federal law.

90. Section 1554 of the Affordable Care Act prohibits the Secretary of Health and Human Services from promulgating 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 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.

91. The Final Rule is contrary to each of the limitations on HHS's rulemaking authority that Congress imposed through Section 1554 of the ACA. And the Department's assertion in the Final Rule that Section 1554 only applies to regulations that themselves implement the ACA, 84 Fed. Reg. at 23,224, is contrary to both the text and judicial application of that statute. 42 U.S.C. § 18114; *see Oregon v. Azar*, No. 19-cv-317, 2019 WL 1897475, at

*12 (D. Or. Apr. 29, 2019); *California v. Azar*, No. 19-cv-1184, 2019 WL 1877392, at *21-22 (N.D. Cal. Apr. 26, 2019).

92. The Medicaid and Medicare statutes that the Final Rule states it is interpreting, *see* 84 Fed. Reg. at 23,263, 23,266-67 (to be codified at 45 C.F.R. § 88.3(h)), provide that with regard to informed consent, those statutes shall not "be construed to affect disclosure requirements under State law." 42 U.S.C. § 1396u-2(b)(3)(B) (Medicaid managed care organization); *see also* 42 U.S.C. § 1395w-22(j)(3)(C) (Medicare+Choice). But the Final Rule seeks to and would interfere with the enforcement of State and local disclosure requirements on just this issue, as described further in ¶¶ 108-09 below.

93. The Emergency Medical Treatment and Labor Act ("EMTALA"), 42 U.S.C. § 1395dd, requires hospitals to provide emergency care. 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).

94. The Final Rule acknowledges EMTALA, noting only that "where EMTALA might apply in a particular case, the Department would apply both EMTALA and the relevant law under this rule harmoniously to the extent possible." 84 Fed. Reg. at 23,188. But the Final Rule contains no provisions that specify how the statutory mandate to provide emergency care will be protected when, in the Department's view, that mandate conflicts with the categorical refusal-of-care rights that the Final Rule confers on employees. *Id.* at 23,263.

95. Title VII of the Civil Rights Act of 1964 prohibits discrimination in employment based on religious beliefs, 42 U.S.C. § 2000e-2(a); and balances protection of religious beliefs against employers' needs by providing that employers are not obligated to accommodate employees' religious beliefs to the extent that such an accommodation would cause "undue hardship" on the employer. *Id.* § 2000e(j).

96. The Final Rule expressly provides that it does not incorporate *any* assessment of undue hardship or other burden on employers. 84 Fed. Reg. at 23,190-91. And the Final Rule does not address how the Department will determine if Plaintiffs have engaged in "discrimination" in instances where an employee's absolute refusal right conflicts with Title VII's balancing test.

4. The Final Rule's Regulatory Impact Analysis.

97. The Final Rule includes a Regulatory Impact Analysis purporting to quantify the costs and benefits of the Final Rule. 84 Fed. Reg. at 23,226.

98. The cost-benefit analysis in the Final Rule expressly refuses to quantify the impact of the Final Rule on access to care, the effect the Final Rule will have on refusals to refer for services, or the effect on patients who delay or forego health care. *Id.* at 23,250-54.

99. Despite expressly declining to assess the true costs of the Final Rule on patient care, the Department concluded without evidence both that the Final Rule would likely enhance access to care, *see id.* at 23,182; and that the Final Rule should be implemented "without regard to whether data exists on the competing contentions about its effect on access to services." *Id.*

III. The Final Rule harms Plaintiffs.

100. The Final Rule harms Plaintiffs' sovereign, quasi-sovereign, economic, and proprietary interests.

A. The Final Rule interferes with Plaintiffs' effective administration and enforcement of their own laws.

101. Each of the Plaintiffs has enacted laws and policies that carefully balance central health care concerns with other – sometimes competing – needs, including protecting employees' religious beliefs and respecting employers' business needs. The Final Rule upsets the carefully crafted, longstanding balances struck in Plaintiffs' statutes and regulations, and harms the Plaintiffs' interests in enforcing their own laws.

102. The Final Rule explicitly purports to preempt conflicting state laws. *Id.* at 23,226 ("To the extent State or local laws or standards conflict with the Federal laws that are the subject of this rule, the Federal conscience and antidiscrimination laws preempt such laws and standards with respect to funded entities and activities . . . . With respect to States, States can decline to accept Federal funds that are conditioned on respecting Federal conscience rights and protections."); *id.* at 23,272 (to be codified at 45 C.F.R. § 88.8) ("Nothing in this part shall be construed to preempt any Federal, State, or local law that is equally or more protective of religious freedom and moral convictions.")

103. As set forth in the paragraphs that follow, the Final Rule interferes with and would undermine the enforcement of Plaintiffs' laws and regulations that include provisions concerning (1) access to emergency and medically necessary care; (2) prohibitions on abandoning patients in medical need; (3) a patient's right to receive information and ask questions about recommended treatments so they can make well-considered choices about care (that is, informed consent); (4) access to lawful prescriptions; (5) how best to balance accommodation of employees' religious or moral beliefs with employers' obligations to patients, their business, and other employees; (6) women's access to comprehensive reproductive health care and related services; and (7) required insurance coverage for contraception and abortion.

1. The Final Rule interferes with Plaintiffs' laws regarding the provision of emergency and medically necessary care.

104. Many of the Plaintiffs have laws requiring the provision of emergency and medically necessary care that would be hindered by the Final Rule. For example:

a. Colorado requires information about emergency contraception to be provided to survivors of sexual assault. *See* Colo. Rev. Stat. § 25-3-110(2).

b. Connecticut law provides that emergency treatment to a victim of sexual assault includes the provision of emergency contraception to the victim of sexual assault at the facility upon the request of such victim. *See* Conn. Gen. Stat. § 19a-112e(b)(3).

c. The law in the District of Columbia requires hospitals that provide emergency care to inform victims of sexual assault of the option to be provided emergency contraception for the prevention of pregnancy, and to immediately provide emergency contraception if the victim requests it and if the requested treatment is not medically contraindicated. D.C. Code § 7-2123. Hospitals are also required to provide the necessary care and treatment to meet the needs of patients. D.C. Mun. Regs. Tit. 22-B, § 2024.

d. Delaware law mandates that health care professionals who decline to comply with an individual instruction or health-care directive or decision for reasons of conscience provide continued care to a patient, including life sustaining care, until a transfer can be accomplished. *See* 16 Del. Code § 2508(e)-(g).

e. Hawai‘i law requires any hospital at which a female sexual assault victim presents for emergency services to provide medically and factually accurate and unbiased information about emergency contraception, and where indicated, offer and

dispense emergency contraception to female assault victims who request it. No hospital is required to dispense emergency contraception to a female assault victim who has been determined to be pregnant. *See* Haw. Rev. Stat. § 321-512. Hawai‘i requires certain emergency services be rendered to *any* ill or injured person who requests treatment at a hospital which has an emergency service department. *See* Haw. Admin. R. § 11-93-10. Hospitals in Hawai‘i shall not deny admission to any individual on account of race, color, religion, ancestry, or national origin. *See* Haw. Admin. R. § 11-93-13(b). Each individual admitted to a hospital in Hawai‘i shall be treated with consideration, respect, and full recognition of dignity and individuality, including privacy in treatment and in care. *See* Haw. Admin. R. § 11-93-26.

f. Illinois law requires the provision of emergency medical care, and provides that individuals with conscience objections are not relieved of their obligations to provide emergency medical care. *See* 210 ILCS 70/1; 210 ILCS 80/1; 745 ILCS 70/6; Ill. Adm. Code 545.35.

g. Massachusetts law requires the provision of emergency care, including the provision of emergency contraception to the survivors of sexual assault. *See* Mass. Gen. Laws ch. 111, § 70E. Hospitals and other health care facilities open to the public are prohibited from refusing care, or otherwise discriminating against patients, on the basis of characteristics including sexual orientation and gender identity. *See* Mass. Gen. Laws ch. 272, § 98.

h. Minnesota law states that it shall be the standard of care for all hospitals that provide emergency care to, at a minimum, provide female sexual assault victims

with medically and factually accurate and unbiased written and oral information about emergency contraception, orally inform female sexual assault victims of the option to be provided with emergency contraception, and immediately provide emergency contraception to each sexual assault victim who requests it provided it is not medically contraindicated and is ordered by a legal prescriber. Minn. Stat. § 145.4712.

i. Nevada law requires the provision of emergency medical care, which can require procedures to which a health professional may object, including abortions. *See* Nev. Rev. Stat. §§ 439B.410, 632.475(3).

j. New Jersey law requires that emergency health care facilities provide emergency care to sexual assault victims, which includes "orally inform[ing] each sexual assault victim of her option to be provided emergency contraception at the health care facility." N.J. Stat. Ann. § 26:2H-12.6c(b).

k. New Mexico law requires a hospital that provides emergency care to sexual assault survivors to provide medically and factually accurate and objective written and oral information about emergency contraception, to inform each survivor of her option to be provided emergency contraception at the hospital, and to provide emergency contraception for those who request it. N.M. Stat. Ann. § 24-10D-3.

l. New York state law requires the provision of emergency medical care, which can require abortions or other procedures to which a health care professional may object. *See* N.Y. Pub. Health Law § 2805-b. New York law also requires that mandatory emergency care include the provision of emergency contraception to survivors of sexual assault. *See* N.Y. Pub. Health Law § 2805-p.

m. New York City law requires that all agency contracts with hospitals provide for prompt counseling about, and on-site administration of, emergency contraception for rape survivors. N.Y.C. Admin. Code § 6-125(b).

n. Oregon law requires health plans to cover the provision of emergency care without preauthorization. ORS § 743A.012.

o. Pennsylvania has established a comprehensive emergency medical services system, recognizing that "[e]mergency medical services are an essential public service." 35 Pa. Cons. Stat. pt. VI ch. 81. As part of this system, Pennsylvania law requires that mandatory emergency care include the provision of emergency contraception to survivors of sexual assault. 28 Pa. Code § 117.53.

p. Rhode Island requires every health-care facility that has an emergency medical-care unit, including free-standing emergency rooms, to provide "prompt, life-saving, medical-care treatment in an emergency, and a sexual-assault examination for victims of sexual assault, without discrimination on account of economic status or source of payment, and without delaying treatment for the purpose of a prior discussion of the source of payment unless the delay can be imposed without material risk to the health of the person." R.I. Gen. Laws § 23-17-26(a).

q. The Commonwealth of Virginia requires all health carriers "providing individual or group health insurance coverage" who provide "any benefits with respect to services in an emergency department of a hospital" to provide such coverage "[w]ithout the need for any prior authorization determination, regardless of whether the emergency services are provided on an in-network or out-of-network basis." Va. Code Ann. § 38.2-3445. The Commonwealth likewise requires

physicians administering anesthesia to "[r]emain physically present or immediately available, as appropriate, to manage complications and emergencies until discharge criteria have been met." 18 Va. Admin. Code 85-20-320.

r. Wisconsin law provides that "[n]o hospital providing emergency services may refuse treatment to any sick or injured person." Wis. Stat. § 256.30(2). Wisconsin law also requires a hospital that provides emergency services to provide emergency contraception to a victim of sexual assault. Wis. Stat. § 50.375.

105. The Final Rule does not address its effect on state laws mandating emergency treatment, and would substantially interfere with these laws.

2. The Final Rule interferes with Plaintiffs' laws that prohibit abandoning a patient in medical need.

106. Many of the Plaintiffs have laws and regulations prohibiting health care professionals from abandoning a patient in medical need without first arranging for the patient's care, including:

a. Colorado Medical Board policy requires providers to provide 15 to 30 days of emergency coverage while a patient obtains a new provider. *See* Colo. Rev. Stat. § 12-36-117(1)(u); Colo. Med. Bd. Pol. 40-2.

b. Connecticut law prohibits health care professionals who are unwilling to comply with a patient's advance directives or living will from abandoning a patient in medical need without first arranging for the patient's care by another provider. *See* Conn. Gen. Stat. § 19a-580a.

c. Delaware law mandates that health care professionals who decline to comply with an individual instruction or health-care directive or decision for reasons of

conscience provide continued care to a patient, including life sustaining care, until a transfer can be accomplished. *See* 16 Del. C. § 2508(e)-(g).

d. In the District of Columbia, regulated professionals, including doctors, nurses and pharmacists, can be disciplined, including by having their licenses revoked, for abandoning patients. D.C. Code § 3-1205.14(a)(30); *see also* D.C. Mun. Regs. tit. 29, § 563 (same with respect to emergency medical services agencies and providers).

e. Hawaiʻi laws include provisions for discipline of physicians for conduct or practice contrary to recognized standards of ethics of the medical profession, including the American Medical Association's standards requiring providing care to patients in emergencies. *See* Haw. Rev. Stat. § 453-8. Hawaiʻi laws also include provisions for discipline of nurses for unprofessional conduct, including abandoning a patient. *See* Haw. Rev. Stat. § 457-12; Haw. Admin. R. § 16-89-60.

f. Illinois law provides that abandoning a patient is grounds for disciplinary action, including license revocation. 225 ILCS 60/22(A)(16).

g. Maryland law prohibits a physician and other health care providers from abandoning a patient. *E.g.*, Md. Code Ann., Health Occ. § 14-404(a)(6).

h. In Massachusetts, health care providers are prohibited from abandoning a patient in need of medical care and may be disciplined, including by the suspension or revocation of their license, for failing to provide proper care. *See, e.g.*, 244 CMR § 9.03(15) (nurses); 243 CMR §§ 1.03(4)(A)(3), 2.07(10)(a)-(b) (physicians).

i. In Michigan, a physician cannot abandon a patient under his or her care. *See Fortner v Koch*, 272 Mich. 273, 280 (1936).

j. Nevada law prohibits a physician working in an emergency situation from transferring a patient to another facility unless certain conditions are met. *See* Nev. Rev. Stat. § 439B.410.

k. New Jersey law requires an "appropriate, respectful and timely transfer of care" and "assur[ance] that the patient is not abandoned or treated disrespectfully," among other patient protections, if a health care professional declines to participate in withdrawing or withholding life-sustaining measures "in accordance with . . . sincerely held personal or professional convictions." *See* N.J. Stat. Ann. § 26:2H-62(b), (c).

l. New Mexico physicians may suffer a loss of license for abandoning a patient in medical need. *See* N.M. Stat. Ann. § 61-6-15(D)(24).

m. New York regulations prohibit health professionals from "abandoning or neglecting a patient or client under and in need of immediate professional care, without making reasonable arrangements for the continuation of such care." 8 NYCRR § 29.2.

n. Pennsylvania law prohibits certain health care professionals from abandoning their patients. 35 Pa. Cons. Stat. § 8121(a)(4) (emergency medical services providers); 28 Pa. Code § 21.18(b)(7) (registered nurses); 49 Pa. Code § 16.61(a)(17) (physicians); 49 Pa. Code § 21.148(b)(7) (licensed practical nurses).

o. Rhode Island law provides that abandoning a patient is grounds for disciplinary action, including license revocation. R.I. Gen. Laws §§ 5-37-5.1 and 5-37-6.3.

p. Vermont law provides that a doctor is prohibited from abandoning a patient and may face misconduct proceedings for doing so. *See* Vt. Stat. Ann. tit. 26, § 1354(a). Additionally, a hospital patient in Vermont has a right to one attending physician who is primarily responsible for coordinating that patient's care, and whose identity is known to the patient. *See* Vt. Stat. Ann. tit. 18, § 1852(a)(2), (9). The patient also "has the right to expect reasonable continuity of care." *Id.* § 1852(a)(11).

q. The Commonwealth of Virginia prohibits medical practitioners from "terminat[ing] the relationship or mak[ing] his [or her] services unavailable without documented notice to the patient that allows for a reasonable time to obtain the services of another practitioner." 18 Va. Admin. Code 85-20-28.

r. Wisconsin law provides that patient abandonment is a form of unprofessional conduct subject to various penalties, including revocation of a doctor's medical license. *See* Wis. Stat. § 448.02(3)(c). Patient abandonment occurs when further treatment is medically indicated and the physician fails to give the patient at least 30 days' notice about the withdrawal of care, or fails to provide for emergency care during the period between giving notice of intent to withdraw, and the date on which the patient-physician relationship ends. *See* Wis. Admin. Code § Med. 10.03(2)(o).

107. The Final Rule would interfere with these laws by allowing health care professionals to refuse to provide services to a patient or to refer that patient to a health care professional willing to do so.

3. The Final Rule dramatically undermines Plaintiffs' laws regarding informed consent.

108. Many of the Plaintiffs have enacted and implemented legislation regarding informed consent – that is, the patient's right to receive information and ask questions about recommended treatments so they can make well-considered choices about care – including:

a. Colorado requires a broad range of facilities to ensure patients are provided informed consent, which include informing patients about the availability of alternative procedures. *See* Colo. Rev. Stat. § 25-3-102(1)(c), 6 Colo. Code Regs. 1011-1 §§ 6.102(3)(c), 6.104(1)(g); *see also* Colo. Rev. Stat. § 25-1-121(4).

b. Connecticut law requires healthcare providers to give patients all facts material to their care so as to ensure that patients can make their own informed medical decisions. *See Logan v. Greenwich Hosp. Ass'n*, 191 Conn. 282, 288 (1983). Additionally, informed consent is required for administration of AIDS vaccine, *see* Conn. Gen. Stat. § 19a-591a; treatment with an investigational drug, biological product, or device, *see* Conn. Gen. Stat. § 20-14q; medication, psychosurgery or shock therapy for the treatment of psychiatric disabilities, *see* Conn. Gen. Stat. § 17a-543; and sterilization, *see* Conn. Gen. Stat. § 45a-699a. Moreover, some facilities are required by regulation as well as the standards of practice to secure informed consent. *See, e.g.*, Conn. Agencies Regs. § 19-13-D3(d)(8) (short term acute care hospitals); Conn. Agencies Regs. § 19a-116-1(c) (abortion services in outpatient clinics); Conn. Agencies Regs. § 19-13-D56(e) (outpatient surgery facilities); Conn. Agencies Regs. § 19a-495-6e(f) (inpatient hospice facilities).

c. Delaware law requires that patients receive sufficient information to make informed medical decisions. *See* 18 Del. C. § 6852.

d. The law in the District of Columbia recognizes the duty of physicians to inform patients of the consequences of a proposed treatment that stems from the right of every competent adult to determine what shall be done with his or her own body. *See Miller-McGee v. Washington Hosp. Ctr.*, 920 A.2d 430, 439 (D.C. 2007) (citing *Crain v. Allison*, 443 A.2d 558, 563-64 (D.C. 1982); *Canterbury v. Spence*, 464 F.2d 772, 780 (D.C. Cir. 1972)). Each patient in every hospital in the District of Columbia has the right to be informed in advance about care and treatment and to make informed decisions regarding care and to receive information necessary to make decisions. D.C. Mun. Regs., tit. 22-B § 2022. In addition, hospitals must provide medically and factually accurate written information developed by the Department of Health regarding emergency contraception for the prevention of pregnancy due to sexual assault, and must orally inform sexual assault victims about the option to be provided emergency contraception. D.C. Code §§ 7-2122 & 7-2123.

e. Hawai‘i mandates that certain information must be provided to a patient prior to obtaining consent to a proposed medical or surgical treatment or a diagnostic or therapeutic procedure, including “[t]he recognized alternative treatments or procedures, including the option of not providing these treatments or procedures,” the “recognized material risks of serious complications or mortality associated with” the proposed procedure, alternative treatments or procedures, and not undergoing any treatment or procedure, and the benefits of alternative treatments

or procedures. Haw. Rev. Stat. § 671-3(b)(4)-(6); *see also* Haw. Admin. R. § 16-85-25.

f. Illinois law requires health care providers to give patients information concerning their condition and proposed treatment, 410 ILCS 50/3, and requires that health care providers conducting HIV testing to first obtain informed consent from individuals undergoing testing. 410 ILCS 305/3.

g. Maryland law requires that patients give informed consent before any nonemergency care is provided, including "the benefits and risks of the care, alternatives to the care, and the benefits and risks of alternatives to the care." 2019 Md. Laws ch. 285 (to be codified at Md. Code Ann., Health-Gen. § 19-342); *see also Sard v. Hardy*, 281 Md. 432 (1977). Informed consent is separately statutorily required for HIV testing, Md. Code Ann. Health-Gen. § 18-336, and for treatment using an investigational drug, biological product, or device, Md. Code Ann., Health-Gen § 21-2B-01.

h. Massachusetts law mandates informed consent for patients. Mass. Gen. Laws ch. 111, § 70E. Patients must be provided all significant medical information material to their decision whether to undergo a procedure, including information concerning "the available alternatives, including their risks and benefits." *Harnish v. Children's Hosp. Med. Ctr.*, 387 Mass. 152, 156 (1982).

i. Michigan requires informed consent, which "requires a physician to warn a patient of the risks and consequences of a medical procedure." *Lucas v. Awaad*, 299 Mich. App. 345, 361 (2013).

j. Minnesota law mandates that physicians give patients "complete and current information concerning their diagnosis, treatment, alternatives, risks, and prognosis as required by the physician's legal duty to disclose[,]" which "shall include the likely medical or major psychological results of the treatment and its alternatives." Minn. Stat. § 144.651, subd. 9.

k. Nevada law mandates informed consent for patients, which ensures that patients can make their own informed medical decisions based on what a reasonable practitioner in the same field of practice would disclose. *See Beattie v. Thomas*, 99 Nev. 579, 584, 668 P.2d 268, 271 (Nev. 1983).

l. New Jersey law requires that patients admitted to a general hospital "receive from the physician information necessary to give informed consent prior to the start of any procedure or treatment," and that a patient "be advised of any medically significant alternatives for care or treatment." N.J. Stat. Ann. § 26:2H-12.8(d).

m. Under New Mexico law, a physician's failure to obtain informed consent constitutes negligence. *Gerety v. Demers*, 92 N.M. 396, 589, 589 P.2d 180 (N.M. 1978).

n. New York law mandates informed consent for patients, which ensures that patients can make their own informed medical decisions. N.Y. Pub. Health L. § 2805-d.

o. Oregon law requires that a physician or physician assistant explain, among other things, that there may be alternative procedures or methods of treatment to a procedure or treatment. *See* ORS 677.097.

p. Pennsylvania mandates informed consent for certain procedures, including the performance of surgery. 40 Pa. Stat. and Cons. Stat. § 1303.504.

q. Rhode Island mandates informed written consent for patients electing abortion procedures. R.I. Gen. Laws § 23-4.7-2.

r. Vermont protects patients' rights to informed consent in multiple contexts. *See* Vt. Stat. Ann. tit. 12, § 1909(d) ("A patient shall be entitled to a reasonable answer to any specific question about foreseeable risks and benefits, and a medical practitioner shall not withhold any requested information."); Vt. Stat. Ann. tit. 18, § 1871 (providing a "right to be informed of all evidence based-options" for palliative care and "all available options" for terminal care); *id.* § 1852(a)(4) (hospital patient has "right to receive from the patient's physician information necessary to give informed consent prior to the start of any procedure or treatment . . . [w]here medically significant alternatives for care or treatment exist, or where the patient requests information concerning medical alternatives, the patient has the right to such information"); *id.* § 1852(a)(8) (hospital patient "has the right to expect that within its capacity a hospital shall respond reasonably to the request of a patient for services").

s. The Commonwealth of Virginia requires physicians to obtain informed consent prior to providing certain procedures, except where the patient is incapable of providing such consent and "a delay in treatment might adversely affect recovery." *See e.g.*, Virginia Code Ann. §§ 54.1-2970, 2971; 18 Va. Admin. Code 85-20-28.

t. Wisconsin law imposes a duty on physicians to inform their patients about the availability of treatments and procedures and their risks and benefits so patients can make informed, voluntary decisions about their medical care. *See* Wis. Stat. § 448.30. In the specific case of emergency contraception, a hospital must provide a sexual assault victim "medically and factually accurate and unbiased written and oral information about emergency contraception and its use and efficacy" so that she can make an informed decision. Wis. Stat. § 50.375(2)(a).

109. The Final Rule does not require that a patient be informed that a health care provider is refusing to counsel them about, or refer them to, certain health care services, which severely undermines Plaintiffs' ability to monitor compliance with and enforce their own laws regarding informed consent.

4. The Final Rule interferes with Plaintiffs' laws requiring pharmacies to fill lawful prescriptions.

110. Several of the Plaintiffs have enacted laws requiring pharmacies to fill lawful prescriptions, including:

a. Colorado law provides that pharmacies that do not have emergency contraception in stock must place a conspicuous notice stating "Plan B Emergency Contraception Not Available." Colo. Rev. Stat. § 25-3-110(4). In addition, the state's emergency contraception law already contains protections for those who refuse to provide information "on the basis of religious or moral beliefs." *Id.* § 25-3-110(3)(a).

b. Connecticut law provides that pharmacies that permit refusal to dispense contraception are prohibited from participating in the Connecticut State employee health plan. *See* Formal Opinion of the Attorney General to the Hon. Nancy

Wyman (Formal Opinion 2006-004, Mar. 2, 2006), available at https://portal.ct.gov/AG/Opinions/2006-Formal-Opinions/Honorable-Nancy-Wyman-Comptroller-Formal-Opinion-2006004-Attorney-General-State-of-Connecticut (last visited May 20, 2019).

c. Delaware regulations mandate that pharmacies "[e]stablish procedures within operation that maintain standard of practice as it relates to the dispensing of pharmaceuticals and refusal to dispense pharmaceuticals based on the religious, moral, or ethical beliefs of the dispensing pharmacist. These procedures shall include proper supervision of supportive personnel and delegation of authority to another pharmacist when not on duty." 24 Del. Admin. Code § 2500-3.1.2.4.

d. Under Maryland law, a pharmacist may only refuse to fulfill a prescription based on "professional judgment, experience, knowledge, or available reference materials." Md. Code. Ann., Health Occ. § 12-501.

e. Minnesota regulations state it is unprofessional conduct for a pharmacist or pharmacy to "refus[e] to compound or dispense prescription drug orders that may reasonably be expected to be compounded or dispensed in pharmacies by pharmacists," with an exception for abortions. Minn. R. 6800.2250, subpt. 1.

f. Nevada law requires pharmacists to fill prescriptions unless they reasonably believe in their professional judgment that it would be unlawful, imminently harmful to the medical health of the patient, fraudulent, or not for a legitimate medical purpose. *See* Nev. Admin. Code § 639.753(1). Nevada law has specific requirements for pharmacists to fill contraception prescriptions. *See* Nev. Rev. Stat. § 639.28075.

g. New Jersey law requires pharmacy practice sites to "fill lawful prescriptions for prescription drugs or devices[,]" even if an employee of the practice objects to filling the prescription based upon "sincerely held moral, philosophical, or religious beliefs." N.J. Stat. Ann. § 45:14-67.1(a).

h. Pennsylvania law allows a pharmacist to decline to fill or refill prescriptions based on a religious, moral, or ethical belief, but recognizes that "the pharmacist has a professional obligation to take steps to avoid the possibility of abandoning or neglecting a patient." 49 Pa. Code § 27.103(a).

i. Under Wisconsin law, "a pharmacy shall dispense lawfully prescribed contraceptive drugs and devices and shall deliver contraceptive drugs and devices restricted to distribution by a pharmacy to a patient without delay." Wis. Stat. § 450.095(2).

111. The Final Rule would potentially preempt or interfere with these laws and allow individual pharmacists or pharmacies to refuse to provide or dispense lawful prescriptions. *See* 84 Fed. Reg. at 23,196, 23,264 (to be codified at 45 C.F.R. § 88.2).

5. The Final Rule hinders Plaintiffs' administration and enforcement of their laws regarding the accommodation of religious objections in the workplace and in the provision of health care.

112. Many of the Plaintiffs have enacted carefully-crafted laws designed to balance accommodation of employees' religious or moral beliefs with employers' obligations to patients, their business, and other employees. For example:

a. The City of Chicago has enacted laws respecting religious objections in the workplace while balancing the needs of employers. Under the City's Human Rights Ordinance, employers are required "to make all reasonable efforts to accommodate the religious beliefs, observances, and practices of employees or

prospective employees unless the employer demonstrates that he is unable to reasonably accommodate an employee's or prospective employee's religious observance or practice without undue hardship on the conduct of the employer's business." Chicago Mun. Code § 2-160-050.

b. Delaware requires health care providers or institutions that decline to comply with an individual instruction or health-care decision on the basis of conscience to promptly inform the patient and to continue providing care, including life-sustaining care, to the patient until a transfer can be effected. *See* 16 Del. C. § 2508(e)-(g). Institutional denials must be based on a prior written policy that was communicated to the patient. *See id.*

c. The District of Columbia provides an exemption for churches and other religious nonprofit entities from the statutory requirement to cover contraceptives in health insurance plans, and requires any employers claiming the exemption to provide notice to its employees. D.C. Code § 31-3834.04(a). District law also prohibits discrimination in employment based on a person's actual or perceived religion, however actions that may have a discriminatory effect are not unlawful if they are not intentionally devised or operated to discriminate based on religion and can be justified by business necessity. *See* D.C. Code §§ 2-1401.03, 2-1401.11, 2-1401.31.

d. Hawai'i law prohibits discriminatory employment practices, including on the basis of religion. *See* Haw. Rev. Stat. § 378-2. This law, however, may not prohibit or prevent employers from "the establishment and maintenance of bona fide occupational qualifications reasonably necessary to the normal operation of a

particular business or enterprise" that "have a substantial relationship to the functions and responsibilities of prospective or continued employment," or from "refusing to hire, refer, or discharge any individual for reasons relating to the ability of the individual to perform the work in question." Haw. Rev. Stat. § 378-3(2)-(3). Hawai'i allows religious employers to provide their employees a health plan without coverage for contraceptive services if the employers provide written notice of the contraceptive services the employer refuses to cover for religious reasons and written information describing how enrollees may directly access contraceptive services in an expeditious manner. *See* Haw. Rev. Stat. § 432:10A-116.7.

e. Maryland law prohibits employers from discriminating against any individual with respect to that individual's religion, except when providing a notice or advertisement indicating a bona fide occupational qualification for employment. *See* Md. Code Ann., State Gov't § 20-606 (West). Additionally, Maryland law provides that a person may not be required "to perform or participate in, or refer to any source for, any medical procedure that results in artificial insemination, sterilization, or termination of pregnancy," except insofar as "the failure to refer a patient to a source for any medical procedure that results in sterilization or termination of pregnancy" would be the cause of death or serious physical injury or serious long-lasting injury to the patient or otherwise contrary to the standards of medical care. Md. Code. Ann., Health Gen. § 20-214.

f. Massachusetts law requires employers to make reasonable accommodations "to an employee's or prospective employee's religious observance or practice," but

does not require accommodations that cause an "undue hardship." Mass. Gen. Laws ch. 151B § 4(1A).

g. Minnesota law states that it is an unfair employment practice for an employer to discriminate against a person with respect to hiring, tenure, compensation, terms, upgrading, conditions facilities or privileges of employment, and to refuse to hire or maintain a system of employment which unreasonably excludes a person seeking employment, except when based on a bona fide occupational qualification. Minn. Stat. § 363A.08, subd. 2.

h. New Jersey carefully balances conscience protection with patients' right to care. Under New Jersey's conscience law, no person, hospital, or health care facility shall be "required to perform or assist in the performance of an abortion or sterilization." N.J. Stat. Ann. § 2A:65A-1, -2. This law is not applicable to non-sectarian non-profit hospitals. *Doe v. Bridgeton*, 366 A.2d 641, 647 (N.J. 1976). New Jersey law also permits "a private, religiously-affiliated health care institution" to "develop institutional policies and practices defining circumstances in which it will decline to participate in withholding or withdrawing of specified measures utilized to sustain life." N.J. Stat. Ann. § 26:2H-65(b). Such policies must be in writing and must be communicated to patients or their health care representatives "prior to or upon admission, or as soon after admission as is practicable." *Id*. "If the institutional policies and practices appear to conflict with the legal rights of a patient wishing to forego health care, the health care institution shall attempt to resolve the conflict" and must ensure that the patient "is not abandoned or treated disrespectfully." *Id.*

i. New Mexico prohibits employers, unless based on a bona fide occupational qualification, from discriminating in employment on the basis of religion. N.M. Stat. Ann. § 28-1-7(A)-(C). Likewise, New Mexico prohibits any person in a public accommodation from distinguishing directly or indirectly in offering or refusing to offer services, facilities, or goods on the basis of religious affiliation. N.M. Stat. Ann. § 28-1-7(F). Further, the State's Religious Freedom Restoration Act prohibits the State from burdening the free exercise of religion, unless a restriction is of general applicability, does not discriminate among religions, and survives strict scrutiny. N.M. Stat. Ann. § 28-22-3.

j. New York state law applies a careful balancing test to the accommodation of religious beliefs in the workplace, prohibiting employers from imposing any employment conditions that would require an individual to forego a sincerely held practice of his or her religion "unless, after engaging in a bona fide effort, the employer demonstrates that it is unable to reasonably accommodate the employee's or prospective employee's sincerely held religious observance or practice without undue hardship on the conduct of the employer's business." N.Y. Exec. L. § 296(10).

k. New York City has enacted laws respecting religious objections that balance competing interests. In the context of employment, the City Human Rights Law prohibits employers from imposing "upon a person as a condition of obtaining or retaining employment any terms or conditions, compliance with which would require such person to violate, or forego a practice of, such person's creed or religion" and requires the employer to make reasonable accommodation to the

religious needs of such person. N.Y.C. Admin. Code § 8-107(3)(a). Employers are required to "engage in a cooperative dialogue within a reasonable time with a person who has requested [a religious] accommodation." *Id.* § 8-107(28).

l. Oregon protects health care providers who decline to participate in physician-assisted dying while balancing the rights of patients to receive care. ORS 127.885. In the area of reproductive health, Oregon law allows individuals to decline to dispense contraception or participate in abortion procedures, provided the individuals provide advance notice to the institution. ORS 435.225; ORS 435.485(2). Likewise, individuals are not required to provide advice on terminating pregnancies if they advise the patient they will decline to provide such advice. ORS 435.485(1). Oregon law also allows institutions to deny admission to individuals for the purpose of terminating a pregnancy, again with the requirement that an institution adopt a policy and inform patients of that policy. ORS 435.475.

m. With regard to lawful objections to assisting in the performance of an abortion or sterilization, Pennsylvania requires employers to "make reasonable accommodations to the needs of their employe[e]s," unless such accommodations would constitute "undue hardship to the conduct of the employer's business." 16 Pa. Code § 51.44(b). "Such undue hardship, for example, may exist where the employe[e]'s needed work cannot be performed by another employe[e] of substantially similar qualifications in the situation where and at the time when the person refuses to perform or participate in the performance of abortion or

sterilization procedures or where the employe[e] refuses to perform his normally assigned duties incident to employment." *Id.* § 51.44(c).

n. Rhode Island regulation under the Department of Health permits a licensed pharmacist to "decline to dispense a drug or device, pursuant to an order or prescription, on ethical, moral, or religious grounds only if the licensed pharmacist has previously notified the pharmacy owner, in writing, of the device(s), drug or class of drugs to which he or she objects, and the pharmacy owner can, without creating undue hardship, provide a reasonable accommodation of the licensed pharmacist's objection. The licensed pharmacy owner shall establish protocols to ensure that the patient has timely access to the prescribed drug or device despite the licensed pharmacist's refusal to dispense the prescription or order. For the purpose of this section, 'reasonable accommodation' shall mean the pharmacy owner has demonstrated that they explored any available reasonable alternative means of accommodating the licensed pharmacist's ethical, moral, or religious objections, including the possibilities of excusing the licensed pharmacist from those duties or permitting those duties to be performed by another person, but is unable to reasonably accommodate the ethical, moral, or religious objections without undue hardship on the conduct of the pharmacy owner's business." 216-RICR-40-15-1.15.2.

o. Vermont law prohibits discriminatory employment practices, including on the basis of religion, except where required by "a bona fide occupational qualification." Vt. Stat. Ann. tit. 21 § 495(a).

p. The Commonwealth of Virginia has pre-existing laws permitting any person "who shall state in writing an objection to any abortion or all abortions on personal, ethical, moral or religious grounds" to be exempted from "procedures which will result in such abortion." Va. Code § 38.2-3445. The Commonwealth likewise allows genetic counselors to opt out of "counseling that conflicts with their deeply-held moral or religious beliefs" and protects such objectors from liability "provided [the counselor] informs the patient that he [or she] will not participate in such counseling and offers to direct the patient to the online directory of licensed generic counselors maintained by the Board." Va. Code Ann. § 54.1-2957.21.

q. Wisconsin law balances the interests of objectors, patients, and medical facilities. Specifically, Wisconsin law provides conscience protection for persons who object to abortion or sterilization on "moral or religious grounds." But a person who objects must state "in writing his or her objection to the performance of or providing assistance to such a procedure . . . shall not be required to participate in such medical procedure." Wis. Stat. § 253.09(1). Such a refusal shall not be the basis for any damages claim or any disciplinary or recriminatory action against such person. *Id.*; *see also* Wis. Stat. §§ 441.06(6); 448.03(5). Further, no hospital, school, or employer may discriminate against any person with respect to admission, hiring, retention, or other condition of student or employee status on the basis of the person's "refus[al] to recommend, aid or perform" abortion or sterilization. Wis. Stat. § 253.09(3).

113. The Final Rule interferes with these laws by requiring the absolute accommodation of all employees with religious objections, without considering the needs of employers or patients.

114. By elevating an objector's rights over the rights of patients and employers, the Final Rule will cause substantial harm to the Plaintiffs' interest in enforcing their employment accommodation laws and in improving patient health outcomes.

6. The Final Rule interferes with Plaintiffs' laws protecting women's access to comprehensive reproductive health care and related services.

115. A number of the Plaintiffs have enacted laws that protect women's access to contraception, abortion, and other reproductive health care services, including laws that accommodate religious objections to the provision of such services by requiring adequate notice of such objections. For example:

a. Colorado law protects women's access to contraception, requiring health plans to provide coverage for contraception under specific circumstances. Colo. Rev. Stat. §§ 10-16-104(3)(a), -104.2. Access to birth control procedures, supplies, and information must also be provided to minors under specific circumstances. Colo. Rev. Stat. § 13-22-105.

b. Connecticut law protects women's access to contraception. Specifically, Connecticut law provides that "[t]he decision to terminate a pregnancy prior to the viability of the fetus shall be solely that of the pregnant woman in consultation with her physician." Conn. Gen. Stat. § 19a-602(a). Connecticut law also allows an individual to refuse to assist in a non-emergency abortion. Conn. Agencies Regs. § 19-13-D54.

c. The District of Columbia does not restrict the right to abortion and District law establishes the right of patients younger than 18 to consent to abortion care without parental involvement. *See* D.C. Mun. Regs. tit. 22-B, § 22-B600.

d. Hawai'i law protects women's access to abortions. Specifically, Hawai'i law provides that "[t]he State shall not deny or interfere with a female's right to choose or obtain an abortion of a nonviable fetus or an abortion that is necessary to protect the life or health of the female. Haw. Rev. Stat. § 453-16(c). Hawai'i law also allows an individual or hospital to refuse to participate in an abortion and such individual or hospital will not be liable for a refusal. Haw. Rev. Stat. § 453-16(e).

e. Illinois law requires certain agencies to deliver specified services either directly on-site or by referral, including contraception and other reproductive health care services. 77 Ill. Adm. Code 635.90.

f. Massachusetts law protects women's access to abortion and contraception, including emergency contraception. *See, e.g.*, Mass Gen. Laws ch. 112, §§ 12L-M, ch. 272 § 21A. Massachusetts law also provides specific conscience protections for health care workers that are limited to religious or moral objections to abortion and sterilization, including the right to refuse to participate in scheduled medical procedures that result in abortion or sterilization after providing written notice of an objection. *See* Mass. Gen. Law ch. 112, § 12I.

g. Nevada law makes it unlawful to require an employee's participation in the induction or performance of an abortion outside of medical emergency situations

upon filing of a written statement indicating a moral, ethical, or religious basis for refusal to participate. *See* Nev. Rev. Stat. § 632.475(3).

h. New Mexico enacted the Family Planning Act, N.M. Stat. Ann. §§ 24-8-1 through 24-8-8, to protect access to family planning services including contraceptive procedures, diagnosis, treatment, and supplies. The legislature found it "desirable that family planning services be readily accessible to all who want and need them" and that "dissemination of information about family planning by the state and its local government units is consistent with public policy." N.M. Stat. Ann. § 24-8-3. The State makes its family planning services available with public funds to the extent that public funds are available, including to medically indigent persons at no cost. N.M. Stat. Ann. 24-8-7. New Mexico requires payment for medically necessary abortions with public funds for indigent women, as its Equal Rights Amendment to the state constitution, N.M. Const., art. II, § 18, provides greater protection against gender discrimination than does federal law. *New Mexico Right to Choose/NARAL v. Johnson*, 1999-NMSC-005, 126 N.M. 788, 975 P.2d 841 (N.M. 1998).

i. New York state law, in order to facilitate staffing and scheduling practices that accommodate conscience and religious beliefs, provides that an individual may refuse to assist in a non-emergency abortion as long as the individual notifies the responsible hospital or other institution in advance. N.Y. Civ. Rights L. § 79-I.

j. Under Oregon law a public body, or an officer, agent, or employee of a public body, may not deprive a consenting individual of the right to obtain and use safe

methods of contraception, nor interfere with or restrict those rights by regulating access to benefits, services or information. ORS 435.200.

k. Pennsylvania law allows hospitals and health care facilities to decline to provide abortions or sterilizations on moral, religious or professional grounds as long as the facility provides a written ethical policy. 43 Pa. Stat. Ann. § 955.2; 16 Pa. Code §§ 51.31–51.33. Pennsylvania law likewise allows individuals to refuse to assist in the performance of abortion or sterilization procedures on moral, religious or professional grounds as long as they notify the responsible hospital or institution in advance. 43 Pa. Stat. Ann. § 955.2; 16 Pa. Code §§ 51.41–51.44. Such individuals may be subject to disciplinary action, however, if their expression of refusal "constitutes an overt act which disrupts hospital procedures, operations, or services or which endangers the health or safety of any patient." 16 Pa. Code § 51.42(a). Pennsylvania also allows hospitals to refuse to provide emergency contraception to sexual assault victims for religious or moral reasons as long as they provide 30 days written notice to the Pennsylvania Department of Health. 28 Pa. Code § 117.57.

l. Rhode Island requires a physician or anyone who works in a healthcare facility to give written notice of objection in performing abortions or sterilization procedures. *See* RIGL § 23-17-11.

m. The Commonwealth of Virginia requires insurers who otherwise provide prescription drug coverage to offer coverage for "any prescribed drug or device approved by the United States Food and Drug Administration for use as a contraceptive." Va. Code Ann. § 38.2-3407.5:1.

116. The Final Rule would undermine these laws and constitutional requirements by allowing an individual or health care entity to refuse to provide contraception or assist in an abortion without adequate notice to the responsible hospital or other appropriate institution.

7. The Final Rule interferes with Plaintiffs' laws that require insurance coverage for contraception and abortion.

117. A number of the Plaintiffs have enacted statutes or regulations requiring insurance providers to offer coverage for contraception and abortion.

a. Connecticut has "Contraceptive Equity Laws" that require insurers to provide coverage for contraception. *See* Conn. Gen. Stat. §§ 38a-503e(a), 38a-530e(a). Healthcare facilities that may find such procedures objectionable are permitted to comply with these requirements by contracting with one or more independent providers. *See* Conn. Gen. Stat. § 19a-112e(c).

b. Delaware requires health insurance plans to cover over-the-counter contraceptives without any cost-sharing, including emergency contraceptives. *See* Del. Senate Bill No. 151, *An act to amend Title 18, Title 29, and Title 31 of the Delaware Code Relating to Insurance Coverage of Contraceptives*, 149th General Assembly.

c. The District of Columbia requires individual and group health plans to cover all FDA-approved contraceptive drugs, devices, products and services for women without cost-sharing. D.C. Code § 31-3834.03. District law also permits pharmacists to prescribe as well as dispense prescription methods of contraception for up to a 12-month supply at one time for women who do not face serious risks from contraception. D.C. Code § 31-3834.01. The provision requires individual

and group health plans to cover a full-year supply of prescription contraceptives. *Id.*

d. Hawai‘i law requires that all employer groups, mutual benefit societies, and health maintenance organizations, provide coverage for contraceptive services or supplies for the subscriber or any dependent of the subscriber who is covered by the policy. Employer groups, mutual benefit societies, and health maintenance organizations that provide contraceptive services or supplies, or prescription drug coverage, shall not exclude any prescription contraceptive supplies or impose any unusual copayment charge, or waiting requirements for such supplies. *See* Haw. Rev. Stat. §§ 431:10A-116.6; 432:1-604.5; 432D-23.

e. Illinois law requires insurers to provide coverage for contraception. 215 ILCS 5/356z.4.

f. Maryland has “Contraceptive Equity Laws” governing access to broad contraceptive coverage. *See* Md. Code Ann., Ins. §§ 15-826 to 826.2. Maryland’s essential health benefits requires non-grandfathered individual and small group plans to cover abortion services. *See* https://insurance.maryland.gov/Insurer/Documents/bulletins/15-33_2017-ACA-Rate-Form-Filing-Deadlines-and-Substitution-Rules.pdf.

g. Massachusetts requires most commercial insurance plans to provide no-cost coverage for women’s contraceptive care and services, including sterilization and emergency contraception. *See* Mass. Gen. Law ch. 175, § 47W; Mass. Gen. Law ch. 176A § 8W; Mass Gen. Law ch. 176B § 4W; Mass. Gen. Law ch. 176G § 4O.

h. Nevada requires insurers to provide coverage for contraception, except for those affiliated with a religious organization who object on religious grounds. *See* Nev. Rev. Stat. §§ 689A.0418, 689B.0378, 689C.1676, 695A.1865, 695B.1919, 695C.1696.

i. New Jersey law requires that certain health insurers, health service corporations, and employee health benefits plans that cover outpatient prescription drugs also provide coverage for female contraceptives. *See e.g.*, N.J. Stat. Ann. § 17B:27A-19.15; N.J. Stat. Ann. § 17B:26-2.1y; N.J. Stat. Ann. § 52:14-17.29j; N.J. Stat. Ann. § 17:48F-13.2; N.J. Stat. Ann. § 17:48E-35.29. The laws allow for limited exemptions for religious employers, requiring written notice of exemption for prospective enrollees. *See e.g.*, N.J. Stat. Ann. § 17B:27A-19.15; N.J. Stat. Ann. § 17B:26-2.1y; N.J. Stat. Ann. § 17:48F-13.2; N.J. Stat. Ann. § 17:48E-35.29.

j. New Mexico in its 2019 legislative session amended group health coverage requirements under the Health Care Purchasing Act to require coverage, at a minimum, for at least one product or form of contraception in each of the contraceptive method categories identified by the federal Food and Drug Administration, a sufficient number and assortment of oral contraceptive pills, and clinical services related to the provision or use of contraception. H. B. 89 (2019), chaptered at Chapter 263, Sec. 9 (signed Apr. 4, 2019).

k. New York requires all fully insured insurance policies that provide hospital, surgical, or medical expense coverage to cover medically necessary abortions without copayments, coinsurance, or annual deductibles. *See* 11 N.Y.C.R.R. 52.16. New York's recently-enacted Comprehensive Contraception Coverage

Act, which will go into effect in January 2020, will require group health insurance companies to cover doctor-prescribed F.D.A. approved contraceptive devices as well as voluntary sterilization procedures for women. N.Y. Ins. Law § 3221(1)(16) (eff. Jan. 1, 2010).

l. Oregon law requires health plans to cover the provision of reproductive health care, including contraception and abortion. ORS 743A.067.

m. Rhode Island requires health plans to provide coverage for F.D.A. approved contraceptive drugs and devices requiring a prescription (except RU 486). R.I. Gen. Laws §§ 27-18-57; 27-19-48; 27-41-59.

n. Vermont law requires reproductive health equity in insurance coverage, such that a health insurance plan must provide coverage for contraceptive drugs and services to the same extent that plan provides coverage for any drugs or services. Vt. Stat. Ann. tit. 8, § 4099c.

o. The Commonwealth of Virginia requires insurers who otherwise provide prescription drug coverage to offer coverage for "any prescribed drug or device approved by the United States Food and Drug Administration for use as a contraceptive." Va. Code Ann. § 38.2-3407.5:1.

118. The Final Rule interferes with Plaintiffs' ability to enforce their laws requiring insurance coverage for contraception and abortion-related services by, among other things, defining the group of individuals and entities authorized to exercise conscience objections to include not only health care professionals but also sponsors of health insurance plans.

B. The Final Rule harms Plaintiffs' health care institutions.

119. Many of the Plaintiffs – including Colorado, Connecticut, Delaware, Hawai'i, Illinois, Massachusetts, New York, New York City, Oregon, Virginia, and Cook County – own and operate health care institutions, including teaching hospitals and medical education centers.

120. In addition, a number of the Plaintiffs – including Hawai'i, Pennsylvania, and Vermont – subcontract or sub-grant HHS funds to private health care institutions within their states.

121. These health care institutions provide a range of services to Plaintiffs' diverse populations, including emergency care, long-term care, and primary and preventative care.

122. The Final Rule places a number of new and stringent limitations upon the ability of Plaintiffs' institutions to inquire about whether members of their staff object to "performing, referring for, participating in, or assisting in the performance of" particular services or activities. First, the Final Rule does not permit any inquiry into prospective staff members' religious or moral objections prior to their hiring, whether or not such objections would materially impact the prospective employee's ability to fulfill their job obligations. *See* 84 Fed. Reg. at 23,263 (to be codified at 85 C.F.R. § 88.2).

123. Second, post-hiring, Plaintiffs' health institutions may inquire about staff members' objections no more frequently than "once per calendar year," absent a "persuasive justification" which is not specified or defined in the Final Rule. *Id.*

124. Third, beyond annual post-hire inquiries initiated by Plaintiffs' institutions, the Final Rule places no duty – and appears to prohibit the Plaintiffs from imposing a duty – on staff members to disclose known religious or moral objections to participating in a service or activity. *See id.*

125. Fourth, to the extent Plaintiffs' institutions learn of a religious or moral objection by a staff member, any accommodation offered to that individual must be "voluntarily accept[ed]" by the staff member and must be "effective" – a term undefined in the Final Rule – in order for Plaintiffs to avoid "engag[ing] in discriminatory action." *Id.*

126. Fifth, any effort Plaintiffs make to continue providing any objected-to service, program, or treatment using alternate staff would itself be impermissible under the Final Rule if that effort "require[s] *any* additional action" by the objecting individual, *id.* (emphasis added); or if it "exclude[s] protected [persons] from fields of practice." *Id.*

127. Alone and in combination, these severe and unrealistic constraints on the operation of Plaintiffs' institutions will dramatically undermine their effectiveness and efficiency, leading to significantly increased costs, worse health outcomes, and greatly increased risk of catastrophic error.

128. Plaintiffs' institutions currently rely on sufficient notice of staff members' religious or moral objections in order effectively to staff and run their various departments. For example, emergency care departments within these institutions must be able to plan and staff for urgent situations in which the absence of a single staff member could threaten the health, safety, and life of patients in distress. The Final Rule's new limitations upon the notice a health institution may seek concerning staff members' religious or moral objections undermines the ability of Plaintiffs' institutions to staff their operations effectively, and as a result, threatens patient care and public health.

129. As a result of this threat, Plaintiffs' institutions must preemptively plan to increase staff, in order to avoid any such risks of patient harm. In some instances, this will take the form of double-staffing emergency rooms, end-of-life care, and other departments in which

the risk of an objection without sufficient notice to Plaintiffs' institutions would have devastating consequences for patients.

130. The cost of this parallel staffing will be unduly burdensome to the Plaintiffs. For example, New York City will be forced to increase expenditures on salaries to ensure there is sufficient staff to comply with objections under the Final Rule. As shown below, in the 2018 fiscal year, New York City Health + Hospitals ("H+H") – the City's municipal hospital system and the largest public health care system in the United States – directly employed 35,860 full-time and part-time staff, 8,433 affiliate and temporary staff persons, and 700 staff persons who provided hourly services. The salaries for these workers amounted to over $4.1 billion in fiscal year 2018. The cost of hiring additional employees to establish the parallel staff needed to comply with the Final Rule would therefore be significant.

FY18	H+H (Full Time & Part Time Staff)	Affiliate	Allowances	Overtime	Temporary Staffing	FY18 Total
Full Time Equivalent (FTEs)	35,860	5,657	700	2,144	2,776	47,138
Health + Hospital Corp ($ in 000s)	$2,588,661	$1,208,964	$51,931	$155,881	$155,529	$4,160,966

131. This burden on Plaintiffs is especially pronounced in areas within the Plaintiffs' states in which there are few other health care providers, such as rural areas, and in areas in which other providers are more likely to be religious and have objections of their own to the provision of certain types of care.

132. The Final Rule also harms Plaintiffs' health institutions by undermining longstanding efforts by those institutions to build trust with the patient communities they serve.

As set forth above, the Final Rule drastically limits the ability of Plaintiffs' institutions to seek advance notice of their staff members' religious or moral objections, and to plan for and accommodate such objections accordingly. The likelihood that Plaintiffs' health institutions may not know of staff members' objections in advance, which may then be expressed at the time of a needed procedure and potentially in front of a patient, jeopardizes the trust of patients that these institutions have worked for years to develop.

C. The Final Rule harms Plaintiffs by threatening billions of dollars in congressionally-appropriated health care funds.

133. Given the threat posed by the enforcement provisions of the Final Rule that the Department may withhold, deny, suspend, or terminate billions of dollars in federal health care funds to the Plaintiffs in the Department's discretion, the Plaintiffs face the "Hobson's choice" of either (1) implementing costly changes to their laws, regulations, and policies, thereby threatening effective patient care and efficient administration of their health care systems; or (2) risking the loss of all of the federal funds they rely on to provide that care.

134. The amount of federal funding at risk runs to the hundreds of billions of dollars when considering appropriated funds from the Department alone.

135. According to publicly available information on the Department's Tracking Accountability in Government Grants System ("TAGGS"), collectively, the Plaintiffs received nearly $200 billion in federal health care funding in the 2018 fiscal year that the Final Rule threatens should the Department determine, in its discretion, that any of the Plaintiffs are not complying with the Final Rule or any of the statutes it implements.

136. The City of Chicago's Department of Public Health (CDPH) receives almost $90 million in annual federal health care funding from the Department, including over $89 million in federal grants and $311,701 in Medicaid reimbursement in 2018. These grants include

approximately $6.5 million for HPV and other vaccine coverage; $9.25 million for maternal and child health, $40 million for HIV prevention and treatment, $3.4 million for sexually transmitted disease and teen pregnancy prevention; and over $19 million for bioterrorism and ebola preparedness and response.

a. CDPH uses these funds to provide a wide array of health services and programs to its residents, including operating thirteen clinics throughout the City that provide free vaccinations, mental-health services, and testing and treatment for sexually transmitted diseases. While CDPH offers free healthcare to all of its residents, the majority of its patients are non-white and medically vulnerable populations. In addition to operating its own clinics, CDPH uses the federal health care grants it receives to help partner with many community-based health centers that offer additional medical services and health education programs. These delegates operate clinics that, for example, provide care for the needs of woman and children, and primary care for people living with HIV/AIDS.

b. This funding is crucial for CDPH's operations: 75% of CDPH's total budget of nearly $177 million comes from federal sources, and 50% of CDPH's total budget comes directly from the Department.

137. According to TAGGS, Colorado received nearly $6.4 billion in federal funds from the Department in federal fiscal year 2018 for entities identified as being at the state level in the TAGGS system. The Colorado Department of Health Care Policy and Financing, responsible for administering Medicaid and Children's Health Insurance Program in Colorado, account for $5.31 billion of those expenditures. Colorado uses these funds, in concert with state funds, to provide health care coverage to its members. As of the end of April 2019, there were

1.24 million Coloradoans enrolled in these programs. For state fiscal year 2019-20, the Colorado Medicaid Department's budget will be $10.66 billion, which includes $6.04 billion in federal funds. This represents 33.35% of the Colorado budget for that fiscal year.

138. According to TAGGS, Connecticut received nearly $5.5 billion in health care funding from the Department in the 2018 federal fiscal year for entities identified as being at the state level in the TAGGS system.

139. Cook County, through CCH, provides healthcare services to vulnerable Cook County residents and received more than $500 million in Department funds in 2018. This figure includes reimbursement for direct medical services as well as grant funding. These funds are used to provide healthcare services to more than 300,000 Cook County residents, more than 65% of whom are uninsured or underinsured and would otherwise lack meaningful access to medical care.

140. According to TAGGS, Delaware received over $1.7 billion in federal health care funding from the Department in the 2018 federal fiscal year for entities identified as being at the state level in the TAGGS system. Delaware receives funds for its participation in Medicaid and the Children's Health Insurance Program, which it uses to provide a full range of health services to over 240,000 citizens of the State. Delaware also receives Title X funding, including $1,100,000 for the 2019 federal fiscal year in Title X family planning service grants. Title X family planning clinics play a critical role in ensuring access to a broad range of family planning and preventative health services.

141. According to TAGGS, the District of Columbia received over $2.6 billion in federal health care funding from the Department in the 2018 federal fiscal year for entities identified as being at the state level in the TAGGS system.

142. According to TAGGS, Hawaiʻi received over $2 billion in federal health care funding from the Department in the 2018 federal fiscal year for entities identified as being at the state level in the TAGGS system.

143. According to TAGGS, Illinois received over $15 billion in federal health care funding from the Department in the 2018 federal fiscal year for entities identified as being at the state level in the TAGGS system. In December 2018, the Department's Office for Civil Rights sent a questionnaire to Illinois inquiring about federal health care funding that Illinois receives from the Department in the context of religious objections.

144. According to TAGGS, Maryland received over $8.6 billion in federal health care funding from the Department in the 2018 federal fiscal year for entities as identified as being at the state level in the TAGGS system.

145. According to TAGGS, Massachusetts received over $12.4 billion in federal health care funding from the Department in the 2018 federal fiscal year for entities as identified as being at the state level in the TAGGS system.

146. According to TAGGS, Michigan received more than $14.5 billion in health care funding from the Department in the 2018 federal fiscal year for entities as identified as being at the state level in the TAGGS system.

147. According to TAGGS, Minnesota received over $9.4 billion in federal health care funding from the Department in the 2018 federal fiscal year for entities identified as being at the state level in the TAGGS system.

148. According to TAGGS, Nevada received over $2.6 billion in federal health care funding from the Department in the 2018 federal fiscal year for entities identified as being at the state level in the TAGGS system. Nevada expects to spend over $6.7 billion on federal

reimbursement for medical services through its two year budget, with significant additional Department monies for additional services. Nevada uses these funds to provide numerous services to its citizens that are wholly unrelated to what the Final Rule regulates. These programs serve more than one million Nevadans. Medicaid funding alone amounts to 20% of Nevada's two year budget.

149. According to TAGGS, New Jersey received $11.8 billion in federal health care funding from the Department in the 2018 federal fiscal year for entities identified as being at the state level in the TAGGS system. Federal health care funds in New Jersey include over $7 billion in Department funding for Medicaid and the Children's Health Insurance Program. New Jersey uses these funds to provide a full range of health services to citizens of the State. For example:

a. Through Medicaid and the Children's Health Insurance Program alone, New Jersey serves over 1.7 million people in the State.

b. New Jersey also received around $30.7 million in funding in the 2018 federal fiscal year under the Older Americans Act, which allows older adults to live with independence and dignity in community settings.

c. New Jersey received approximately $850.9 million to support individuals with disabilities in the 2018 federal fiscal year. These funds allowed New Jersey to provide services, education, or residential placement for nearly 25,000 adults through more than 200 agencies across the State.

d. Federal funding also supports disease prevention, public health programs, opioid addiction treatment, federally-qualified health centers, and emergency programs throughout the State of New Jersey.

150. According to TAGGS, New Mexico received over $4.7 billion in federal health care funding from the Department in the 2018 federal fiscal year for entities as identified as being at the state level in the TAGGS system.

151. According to TAGGS, New York received over $46.9 billion in federal health care funding from the Department in the 2018 federal fiscal year for entities as identified as being at the state level in the TAGGS system.

152. New York City relies on billions of dollars in federal health care funding from the Department.

a. H+H alone receives approximately $3.4 billion in federal health care funding that is threatened should the Department determine that New York City's laws, rules, or policies do not comply with the Final Rule or related statutes. Specifically, H+H receives: $5,933,864 for CHIP; $1,153,400,144 for Medicaid; $29,459,286 in federal grants related to HIV/AIDS, STD Treatment and Prevention, Substance Abuse Treatment, Public Health and Prevention, Immunization, Biomedical and Behavioral Research; $112,799,439 in other grants; $521,003,737 for DSH (disproportionate share hospitals); $457,229,525 for UPL (upper payment limit); and $1,114,354,374 for Medicare. This funding allows H+H to serve around one million patients annually.

b. The NYC Department of Health and Mental Hygiene – one of the largest public health agencies in the world – receives over $330 million in federal health care funding from the Department. It uses this money to operate clinics and programs that provide vaccinations, tuberculosis testing and treatment, and services for sexually transmitted diseases and reproductive health.

153. According to TAGGS, Oregon (including the Oregon Health Authority ("OHA") and the Oregon Department of Human Services) received over $8.1 billion in federal health care funding from the Department in the 2018 federal fiscal year for entities identified as being at the state level in the TAGGS system, including:

a. $5 billion in funding for Oregon's Medicaid program (Oregon Health Plan) and the Children's Health Insurance Program combined, providing health coverage to over 970,000 Oregon residents, over 400,000 of whom are children;

b. Over $300 million in funding for public health and prevention programs used for infectious disease screening and prevention, nutrition outreach and education, and reduction and prevention of tobacco, alcohol, and opioid abuse; and

c. Federal grants for health care research and health care delivery. Other state institutions of higher learning also receive HHS grants for biomedical research and education.

d. The Oregon Department of Human Services received $966 million in Medicaid Funds. Sixty-six percent of those funds represent services for older Americans ($638 million), serving 275,000 clients over the course of fiscal year 2018.

154. According to TAGGS, Pennsylvania received over $21.8 billion in federal health care funding from the Department in the 2018 federal fiscal year for entities identified as being at the state level in the TAGGS system.

155. According to TAGGS, Rhode Island received over $2.1 billion in federal health care funding from the Department in the 2018 federal fiscal year for entities identified as being at the state level in the TAGGS system. Rhode Island receives an annual amount of federal funding totaling approximately $7,054,232 for programs for arthritis, asthma, cancer registry,

breast and cervical cancer, comprehensive cancer, colorectal cancer, diabetes, heart disease and stroke, and screening for heart disease. The Rhode Island Department of Health was awarded $2,725,000 in Title X funds for family planning program services for project period April 1, 2016 through August 31, 2018. The number of clients served by Title X service sites in 2018 was 29,098.

156. According to TAGGS, Vermont received over $1.2 billion in federal health care funding from the Department in the 2018 federal fiscal year for entities identified as being at the state level in the TAGGS system. The Vermont Department of Health has received approximately $780,000 in Title X grants each year over the past ten years, with minor fluctuations. The Vermont Department of Health is the sole Title X grantee for the State of Vermont.

157. According to TAGGS, Virginia received over $6.7 billion in federal health care funding from the Department in the 2018 federal fiscal year for entities identified as being at the state level in the TAGGS system.

158. According to TAGGS, Wisconsin received over $6.7 billion in federal health care funding from the Department in the 2018 federal fiscal year for entities identified as being at the state level in the TAGGS system.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

(Administrative Procedure Act – Exceeds Statutory Authority)

159. Plaintiffs incorporate by reference the allegations set forth in each of the preceding paragraphs of this Complaint.

160. Under the Administrative Procedure Act, courts must "hold unlawful and set aside agency action" that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C).

161. Defendants may only exercise authority conferred by statute. *City of Arlington v. FCC*, 569 U.S. 290, 297-98 (2013).

162. The Final Rule exceeds Defendants' authority under the statutes it purports to implement because the Final Rule legislates and implements excessively broad definitions of statutory text, including "assist in the performance," "health care entity," and "discriminate or discrimination." 84 Fed. Reg. at 23,263-64.

163. In addition, the Final Rule establishes an extraordinarily broad enforcement scheme that would authorize the Department to withhold, deny, suspend, or terminate billions of dollars in federal health care funds to the Plaintiffs if in Defendants' determination there is a failure to comply with the Final Rule or any of the underlying statutes. 84 Fed. Reg. at 23,271-72. This enforcement scheme is not authorized by the relevant federal statutes.

164. The Final Rule also establishes an enforcement scheme that would authorize the Department to withhold or suspend all federal financial assistance from the Department of Labor and Department of Education to the Plaintiffs if in Defendants' determination there is a failure to comply with the Final Rule or the Weldon Amendment. *Id.* This enforcement scheme is not authorized by the relevant federal statutes.

165. The Final Rule is therefore "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," in violation of the APA. 5 U.S.C. § 706(2)(C).

166. Defendants' violation causes ongoing harm to Plaintiffs and their residents.

SECOND CLAIM FOR RELIEF

(Administrative Procedure Act – Not in Accordance with Law)

167. Plaintiffs incorporate by reference the allegations set forth in each of the preceding paragraphs of this Complaint.

168. Under the APA, a court must set "aside agency action" that is "not in accordance with law." 5 U.S.C. § 706(2)(A).

169. The Final Rule violates Section 1554 of the Affordable Care Act, which prohibits the Department from implementing 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 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.

170. The Final Rule conflicts with the Medicaid and Medicare statutes it purports to implement, which provide that with regard to informed consent, those statutes shall not "be construed to affect disclosure requirements under State law." 42 U.S.C. § 1396u-2(b)(3)(B) (Medicaid managed care organization); *see also* 42 U.S.C. § 1395w-22(j)(3)(C) (Medicare+Choice).

171. The Final Rule violates the Emergency Medical Treatment and Labor Act ("EMTALA"), which requires hospitals to provide emergency care. 42 U.S.C. § 1395dd.

172. The Final Rule conflicts with Title VII of the Civil Rights Act of 1964, which prohibits discrimination in employment based on religious beliefs, and further provides that employers are not obligated to accommodate employees' religious beliefs where the accommodation would cause "undue hardship" on the employer. 42 U.S.C. § 2000e(j)

173. The Final Rule is therefore "not in accordance with law" as required by the APA. 5 U.S.C. § 706(2)(A).

174. Defendants' violation causes ongoing harm to Plaintiffs and their residents.

THIRD CLAIM FOR RELIEF

(Administrative Procedure Act – Arbitrary and Capricious)

175. Plaintiffs incorporate by reference the allegations set forth in each of the preceding paragraphs of this Complaint.

176. The APA provides that courts must "hold unlawful and set aside" agency action that is "arbitrary, capricious, [or] an abuse of discretion." 5 U.S.C. § 706(2)(A).

177. The Final Rule is arbitrary and capricious because Defendants' justification for its decision runs counter to the evidence before the agency, relies on factors Congress did not intend the agency to consider, and disregards material facts and evidence, including nationally recognized standards of care for medical professionals.

178. The Final Rule is arbitrary and capricious because its definitions of "assist in the performance," "discriminate or discrimination," "health care entity," and "referral or refer for," taken together, arbitrarily require Plaintiffs to guess whether routine procedures and services would require additional steps to accommodate workers or protect patients, and unreasonably ignore evidence in the rulemkaing record that these definitions create an unworkable situation for Plaintiffs and other health care providers and regulators.

179. The Final Rule is arbitrary and capricious because the Department conducted and relied on a flawed cost-benefit analysis, citing benefits the Final Rule would confer without any evidentiary basis, and failing adequately to account for the true costs the Final Rule will impose, including the significant costs to Plaintiffs and to the public health and safety of their residents.

180. The Final Rule is arbitrary and capricious because it fails to consider important aspects of the problem, including the Rule's interference with the administration of EMTALA and Title VII.

181. The Final Rule is therefore "arbitrary, capricious, [or] an abuse of discretion" in violation of the APA. 5 U.S.C. § 706(2)(A).

182. Defendants' violation causes ongoing harm to Plaintiffs and their residents.

FOURTH CLAIM FOR RELIEF

(U.S. Constitution art. I, § 8, cl. 1 – Spending Clause)

183. Plaintiffs incorporate by reference the allegations set forth in each of the preceding paragraphs of this Complaint.

184. The Spending Clause of the Constitution does not permit the Department to "exert a power akin to undue influence" over the Plaintiffs by attaching conditions to federal funds that are "so coercive as to pass the point at which pressure turns into compulsion." *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 578-88 (2012) (op. of Roberts, C.J.) (citations omitted).

185. The Department's threat to withhold, deny, suspend, or terminate billions of dollars in federal health care funds to the Plaintiffs – as well as *all* funds appropriated under the Departments of Labor, HHS, Education, and Related Agencies Appropriations Act, Pub. L. No. 115-245, Div. B, including funds entirely unrelated to health care – is unconstitutionally coercive and violates the Spending Clause.

186. The Spending Clause also requires that any conditions attached to the receipt of federal funds must be unambiguous and clearly stated in advance, so that states and local governments considering acceptance of those funds can do so knowingly and voluntarily. *South Dakota v. Dole*, 483 U.S. 203, 207 (1987).

187. The Final Rule is unconstitutionally vague and ambiguous, and attaches new after-the-fact conditions to Plaintiffs' receipt of federal funds, in violation of the Spending Clause.

188. The Spending Clause further requires that conditions placed on federal funds be reasonably related to the purposes of the federal programs at issue. *Id.* at 213.

189. The Final Rule unconstitutionally imposes conditions on Plaintiffs' receipt of federal funds that have no nexus to the purposes of those federal funding programs.

190. Defendants' violation causes ongoing harm to Plaintiffs and their residents.

FIFTH CLAIM FOR RELIEF

(U.S. Constitution – Separation of Powers)

191. Plaintiffs incorporate by reference the allegations set forth in each of the preceding paragraphs of this Complaint.

192. The Constitution vests the spending power in Congress, not the Executive Branch. U.S. Const. art. I, § 8, cl. 1.

193. Congress may delegate some discretion to the Executive Branch to decide how to spend appropriated funds, but that discretion is cabined by the scope of the delegation. *City of Arlington*, 569 U.S. at 297.

194. The Executive Branch cannot amend or cancel appropriations that Congress has duly enacted. *Clinton v. City of New York*, 524 U.S. 417, 439 (1998); *Train v. City of New York*, 420 U.S. 35, 38, 44 (1975).

195. The Final Rule imposes requirements not authorized by the underlying federal statutes and would allow Defendants to withhold, deny, suspend, or terminate federal financial assistance for noncompliance with those requirements.

196. The Final Rule's conditions improperly usurp Congress's spending power and amount to an unconstitutional refusal to spend money appropriated by Congress, in violation of constitutional separation of powers principles.

197. Defendants' violation causes ongoing harm to Plaintiffs and their residents.

SIXTH CLAIM FOR RELIEF

(U.S. Constitution amend. I – Establishment Clause)

198. Plaintiffs incorporate by reference the allegations set forth in each of the preceding paragraphs of this Complaint.

199. Laws that compel employers to "conform their business practices to the particular religious practices of . . . employees" violate the Establishment Clause of the United States Constitution. *Estate of Thornton v. Caldor*, 472 U.S. 703, 709 (1995).

200. By requiring employers, including State and local governments, to accommodate their employees' religious beliefs to the exclusion of other interests, the Final Rule will impose substantial burdens on third parties – including Plaintiffs' other employees and patients – in contravention of the First Amendment.

201. Defendants' violation causes ongoing harm to Plaintiffs and their residents.

PRAYER FOR RELIEF

Wherefore, Plaintiffs respectfully request that this Court:

1. Declare that the Final Rule is in excess of the Department's statutory jurisdiction, authority, or limitations, or short of statutory right within the meaning of 5 U.S.C. § 706(2)(C);

2. Declare that the Final Rule is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law within the meaning of 5 U.S.C. § 706(2)(A);

3. Declare that the Final Rule is unconstitutional;

4. Vacate and set aside the Final Rule;

5. Enjoin the Department and all its officers, employees, and agents, and anyone acting in concert with them, from implementing, applying, or taking any action whatsoever under the Final Rule;

6. Stay the effective date of the Final Rule pursuant to 5 U.S.C. § 705;

7. Award Plaintiffs their reasonable fees, costs, and expenses, including attorneys' fees, pursuant to 28 U.S.C. § 2412; and

8. Grant other such relief as this Court may deem proper.

DATED: May 21, 2019

Respectfully submitted,

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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)

PLAINTIFFS' NOTICE OF MOTION
(Fed. R. Civ. P. 65 and 5 U.S.C. § 705)

PLEASE TAKE NOTICE that pursuant to Federal Rule of Civil Procedure 65, Plaintiffs hereby move the Court for a preliminary injunction to enjoin Defendants from implementing, applying, or taking any action under the Final Rule entitled *Protecting Statutory Conscience Rights in Health Care: Delegations of Authority*, 84 Fed. Reg. 23,170 (May 21, 2019), in order to preserve the status quo until this case is decided on the merits and final judgment is entered.

Alternatively, pursuant to 5 U.S.C. § 705, Plaintiffs move for a stay postponing the effective date of the Final Rule until this case is decided on the merits and final judgment is entered.

In support of this motion, Plaintiffs rely on the accompanying Memorandum of Law, the Declaration of Matthew Colangelo, the exhibits attached to that Declaration, the pleadings and papers on file in this action, and any argument and evidence that is presented on the hearing of this motion.

DATED: June 14, 2019

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