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)

PLAINTIFFS' REPLY MEMORANDUM OF LAW IN SUPPORT OF CROSS-MOTION FOR SUMMARY JUDGMENT

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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):

CMDA Mem.	Memorandum of Law of Defendants-Intervenors Dr. Regina Frost and Christian Medical and Dental Associations in Support of Motion for Summary Judgment, and in Opposition to Plaintiffs' Motions for Preliminary Injunction, Dkt. 150 (filed Aug. 14, 2019).
CMDA Reply	Memorandum of Law in Opposition to Plaintiffs' Cross-Motions for Summary Judgment, and Reply in Support of Defendants-Intervenors' Motion for Summary Judgment, Dkt. 223 (filed Sept. 19, 2019).
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.' Reply	Defendants' Consolidated Reply 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. 224 (filed Sept. 19, 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). Citations to Exhibits 137 to 139 are to the excerpts from the administrative record as exhibits to the Declaration of Matthew Colangelo, Dkt. 231 (filed Oct. 3, 2019).
Pls.' PI Mem.	Memorandum of Law in Support of Plaintiffs' Motion for Preliminary Injunction, Dkt. 45 (filed June 14, 2019).
Pls.' SJ Mem.	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, Dkt. 182 (filed Sept. 5, 2019).
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Provider SJ Mem.	Memorandum of Law in Support of [Provider] Plaintiffs' Cross-Motion for Summary Judgment, in Opposition to Defendants' Motion for Summary Judgment, and Reply in Support of [Provider] Plaintiffs' Motion for Preliminary Injunction, Dkt. 184 (filed Sept. 5, 2019).
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INTRODUCTION

Plaintiffs are public providers and regulators of health care who work to ensure the health and safety of our residents while simultaneously respecting the conscience rights of our many employees. Each day, our health systems address real problems, including limited finances and resources, in pursuit of protecting our residents' health. This job is made more difficult when the United States Department of Health and Human Services ("HHS") proposes and adopts a rule, like the Final Rule, that imposes unprecedented burdens to address a manufactured problem. In opposition to Plaintiffs' cross-motion for summary judgment, Defendants deploy a number of tactics: responding to arguments that Plaintiffs did not make; presenting internally inconsistent arguments; and taking pains to walk back the clear text of the Final Rule. These are hallmarks of arbitrary and capricious decisionmaking, and its defense, which the Court should reject. As argued further below, Plaintiffs' constitutional claims are ripe, and the Final Rule violates both the Administrative Procedure Act and the Constitution.

ARGUMENT

I. Plaintiffs' Spending Clause and Establishment Clause claims are ripe.

Plaintiffs' constitutional claims are ripe, and Defendants' protests to the contrary either mischaracterize or entirely ignore Plaintiffs' arguments.

1. The Final Rule requires Plaintiffs to immediately adjust their conduct, in order to ensure compliance with it, thus rendering both the Spending Clause and Establishment Clause claims sufficiently concrete and fit for judicial review. *See* Pls.' SJ Mem. 3-6; *Abbott Labs. v. Gardner*, 387 U.S. 136, 148 (1967). Regarding the Spending Clause claim, Defendants again maintain that ripeness "turns on" the uncertain event of an enforcement action by HHS and argue it is "unfounded for Plaintiffs to state that they would lose money 'on the day [the Rule] takes effect.'" Defs.' Reply 35. Plaintiffs never made this argument. Rather, Plaintiffs argued that the

Final Rule "seeks to compel changes in Plaintiffs' behavior or expose them to the risk of fund termination on the day it takes effect." Pls.' SJ Mem. 5. It is this compulsion to come into compliance with the Final Rule prior to its November 22 effective date, or face the alternative *risk* of funding loss, that constitutes an immediate and concrete situation warranting judicial review.

This is precisely the type of threat that limits on the spending power proscribe, *see id.* at 4, and that—prior to any enforcement action—presents a situation ripe for review in the Spending Clause context. *See, e.g.*, *Sch. Dist. v. Sec'y of the U.S. Dep't of Educ.*, 584 F.3d 253, 262 (6th Cir. 2009) (in declaratory judgment action, Spending Clause claim held ripe, prior to federal enforcement action, where plaintiffs "already have suffered injury . . . in pursuit of compliance"). In any event, even under Defendants' arguments, Plaintiff the State of Illinois—and one of its subrecipients—are each the subject of different pending investigations by OCR. *See* Pls.' PI Mem. 13.

The Final Rule presents a sufficiently concrete situation with respect to the Establishment Clause claim as well, thus warranting review. Defendants argue that, because the Final Rule's definition of "discrimination" might not violate the Establishment Clause in every one of its applications, the Court would "undoubtedly benefit from having a concrete application of the Rule in front of it," and consequently Plaintiffs' claim is unripe. Defs.' Reply 37-38. Defendants cite no authority for this chain of reasoning, and their reference to the distinction between facial and as-applied challenges erroneously conflates the merits of Plaintiffs' claim with the standard for ripeness. Rather, the standard is whether Plaintiffs have alleged sufficiently concrete and immediate facts that would prevent the court from becoming entangled in abstract disagreements. *See Abbott Labs.*, 387 U.S. at 148.

Plaintiffs have alleged such concrete facts and supplemented these allegations with detailed declarations specifying how the required pursuit of compliance with the Final Rule immediately affects Plaintiffs' health institutions. Plaintiffs' complaint alleged that the definition's requirement of "voluntary acceptance" of a proposed accommodation, among other elements, inhibits Plaintiffs' delivery of health care to their residents. *See* Compl. ¶¶ 73, 122-32. Plaintiffs then provided evidence that many of their health institutions maintain policies for religious objection and the provision of care, especially emergency care, requiring only the reasonable accommodation of known employee objections that do not depend upon the "voluntary acceptance" provision of the Final Rule. *See* Pls.' PI Mem. 15-22 (citing declarations concerning institutional policies). These policies are not abstract, and the need to take immediate action to change and implement them to comply with the Final Rule, or risk loss of funding, is sufficiently concrete to warrant judicial review.

2. Plaintiffs will also face significant hardship absent the Court's consideration, further supporting the ripeness of the constitutional claims here. Pls.' SJ Mem. 6-9. Plaintiffs face hardship "where a regulation requires an immediate and significant change in the conduct of their affairs with serious penalties attached to noncompliance." *Abbott Labs.*, 387 U.S. at 153. Defendants entirely ignore Plaintiffs' argument on this score, including (i) Plaintiffs' evidence of efforts already underway to come into compliance with the Final Rule, and (ii) case law noting the severity of harm in forcing a plaintiff to wait and seek relief in a defensive posture, when the plaintiff works in a sensitive industry, like health care, where reputation is critical. *See* Pls.' SJ Mem. 7-8. This hardship strongly supports judicial review of Plaintiffs' Spending Clause and Establishment Clause claims.

II. The Final Rule violates the Administrative Procedure Act.

A. The Final Rule violates the APA because its requirement that Plaintiffs submit written assurances and certifications of compliance is not in accordance with law.

Defendants mischaracterize Plaintiffs' argument under the Paperwork Reduction Act ("PRA") as stating that the PRA required HHS to obtain OMB approval of the substance of the Final Rule. Defs.' Reply 23. Plaintiffs have instead made the narrower argument that OMB was required to approve the Final Rule's assurance and certification requirements—an express statutory protection against agencies imposing burdensome demands for information on recipients without the review mandated by Congress. Pls.' SJ Mem. 12; Pls.' PI Mem. 35-36.

HHS has three responses. First, HHS reiterates that it "fully expects" OMB to approve the agency's PRA submission before the Final Rule's effective date. Defs.' Reply 23. For the reasons Plaintiffs have already articulated, counsel's hope of future action by a non-party to the litigation is not a serious ground on which to defend an illegal data collection requirement. *See* Pls.' SJ Mem. 12. HHS could have—but did not—make the assurance and certification requirements contingent on OMB approval. *Cf.* Fed. Commc'ns Comm'n, In the Matter of Restoring Internet Freedom, 33 FCC Rcd. 311, 505 (2018) ("[A]mendments which contain new or modified information collection requirements that require approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act WILL BECOME EFFECTIVE upon the effective date announced when the Commission publishes a notice in the Federal Register announcing such OMB approval and the effective date."). And the Final Rule's Regulatory Impact Analysis makes clear that HHS expects the assurance and certification requirements to impose a meaningful burden on recipients to review their policies and practices *now*, in order to be in position to accurately assure and certify their compliance once the assurance and certification requirements do take effect. 84 Fed. Reg. at 23,240-41.

HHS next asserts that although the written assurance has concededly not been authorized, the certification requirement has in fact been approved by OMB. Defs.' Reply 23. This assertion is incorrect. The Information Collection Request that the Department submitted to OMB does *not* at all show that OMB has "already approved" the certification requirement in the Final Rule. *Id.* Instead, that document shows that HHS intends to "operationaliz[e] this certification through the existing signature block of the government-wide Application for Federal Assistance." Information Collection Request, *Request for OMB Review and Approval*, at 5 (June 19, 2019), at https://www.reginfo.gov/public/do/DownloadDocument?objectID=92774800. But the PRA requires *approval* from the OMB Director for each collection of information, 44 U.S.C. § 3507(a)(2), and does not permit an agency simply to add new information-collection obligations to a previously-approved collection—that would defeat the statute's purpose of requiring an assessment of the burdens, benefits, and practical utility of a proposed collection of information. *Id.* §§ 3501(1)–(2); 3506(c)(1)(A)–(B); 3506(c)(3); 3507(a).

HHS finally points out that the PRA includes an affirmative defense, Defs.' Reply 23-24 (citing 44 U.S.C. § 3512(b)), apparently suggesting for the first time that recipients may simply ignore the assurance and certification requirements if not approved before the Final Rule's effective date. The financial exposure from noncompliance with these requirements—including the risk of immediate suspension of all federal health care funds, *see* 84 Fed. Reg. at 23,271-72 (§§ 88.7(i), (j))—is too great for any responsible fund recipient to ignore. Nor does the agency indicate how recipients are to know if ignoring the assurance and certification requirements is a safe prospect; it would surely be unreasonable to expect health care providers to assign staff to monitor the Information Collection Review dashboard on RegInfo.gov each day to know when or whether HHS's demands for information have become lawful.

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

1. HHS failed to provide a rational connection between the facts in the record and the choice that it made in promulgating the Final Rule.

As Plaintiffs previously explained, Pls.' SJ Mem. 13-20, Defendants' rationales for upending decades-long reliance on various federal conscience protections—that the Final Rule is necessary because of "(1) Inadequate enforcement tools to address unlawful discrimination and coercion . . . , and (2) lack of awareness, and . . . confusion, concerning Federal conscience protection obligations . . . leading to possible violations of law," 84 Fed. Reg. at 23,228—are unsupported by the record and therefore arbitrary and capricious. In their reply brief, Defendants reiterate these rationales, Defs.' Reply 24-25, but fail to adequately dispute that the decision to issue the Final Rule "runs counter to the evidence before the agency." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). And once again, Defendants fail entirely to "articulate a satisfactory explanation for [HHS's] action, including a 'rational connection between the facts found and the choice made.'" *Id.* (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962)).

Consistent with statements in the proposed and Final Rule, Defendants double down on their claim that the complaints that OCR received in recent years were a central factor on which HHS relied to justify the Final Rule. Defs.' Reply 25 (listing three main factors). Indeed, HHS repeatedly made clear in the Proposed Rule that the alleged "significant increase" in complaints from November 2016 onwards provided substantial evidence for its conclusion that the Final Rule is necessary. 83 Fed. Reg. 3880, 3887 (Jan. 26, 2018) (explaining that "[t]he increase [in complaints] underscores the need for the Department to have the proper enforcement tools available to appropriately enforce Federal health care conscience and associated

anti-discrimination laws").[1]

In issuing the Final Rule, HHS repeated its claim that it received a "significant increase" in complaints, and its conclusion that such "increase underscore[d] the need for the Department to have the proper enforcement tools available to appropriately enforce" the federal conscience statutes. 84 Fed. Reg. 23,170, 23,175 (May 21, 2019); *see also id.* at 23,183. Moreover, in response to comments questioning whether the thirty-four complaints OCR received between November 2016 and mid-January 2018 justified the Final Rule, HHS again confirmed that it relied on the complaints to justify the Final Rule, and represented that it "received 343 complaints alleging conscience violations" during fiscal year 2018. *Id.* at 23,229; *see also id.* at 23,245 ("[D]uring FY 2018 . . . OCR received 343 complaints alleging conscience violations.").

Despite the fact that these complaints were plainly integral to, and indeed inextricable from HHS's justification for the Rule, Defendants once again capitulate—as they must—to the undeniable fact that the vast majority of the complaints OCR received have nothing whatsoever to do with the federal conscience statutes. Indeed, Defendants take no issue with the substance of Plaintiffs' detailed analysis revealing that, at a minimum, 94% of the complaints in the record do not allege conduct covered by the underlying statutes. *See* Pls.' SJ Mem. 15-16. Instead, Defendants' answer is to incorrectly ask the Court to disregard Plaintiffs' summary of the complaints in the administrative record,[2] *see* Defs.' Reply 47; and to identify—without

[1] *See also* 83 Fed. Reg. at 3887 ("Although OCR received on average only approximately 1.25 complaints per year from the 2008 Rule until November 2016, OCR has received thirty-four complaints between November 2016 and mid-January 2018."); *id.* at 3903 (citing the same thirty-four complaints to support the assertion that "OCR is aware that persons who are unlawfully coerced to violate their consciences . . . claim that their harm amounts to an actionable violation of the Federal health care conscience and associated anti-discrimination laws that OCR can remedy through administrative enforcement").

[2] Even assuming a declaration that summarizes information plain from the face of the complaints in the administrative record would be "extra-record evidence," the Court may consider evidence outside of the administrative record where such evidence "is necessary to explain technical terms or complex subject

discussion—nine purportedly relevant complaints among the hundreds they once claimed to exist, and once claimed to be a crucial premise for the Final Rule. *Id.* at 26 n.5. Plaintiffs have already acknowledged that eight of these complaints arguably implicate the underlying statutes. Pls.' SJ Mem. 16. The ninth complaint Defendants cite only further undermines the credibility of HHS's claims.[3] This complaint alleges that the Commonwealth of Pennsylvania engaged in "religious discrimination" because it brought an ultimately successful lawsuit challenging the federal government's decision to exempt certain religious groups from the federal contraceptive coverage requirement.[4] But that lawsuit involved the distinct question of whether and how Congress mandated particular health coverage for employees; Defendants fail to explain how that legal question has anything to do with the asserted conscience discrimination or federal conscience protection statutes at issue here.[5]

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matter" involved in the agency decision at issue. *Lands Council v. Powell*, 395 F.3d 1019, 1030 (9th Cir. 2005) (internal quotation marks omitted); *see also New York v. U.S. Dep't of Commerce*, 351 F. Supp. 3d 502, 633 (S.D.N.Y. 2019) ("[A] court may consider [supplemental] materials . . . to illuminate a complex record and to help the court better understand the issues involved"); *Nat'l Mining Ass'n v. Jackson*, 856 F. Supp. 2d 150, 157 (D.D.C. 2012) (extra record evidence will be considered "if it is needed to assist a court's review"). Absent such explanatory evidence, a court would not be able to "evaluate the challenged action on the basis of the record before it." *Nat'l Audubon Soc'y v. Hoffman*, 132 F.3d 7, 14 (2d Cir. 1997). Here, it would be both silly and unjust to permit HHS to purport to rely on hundreds of complaints of discrimination in support of the Final Rule, but then bar the Court from considering Plaintiffs' summary—and an undisputed summary at that—showing that over 94% of those complaints have nothing to do with the problems the agency claims the Final Rule will solve.

[3] *See* Defs.' Reply Ex. 9. Defendants did not include the full complaint so Plaintiffs include it here for the Court's reference. Ex. 139, AR 542316.

[4] *See Pennsylvania v. President United States of America*, 930 F.3d 543 (3d Cir. 2019).

[5] Nor can HHS justify the Final Rule by pointing to complaints that allegedly "indicate both general and specific concerns about the conscience rights of individuals in the health care field." Defs.' Reply 27 n.6. The refusal statutes do not protect "conscience rights" *writ large* but only cover recipients of specific sources of federal funds, and (depending on the funding source) only permit certain individuals to refuse to engage in certain activities, mostly relating to abortion. Thus, as Plaintiffs have explained, neither the complaint against the American College of Obstetricians and Gynecologists nor the complaint by a state correctional employee who objects to providing hormone therapy to transgender incarcerated persons implicate the underlying statutes. Pls.' SJ Mem. 18-19. Indeed, HHS's claim that the correctional employee's complaint "could relate to" some of the refusal statutes, Defs.' Reply 27 n.6, is disingenuous.

In short, Defendants concede both that HHS relied heavily on the now-disproven claim that there was a significant increase in complaints involving conscience protections after November 2016, and that nearly all of these complaints lack a rational connection to why HHS promulgated the Final Rule. These damning admissions alone require vacatur: "[A]n agency decision is arbitrary and must be set aside when it rests on a crucial factual premise shown by the agency's records to be indisputably incorrect." *Mizerak v. Adams*, 682 F.2d 374, 376 (2d Cir. 1982); *see also Make the Road N.Y. v. McAleenan*, No. 19-cv-2369 (KBJ), 2019 WL 4738070, at *39 (D.D.C. Sept. 27, 2019) ("[C]lear and binding precedent holds that it is the very definition of arbitrariness in rulemaking if an agency refuses to acknowledge (or fails to obtain) the facts and figures that matter prior to exercising its discretion to promulgate a rule.") (citing *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2569 (2019)); *City of Phila. v. Sessions*, 280 F. Supp. 3d 579, 623-24 (E.D. Pa. 2017) (vacating agency's new conditions on grant funds where the stated basis for the agency's decision rested on claims that were factually untrue).

Defendants cannot minimize the importance of HHS's now-disproven factual claim: HHS's alleged "significant increase" in relevant complaints was prominently highlighted by the agency in its "Overview of Reasons for the Final Rule." 84 Fed. Reg. at 23,175. Regardless of the other factors the agency's counsel now wishes to emphasize instead, the complaints were plainly "a crucial factual premise" for HHS's decision. *Mizerak*, 682 F.2d at 376; *cf. Animal Legal Def. Fund, Inc. v. Perdue*, 872 F.3d 602, 619 (D.C. Cir. 2017) (holding that an agency decision based "in part" on a rationale that "r[an] counter to the evidence allegedly before it"

HHS knows whether the Washington Department of Corrections receives any of the HHS funds that would implicate the few provisions of the refusal statutes that could cover this particular care. Defendants cannot defend the Final Rule by simply feigning ignorance over the validity of these complaints.

was arbitrary and capricious). In any event, the other two factors Defendants cite—the comments that HHS received on the Proposed Rule, and the existence of "litigation regarding new, potentially discriminatory laws passed by various States," Defs.' Reply 25—suffer from the same problem: Defendants fail to adequately explain how these factors justify HHS's issuance of the Final Rule. *State Farm*, 463 U.S. at 43; *see also Olenhouse v. Commodity Credit Corp.*, 42 F.3d 1560, 1575 (10th Cir. 1994) (to survive arbitrary and capricious review an "agency must make plain its course of inquiry, its analysis and its reasoning").

The comments that supposedly reflect "inadequate information and understanding about . . . federal law," 84 Fed. Reg. at 23,228, do not justify the sweeping new provisions of the Final Rule, especially in light of the fact that HHS failed to adequately explain how the Final Rule is needed to address the commenters' purported concerns. *See State Farm*, 463 U.S. at 48 ("agency must cogently explain" decision); *Clark County v. FAA*, 522 F.3d 437, 443 (D.C. Cir. 2008) (agency's "lack of any coherent explanation" fails to "satisfy the reasoned decisionmaking requirement"). For example, none of the comments that Defendants highlight support HHS's claim that it lacked the enforcement tools necessary to investigate or remedy alleged violations of the underlying statutes. Rather, the comments to which Defendants point in reply contain only one example of a complainant who reported an alleged violation of the conscience statutes to HHS for investigation, which resulted in the alleged target changing its relevant policies. *See* Defs.' Ex. 2 at 5-6; Defs.' Ex. 4 at 8.

The claim that the Final Rule was needed in light of "litigation regarding new, potentially discriminatory laws passed by various States," Defs.' Reply 25, fares no better. To begin with, even under the most general interpretation of the refusal statutes, not all laws mandating "notices related to abortion" implicate those statutes. 84 Fed. Reg. at 23,176. For example, Baltimore's

law (*id.* at 23,177) merely required pregnancy clinics that do not offer or refer for abortions to disclose that they did not offer or refer for abortion. *See Greater Baltimore Ctr. for Pregnancy Concerns, Inc. v. Mayor & City Council of Baltimore*, 879 F.3d 101, 105 (4th Cir. 2018). Likewise, New York's law (84 Fed. Reg. at 23,177) required merely, *inter alia*, that such centers disclose whether there was a licensed medical provider on staff, whether abortion referrals were provided, and to state that New York City encouraged pregnant patients to consult with licensed medical providers, *see Evergreen Ass'n, Inc. v. City of New York*, 740 F.3d 233, 238 (2d Cir. 2014). Complaints filed with OCR against Hawaii's law, Haw. Rev. Stat. Ann. § 321-561, which did not even mention the word abortion, were resolved without any finding that Hawaii violated any Federal conscience or antidiscrimination laws. *See* 84 Fed. Reg. at 23,177.

Further, even if some or all state and local laws requiring licensed medical facilities to provide certain disclosures regarding the availability of abortion services implicated the refusal statutes, the Supreme Court struck down one such law as likely violating the First Amendment nearly one year before the Final Rule was promulgated, as HHS acknowledged. *See* Fed. Reg. at 23,176 (citing *Nat'l Institute of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361 (June 26, 2018)). Moreover, as HHS also acknowledged, the absence of the Final Rule did not prevent OCR from attempting to take action against such disclosure laws the agency believed to violate the refusal statutes. *See* 84 Fed. Reg. at 23,177.

Nor can HHS point to complaints about state laws requiring health insurance plans to cover abortions as evidence of widespread confusion over the meaning of the refusal statutes, *see id.*, when it was HHS's own opinion—at least until 2017—that these complaints failed to state a violation of the refusal statutes, *see id.* at 23,179.[6] In any event, as HHS concedes, the most

[6] Here too, the Final Rule glosses over the specifics of these laws, lawsuits, and complaints, in an attempt

these laws evidence is "a notable number of *disputes* about *alleged* violations" of the refusal statutes. *Id.* at 23,178 (emphasis added). When even the agency itself is unprepared "to opine on or judge the legal merits or sufficiency of any of the . . . cited lawsuits or challenged laws," *id.*, it can hardly claim that this is the sort of evidence that justifies the Final Rule, which vastly expands the meaning and the scope of those statutes.[7] In sum, HHS's attempt to fix a problem that does not exist is arbitrary and capricious. *See Nat'l Nutritional Foods Ass'n v. Goyan*, 493 F. Supp. 1044, 1046 (S.D.N.Y. 1980) ("[A] 'regulation perfectly reasonable and appropriate in the face of a given problem may be highly capricious if that problem does not exist.'" (quoting *Chicago v. Fed. Power Comm'n*, 458 F.2d 731, 742 (D.C. Cir. 1971)); *see also Home Box Office, Inc. v. FCC*, 567 F.2d 9, 40 (D.C. Cir. 1977) (explaining that a regulation is arbitrary and capricious because "[w]hatever may be the ultimate validity of [the agency's] argument, its principal defect on . . . review is that there is no record evidence to support it").

Finally, HHS's purported rationales for the Final Rule are further belied by the contradictory positions taken in this litigation. First, while the agency claims that the rule was

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to manufacture a problem in need of a regulatory solution. *See* 84 Fed. Reg. at 23,177. The gravamen of these lawsuits and complaints is not that institutional or individual health care entities opposed to providing coverage for abortion were subject to discrimination in violation of the Weldon Amendment. *See id.* at 23,172 ("Weldon provides that none of the funds made available in [the applicable] appropriations act be made available to . . . a State or local government, if such . . . government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not . . . provide coverage of . . . abortions."). Rather, individuals and churches (not health care entities) were upset that they could not purchase insurance plans that denied coverage for abortion. Regardless of whether it is a question of conscience to purchase an insurance plan that provides coverage for services you do not intend to use, the right not to do so is not something Congress intended to protect through the particular statutes that the Final Rule seeks to implement.

[7] HHS's attempt to link the Final Rule to lawsuits requiring private entities to perform emergency abortions pursuant to EMTALA and to offer sterilization procedures and gender-affirming surgeries on a non-discriminatory basis is equally lacking. *See* 84 Fed. Reg. at 23,178. These lawsuits concern hospital policies that categorically deny access to care regardless of a provider's willingness to perform the procedure. *See id.* (citing cases). Under HHS's own interpretation of the refusal statutes, however, entities cannot rely on them as a defense to such claims. *See id.* at 23,171.

meant to address "confusion[] concerning Federal conscience protection obligations," 84 Fed. Reg. at 23,228, Defendants now seek to explain HHS's definitions of key terms in the Final Rule in a way that sows even more confusion. *See, e.g.*, Defs.' Reply 12-13. Second, Defendants now apparently contend that—pursuant to various existing statutes and regulations, including the federal "housekeeping" statute—HHS has always had the enforcement authority that the Final Rule establishes. Defs.' Reply 3-5 (citing, for example, 5 U.S.C. § 301). This argument is fatally inconsistent with HHS's proffered rationale that the Final Rule is needed to address "[i]nadequate enforcement tools to address unlawful discrimination and coercion faced by protected persons, entities, or health care entities." 84 Fed. Reg. at 23,228; *see also id.* at 23,229, 23,254. And this claim directly contradicts the agency's own arguments in this very litigation. Defs.' Mem. 14 ("[T]he Rule *establishes* enforcement tools to protect conscience rights." (emphasis added)). Such "[i]llogic and internal inconsistency [is] characteristic of arbitrary and unreasonable agency action." *Chamber of Commerce v. U.S. Dep't of Labor*, 885 F.3d 360, 382 (5th Cir. 2018).

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

HHS's failure to explain the connection between the factors on which it relied and the two rationales for its issuance of the Final Rule is especially egregious given the fact that the Final Rule "rests upon factual findings that contradict those which underlay its prior policy" and that "prior policy has endangered serious reliance interests that must be taken into account." *Perez v. Mortg. Bankers Ass'n*, 135 S. Ct. 1199, 1209 (2015) (internal quotation marks omitted); *see also* Pls.' SJ Mem. 20-22.

Defendants do not dispute that HHS was required to provide a "more substantial justification or reasoned explanation" because of the nature of its change in course. *Organized Vill. of Kake v. U.S. Dep't of Agric.*, 795 F.3d 956, 967 (9th Cir. 2015) (en banc) (internal

quotation marks omitted); *see* Defs.' Reply 24-25. In response, Defendants state the unremarkable fact that HHS "was entitled . . . to give more weight" to concerns expressed in previous years. *Id.* at 24 (quoting *Kake*, 795 F.3d at 968). "But, *State Farm* teaches that even when reversing a policy after an election, an agency may not simply discard prior factual findings without a reasoned explanation." *Kake*, 795 F.3d at 968. That is exactly what HHS did here. As Plaintiffs explained in their summary judgment memorandum, HHS reached precisely the opposite conclusions in 2011 than it does now, and disregarded prior key factual findings from the 2011 rulemaking, including that the Final Rule would jeopardize patient access to care. Pls.' SJ Mem. 20-21. HHS's recitation that it reviewed the previous rulemakings and comments, *see* Defs.' Reply 24-25, cannot possibly suffice for "the more substantial justification or reasoned explanation" HHS was required to provide. *Kake*, 795 F.3d at 968 (internal quotation marks omitted).

Moreover, Defendants continue to ignore Plaintiffs' strong reliance interests after decades of compliance with the underlying statutes. *See* Pls.' SJ Mem. 22. As Plaintiffs have repeatedly explained—and as HHS was aware from many comments in the administrative record—the Final Rule radically upends the status quo in the provision of health care, and harms Plaintiffs as regulators, insurers, and direct providers of care. Pls.' PI Mem. 10-23. The Final Rule expands who can object and to what, while simultaneously hamstringing Plaintiffs from making alternative arrangements to accommodate these objections. This dramatic shift will create chaos for Plaintiffs in their efforts to ensure patient care, most especially in emergency medical services, rural health care settings, and end-of-life care. Pls.' PI Mem. 17-22. HHS's failure to confront these reliance interests requires vacatur of the Final Rule. *See Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2127 (2016) ("In light of the serious reliance

interests at stake, the Department's conclusory statements do not suffice to explain its decision.").

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

The Government Plaintiffs directly deliver health care to their residents, as well as the Provider Plaintiffs to their patients—at times acting as the safety net or exclusive provider in their geographies—and the operational consequences of the Final Rule immediately affect that delivery. Plaintiffs set out four categories of operational concerns caused by the Final Rule, which were identified by commenters in the rulemaking process and known to HHS. Pls.' SJ Mem. 24. Defendants' arguments as to each category, addressed below, are unpersuasive.

Defendants note generally that HHS responded to comments that raised concerns about the Final Rule's definitions, *see* Defs.' Reply 27-28, but Plaintiffs' argument has never been that HHS failed to discuss the Final Rule's definitions. Rather, Plaintiffs argue that Defendants either failed to consider fundamental operational problems resulting from the Final Rule, which were raised by commenters—themselves health providers or industry organizations—or papered over such problems with non-responsive changes in the Final Rule's text or language in its preamble. A failure to address serious harms presented to the agency constitutes arbitrary decision-making. *See SecurityPoint Holdings, Inc. v. Transp. Sec. Admin.*, 769 F.3d 1184, 1188 (D.C. Cir. 2014). Similarly, when an agency provides mere "lip service" in its determination, when in possession of evidence that undermines that determination, this also amounts to arbitrary decision-making. *Anglers of the Au Sable v. United States Forest Serv.*, No. 05-cv-10152-BC, 2006 WL 5908358, at *15 (E.D. Mich. June 20, 2006), *report & recommendation adopted in part, rejected in part*, 565 F. Supp. 2d 812 (E.D. Mich. 2008).

1. The AMA and other medical organizations and providers cautioned against expanding

the universe of individuals allowed to refuse to provide services because it "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." Pls.' SJ Mem. 24. The Final Rule fails to address this specific and serious operational concern. In their opposition, Defendants seek to fill this gap with general or circular language. HHS argues that this concern was addressed by removing the term "workforce" from the definition of "assist in the performance"—purportedly narrowing the scope of the latter—but simultaneously notes that the definition still sweeps in administrative employees (like schedulers) who are precisely the type of unrelated employees whose inclusion commenters argued could lead to operational problems. Defs.' Reply 30 n.7. This is lip service that fails to consider the problem raised.[8]

2. Hospital organizations from around the country, as well as other private and public providers, informed HHS that an employee's duty to disclose a religious objection to an employer, with meaningful advance notice, is essential to the operations of health providers and their ability to provide patients the care they need. *See* Pls.' SJ Mem. 24. Defendants respond that HHS considered these comments because it altered the definition of "discrimination" to permit an employer to require an employee to inform them of objections after hiring, and then only "once per calendar year thereafter, unless supported by a persuasive justification," which is undefined. 84 Fed. Reg. at 23,263; *see also* Defs.' Reply 28-29. This argument entirely ignores the clear problem raised by commenters—namely that, consistent with existing state laws and

[8] Defendants claim that HHS also addressed this operational concern in an examination of "the Rule's impact on physicians, hospitals, and other health care institutions," which purportedly concluded that the Rule "creates net benefits" and "is tailored to impose the least burden on society." Defs.' Reply Mem. 30 n.7 (citing 84 Fed. Reg. at 23,288-363). Defendants' citation appears to be a typographical error, as the Federal Register page range Defendants cite pertains to a subject entirely unrelated to the Final Rule or this action. To the extent Defendants intended to cite the Final Rule's Regulatory Impact Analysis, 84 Fed. Reg. at 23,228-63, that analysis nowhere mentions or analyzes operational impacts on physicians, hospitals, or other health care institutions. *See* 84 Fed. Reg. at 23,227.

provider policies, the obligation is on the *employee* to affirmatively disclose any objection to providing care, and that such obligation is essential to provider operations. Pls.' SJ Mem. 24; Ex. 101, AR 147826 (Comment, Greater N.Y. Hosp. Ass'n) ("The duty to notify is an important feature of ethical practice to ensure minimal disruption to hospital operations in evaluating and accommodating individual conscience rights" and, accordingly, hospital policies typically "include the worker's duty to notify the hospital [of objections] on hire, or at another appropriate time.")

Defendants' argument also overlooks the limits the Final Rule places upon an employer's ability to inquire about an employee's objections. Defendants note that HHS modified the definition of "discrimination" in the Final Rule "'to clarify that . . . employers may require a protected employee to inform them of objections.'" Defs.' Reply 28 (quoting 84 Fed. Reg. at 23,191). What Defendants leave out of this quoted language, by way of ellipsis, is "within limits"—*i.e.*, the limits the Final Rule places on an employer's ability to inquire about an employee's possible objections. *See* 84 Fed. Reg. at 23,191. As noted above, the Final Rule states that "[s]uch inquiry may only occur after the hiring of . . . a protected entity, and once per calendar year thereafter, unless supported by a persuasive justification." *Id.* at 23,263. These limits not only restrict any affirmative disclosure requirement an employer might try to impose, but also fail to account for how a provider can operationalize compliance when HHS fails to specify what amounts to a "persuasive justification" for such inquiry by an employer. Providers like Plaintiffs are left to speculate about such a justification, presumably a crisis that—*post hoc* and too late—compromised patient care. *Cf.* CMDA Reply 16-17. HHS failed to address, or offered mere lip service in response to, operational concerns that could jeopardize patient care.

Finally, Defendants argue that Plaintiffs "fail to identify any applicable law that requires

a protected employee to voice all objections in advance" and that, consequently, HHS sufficiently modified the Final Rule to address commenters' concerns. Defs.' Reply 29. The administrative record does in fact show that the agency was made aware of laws that place the onus of notification upon an objecting employee.[9] And in any event, Defendants again misconstrue Plaintiffs' argument. Irrespective of the existence of such laws, HHS's adoption of the Final Rule is arbitrary because, in the face of specific and repeated comments about how hospitals operate, and concerns about compliance with HHS's proposed rulemaking, the agency failed to consider those concerns or responded with mere conclusory statements as opposed to reasoned explanation. *See SecurityPoint Holdings*, 769 F.3d at 1187-88.

3. Major health providers also expressed operational concerns over how the Final Rule's definitions affect their duties under collective bargaining agreements and the fair administration of labor contracts covering their employees. Pls.' SJ Mem. 24. Defendants attempt to downplay these concerns as amounting to "two cursory references" that did not contain meaningful analysis or data to evaluate and, consequently, did not cross a threshold of materiality warranting response from HHS. *See* Defs.' Reply 30 n.7.

With respect to materiality, Plaintiffs have identified at least three providers who raised this concern in comments, including (i) Kaiser Permanente, "a large employer of approximately 290,000 persons, including 22,100 physicians and 58,000 nurses," delivering health care to nearly 12 million members in eight states and the District of Columbia (Ex. 92, AR 139639), (ii) the San Francisco Department of Public Health, which operates fifteen primary care community clinics and hospitals, including Zuckerberg San Francisco General Hospital, the city's "safety net hospital . . . serving a region of more than 1.5 million people" (Ex. 81, AR

[9] *See, e.g.*, Ex. 101, AR 147826 (GNYHA Comment) (citing N.Y. Civil Rights Law § 79-i).

134791), and (iii) Whitman-Walker Health, a Federally Qualified Health Center in Washington, D.C. that served more than 20,000 patients in 2017 (Ex. 137, AR 135450).

Each of these comments raised the concern in the same manner: preexisting collective bargaining agreements govern the rights and relationship of objecting employees vis-à-vis non-objecting employees, and the proposed rule appeared to upset that balance and raise problems concerning the administration of labor contracts. *See* Ex. 92 at AR 139649; Ex. 81 at AR 134793; Ex. 137 at AR 135457. This is not a case like those cited by the Defendants, *see* Defs.' Reply 30 n.7, in which a commenter made a "cryptic and obscure reference" and then, following an agency's repeated invitations for more information, "declined to participate" further in the administrative process. *Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 554 (1978). Rather, at least three major health providers voiced the same operational concern, and HHS entirely failed to consider it. This is arbitrary.[10]

4. Finally, major health providers and medical organizations expressed grave operational concerns in emergency contexts—namely, that the Proposed Rule's vastly expanded scope of potential objectors, coupled with limits on providers' ability to inquire about objections, made staffing and planning an "impossible task that jeopardizes the ability to provide care, both for

[10] Defendants argue that these comments were "not submitted by any plaintiff," but fail to state the legal significance of that fact. Defs.' Reply 30 n.7. To the extent Defendants intend to suggest waiver of any arguments based on labor agreements, that argument would fail. *See Portland Gen. Elec. Co. v. Bonneville Power Admin.*, 501 F.3d 1009, 1023-24 & n.13 (9th Cir. 2007) (waiver does not apply where an issue was raised by someone other than the petitioning party, because "[i]f we required each participant in a notice-and-comment proceeding to raise every issue or be barred from seeking judicial review of the agency's action, we would be sanctioning the unnecessary multiplication of comments and proceedings"). Defendants further observe that "it appears self-evident that a provision in a labor agreement that conflicts with federal law should not be enforced," *id.*, but questions of supremacy or conflict of laws have no bearing on the arbitrary and capricious analysis. Commenters stated to HHS that the agency's new proposed rulemaking posed concerns for their preexisting contractual obligations to their workforces, and how to operationalize these preexisting duties with new duties under the proposed rule; the agency's failure to even consider their comments is arbitrary.

standard emergency room readiness and for emergency preparedness." Pls.' SJ Mem. 24-25 (quoting Ex. 106 (Comment, American College of Emergency Physicians)).

Again, HHS entirely failed to consider these clearly expressed operational concerns. In response, Defendants point to two sections of the Final Rule's preamble, but neither demonstrate that the agency "articulate[d] a satisfactory explanation for its action." *SecurityPoint Holdings*, 769 F.3d at 1187-88 (internal quotation marks omitted). In the first, HHS states that it "generally agrees" that the Emergency Medical Treatment and Labor Act ("EMTALA") is consistent with federal conscience statutes, but HHS's view as to the "general" harmony of these laws is non-responsive lip service that fails to address commenters' specific concerns. Defs.' Reply 29. HHS also points to the fact that it responded to a specific comment about whether the definition of "assist in the performance" applied to ambulance drivers. Rather than address any of these broader staffing or planning concerns raised by commenters, HHS repeatedly stated that the scope of that definition would "depend on the facts and circumstances" of each case. 84 Fed. Reg. at 23,188; Defs.' Reply 29-30. Again, this is non-responsive.[11]

HHS's failure to consider or address these operational concerns—along with the others articulated by commenters and set out above—is arbitrary and capricious. *Ass'n of Private Sector Colls. & Univs. v. Duncan*, 681 F.3d 427, 449 (D.C. Cir. 2012). And where HHS purports to address these concerns, but offers a mere statement of conclusion without reasoned explanation, its actions are similarly arbitrary. *SecurityPoint Holdings*, 769 F.3d at 1187-88.

[11] Relatedly, Plaintiffs argue that the Final Rule is arbitrary because HHS failed to consider its interference with EMTALA. *See* Pls.' SJ Mem. 29-30. Defendants do not specifically respond to Plaintiffs' claim that HHS failed to "provide any non-conclusory explanation of its unsupported conclusion that EMTALA's requirement 'does not conflict with Federal conscience and antidiscrimination laws,'" thus rendering the agency's action arbitrary and capricious. Pls.' SJ Mem. 30 (quoting 84 Fed. Reg. at 23,183).

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

Plaintiffs have also shown that the Final Rule is arbitrary and capricious because HHS failed to consider or conduct a reasoned analysis of how the Final Rule's definitions violate basic principles of medical ethics, identifying three such principles: (1) a required balancing of a practitioner's objection against the needs of a patient; (2) a duty to provide medically indicated care in an emergency, regardless of a physician's religious or moral beliefs; and (3) a duty to inform patients of all treatment options. *See* Pls.' SJ Mem. 31.

Regarding the first principle, Defendants dodge the real issue and argue that the Final Rule "does not force any individual to refuse to provide medical care in any given circumstance and thus does not run afoul of the medical industries' suggested limitations" on an individual's right to object. Defs.' Reply 34. Neither Plaintiffs nor the numerous commenters who raised concerns about the Final Rule's interaction with medical ethics have argued that the Final Rule compels a refusal of medical care. Rather, Plaintiffs and commenters were clear in their concerns: the Final Rule's definitions permit and protect objections from individuals that fail to balance the needs of patients as set out in longstanding medical codes of ethics. HHS's failure to consider the ethical conflicts of protecting such objections, and the consequences for *patients*, is arbitrary. Notably, despite many non-responsive references to "ethics" throughout the Final Rule's preamble, *see* Pls.' SJ Mem. 32 n.29, Defendants do not, and cannot, cite to any discussion or acknowledgement in the Final Rule suggesting the agency considered or analyzed this problem. Indeed, the only reference to the Final Rule actually cited in Defendants' papers on this score is to the general, and unrelated, concept that HHS purports to implement congressional objectives. *See* Defs.' Reply 34 (quoting 84 Fed. Reg. at 23,182).

Regarding the second principle, Defendants similarly—and disingenuously—invert

Plaintiffs' argument and respond that Plaintiffs "do not identify a situation in which the Rule compels a physician to violate his or her ethical duties to provide medically required care in an emergency situation." *Id.* at 34. Again, Plaintiffs argue that (i) the Final Rule's definitions permit and protect refusals of service by employees made with limited or no notice to any employer, including in emergency settings, in contravention of their ethical duties, and (ii) although HHS was aware of this concern, it failed to consider or conduct a reasoned analysis of it. And again, Defendants fail to cite to any discussion in the Final Rule that would indicate such consideration or analysis. On this point, Defendants merely refer to a statement about HHS's belief in the "general" harmony of EMTALA and federal conscience statutes, without any reference to codes of ethics or ethical concerns. *See id.* (quoting 84 Fed. Reg. at 23,183).

Finally, regarding the third principle, Defendants repeat conclusory language from the Final Rule's preamble, also cited in their prior filing, stating that HHS "does not believe that enforcement of conscience protections, many of which have been in place for nearly fifty years, violates or undermines the principles of informed consent." Defs.' Reply 35. In this repetition, Defendants simply refuse to engage with Plaintiffs' argument that it is the Final Rule itself—and specifically its definitions—that uniquely upends the balance that codes of ethics have struck, for decades, concerning religious objection and informed consent. *See* Pls.' SJ Mem. 32-34.

HHS's failure to consider, or to conduct a reasoned analysis of, the Final Rule's contravention of medical ethics is arbitrary and capricious. *See State Farm*, 463 U.S. at 42-43.

5. HHS failed adequately to explain its departure from the Title VII framework.

HHS has no response to Plaintiffs' arguments (Pls.' SJ Mem. 34-36) that the Rule is arbitrary and capricious because HHS failed to explain why (1) existing remedies under Title VII are inadequate; (2) Congressional silence permits it to incorporate some components of Title

VII's accommodation framework, but not the undue hardship exception; and (3) a policy that provides a single employee the unilateral right to identify and receive a "voluntarily acceptable" accommodation at the expense of all the other interests at play in the workplace is reasonable.

Instead, HHS defends exempting a huge segment of the American economy from Title VII's balancing of interests with the illogical claim that Title VII "applies in far more contexts, and is more vast, variable, and potentially burdensome (and, therefore, warranting of greater exceptions)" than the refusal statutes. Defs.' Reply 32. But Title VII has long applied with full force in the health care industry, existing harmoniously with the refusal statutes in the decades since their respective enactments.[12] If anything, it is precisely because an employee's religious objection in the health care context can be a matter of life or death—a fact documented by several commenters, *see* Provider SJ Mem. 28-35 & nn. 17-18—that Title VII's balancing of hardships is so critical. HHS's claims fall far short of the "reasoned explanation" necessary to justify a departure from decades of settled law. *Encino Motorcars*, 136 S. Ct. at 2125; *Am. Wild Horse Pres. Campaign v. Perdue*, 873 F.3d 914, 927 (D.C. Cir. 2017).

III. The Final Rule is unconstitutional.

A. The scope of judicial review of Plaintiffs' constitutional claims.

The Court's review of Plaintiffs' constitutional claims is not limited to the administrative record, and the Court may consider the additional evidence Plaintiffs have cited in support of those claims. *See Webster v. Doe*, 486 U.S. 592, 604 (1988) (noting that discovery was available against the CIA in a case alleging both APA and constitutional claims); *see also Puerto Rico Pub. Hous. Admin. v. U.S. Dep't of Hous. & Urban Dev.*, 59 F. Supp. 2d 310, 328 (D. P.R. 1999) ("[A] plaintiff who is entitled to judicial review of its constitutional claims under the APA is

[12] *See, e.g.*, Ex. 138, AR 147884 (Comment, Former EEOC Chair Jenny Yang & Former EEOC Legal Counsel Peggy Mastroianni).

entitled to discovery in connection with those claims" (citing *Webster*, 486 U.S. at 604)); *Rydeen v. Quigg*, 748 F. Supp. 900, 905-06 (D.D.C. 1990) (considering extra-record affidavits because "[w]hen reviewing constitutional challenges to agency decisionmaking, courts make an independent assessment of the facts and the law").

Defendants cite "multiple courts across the country" that they believe have "restrict[ed] the review of constitutional claims to the administrative record." Defs.' Reply 48 (citing cases). Each of these out-of-circuit cases can be distinguished,[13] but more to the point, Defendants ignore three recent opinions from the Southern District of New York and the Eastern District of New York that squarely reject this contention and hold that courts may and should consider all evidence—not just the administrative record—in assessing Plaintiffs' constitutional claims. *See Saget v. Trump*, 375 F. Supp. 3d 280, 368 (E.D.N.Y. 2019); *New York v. U.S. Dep't of Commerce*, 351 F. Supp. 3d 502, 667-69 (S.D.N.Y. 2019) ("[T]here is no basis in law or logic to restrict judicial review of the due process claim to Defendants' handpicked evidence."); *New York v. U.S. Dep't of Commerce*, 345 F. Supp. 3d 444, 451-52 (S.D.N.Y. 2018).

This Court may therefore consider all of the evidence Plaintiffs cited, administrative

[13] *See Harkness v. Sec'y of Navy*, 858 F.3d 437, 446 n.6, 451 n.9 (6th Cir. 2017) (affirming denial of discovery because "[plaintiff's] Establishment Clause claim is not a standalone claim, but rather another basis on which [the plaintiff] may challenge the Secretary's" actions as arbitrary and capricious under the APA); *Chang v. U.S. Citizenship & Immigration Servs.*, 254 F. Supp. 3d 160, 162 (D.D.C. 2017) (denying discovery where the constitutional claims raised such similar issues as the APA claims—whether the agency action was rational or irrational—as to "fundamentally overlap"); *Jarita Mesa Livestock Grazing Ass'n v. U.S. Forest Serv.*, 58 F. Supp. 3d 1191, 1238 (D.N.M. 2014) (discovery denied where the relationship between the plaintiffs and the agency "was fundamentally that of tribunal and litigant, and not that of adversarial parties to a lawsuit"); *Evans v. Salazar*, No. C08-0372, 2010 WL 11565108, at *2 (W.D. Wash. July 7, 2010) (court allowed plaintiffs to present specific discovery requests and only subsequently entered protective order); *Harvard Pilgrim Health Care of New England v. Thompson*, 318 F. Supp. 2d 1, 10 (D. R. I. 2004) (discovery denied because plaintiff failed to exhaust constitutional claims during the administrative process); *Charlton Mem'l Hosp. v. Sullivan*, 816 F. Supp. 50, 51 (D. Mass. 1993) (discovery denied where plaintiffs failed to show good cause to conduct "broad-ranging, open-ended discovery" in action that "primarily" involved judicial review of agency action setting Medicare payment rates).

record and otherwise, in support of their constitutional claims.

B. Defendants again dodge the Final Rule's violation of the Spending Clause.

For all of the reasons that Plaintiffs have previously explained, the Final Rule violates each and every prohibition that the Spending Clause places on the federal government's power to condition the receipt of Plaintiffs' federal funds. Pls.' PI Mem. 45-53; Pls.' SJ Mem. 39-47; *see South Dakota v. Dole*, 483 U.S. 203, 207-08, 211 (1987).

Defendants dodge each of these constitutional infirmities by simultaneously ignoring Plaintiffs' arguments and the plain text of the Final Rule. For example, with respect to the fact that the Final Rule attaches retroactive and ambiguous conditions to Plaintiffs' receipt of federal funds, Defendants completely fail to address that the Final Rule (1) imposes new and burdensome compliance requirements on Plaintiffs, *see* Pls.' PI Mem. 47 (quoting 84 Fed. Reg. at 23,269-70 (§§ 88.4(a), (b)(5)); Pls.' SJ Mem. 40; and (2) interprets federal law in a way that will impair the application of state and local laws on critical issues affecting the health and well-being of Plaintiffs' residents like emergency care, patient abandonment, informed consent, the availability of lawful prescriptions, religious accommodations in the workplace, access to comprehensive reproductive health care, and insurance coverage for contraception and abortion, *see* Pls.' PI Mem. 47-48; Pls.' SJ Mem. at 40; 84 Fed. Reg. at 23,272 (§ 88.8). These provisions—along with the Final Rule's massive and unclear expansions of who may object, to what, and when, and the amount of funding at stake for a perceived violation—spring into effect immediately and require Plaintiffs to guess at what is required of them to comply with HHS's new requirements and broad, unprecedented view of discrimination. This is exactly what the Spending Clause prohibits. *See Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 296 (2006) ("States cannot knowingly accept conditions of which they are 'unaware' or which they are 'unable to ascertain.'") (quoting *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S.

1, 17 (1981)).

With respect to the fact that the Final Rule is coercive, Defendants again refuse to even acknowledge the Final Rule's plain text. *See* Defs.' Reply 40-41. As Plaintiffs have repeatedly emphasized, the Final Rule provides HHS with the authority to withhold, deny, suspend, or terminate all federal funds that it administers based on (1) the Department's determination that "there is a failure to comply" with any provision of the Final Rule or the statutes it implements, including during the pendency of good-faith voluntary compliance efforts; or (2) a recipient's failure to "furnish an assurance or certification" required by Section 88.4. *See* Pls.' SJ Mem. 43-44 (citing 84 Fed. Reg. 23,271-72 (§§ 88.7 (h)-(j)). Defendants have never disagreed that by its terms, the Final Rule provides HHS with the authority to withhold all of the federal funds that HHS administers in these circumstances. At most, Defendants have asserted through counsel that the agency's "enforcement procedures under the Rule will remain individualized and will begin with informal means," Defs.' Reply 40, but representations from defense counsel in APA litigation do not modify the substantive provisions of an agency's regulation, and provide insufficient basis for concluding that the risk of harm has been mitigated—as this Court and other courts have recognized. *See* Order, Dkt. 82 at 1-2 (June 27, 2019) (denying motion to continue where counsel's representation that HHS will delay enforcement of the Final Rule does not "supply conclusive evidence that the *effective date* of the Final Rule has been officially postponed"); *City & Cty. of San Francisco v. Azar*, No. 19-cv-2405-WHA, Dkt. 81 at 1 (N.D. Cal. June 27, 2019) (order denying motion to adjust schedule based on counsel's representations because "[u]ntil there is an official postponement, counsel's and the agency's indications are too uncertain to rely on").

To the extent that Defendants now argue that the Final Rule's enforcement scheme goes

no further than what HHS was already permitted to do in various regulations that govern general grants, contracts, and acquisitions, Defs.' Reply 4, such argument finds no support in the Final Rule itself.[14] To the contrary, the Final Rule contains a laundry list of involuntary enforcement mechanisms untethered to particular statutes or regulations, including that the Department may "[t]erminat[e] Federal financial assistance or other Federal funds from the Department, *in whole or in part*," and "deny[] or withhold[], *in whole or in part*, new Federal financial assistance or other Federal funds from the Department administered by or through the Secretary for which an application or approval is required." 84 Fed. Reg. at 23,272 (§ 88.7(i)(3)(iv)-(v)) (emphasis added).

Additionally, despite counsel's hollow representations otherwise, Defs.' Reply 4, the Final Rule authorizes HHS to pursue these and other involuntary enforcement actions once the Department determines "an investigation or compliance review indicates a failure to comply with Federal conscience and anti-discrimination laws." 84 Fed. Reg. at 23,271 (§ 88.7(i)(2)). Indeed, the Final Rule makes clear that "[a]ttempts to resolve matters informally shall not preclude OCR from simultaneously pursuing any action described in paragraphs (a)(5) through (7) of this section," which includes involuntary enforcement. *Id.* This authorization directly contradicts several of the regulations that provide HHS may only pursue involuntary enforcement once certain conditions are met. *See, e.g.*, 45 C.F.R. § 75.371 (instructing that HHS may only impose involuntary enforcement remedies if it determines that noncompliance cannot be remedied by imposing additional conditions); 45 C.F.R. § 96.51(c) ("The Department will withhold funds from a State only if the Department has provided the State an opportunity for a hearing."). Nor

[14] In any event, "courts may not accept . . . counsel's *post hoc* rationalizations for agency action." *State Farm*, 463 U.S. at 50.

have Plaintiffs found anything in the housekeeping statutes to suggest that a failure to submit an assurance or certification of compliance warrants the termination of federal funds.

More fundamentally, the "nature of the threat" at issue here—comply with the new federal conscience regime or stand to lose billions of dollars in federal funding on which Plaintiffs rely—is precisely the threat that the Spending Clause proscribes. *Nat'l Fed. of Independent Business v. Sebelius ("NFIB")*, 567 U.S. 519, 580 (2012); *see* Pls.' SJ Mem. 45-46. Even if Plaintiffs were to accept Defendants' crabbed and unfounded representations of what the Final Rule authorizes HHS to do—which they cannot—the loss of Medicaid funding alone would likely leave Plaintiffs with no choice but to capitulate to Defendants' new program. *See NFIB*, 567 U.S. at 582 ("The threatened loss of over 10 percent of a State's overall budget . . . is economic dragooning that leaves the States with no real option but to acquiesce in the Medicaid expansion.").

With regard to Plaintiffs' argument that the Final Rule places funds from the Departments of Labor and Education in jeopardy, Pls.' SJ Mem. 46-47, Defendants' reply suffers from the same problems: Defendants fail to acknowledge the plain text of the Final Rule, and rely on counsel's empty assurances to the contrary. *See* Defs.' Reply 41-42.

Finally, for the same reasons the Provider Plaintiffs explain in their summary judgment brief and reply, Defendants' arguments that the Final Rule does not impose unconstitutional conditions on the receipt of Plaintiffs' funds fails. *See* Provider SJ Mem. 41-44; Provider Reply Section II.C.4.

IV. The Court should vacate the Final Rule in full and without geographic limitation.

Plaintiffs have established that the most significant provisions of the Final Rule—including key definitions, 84 Fed. Reg. at 23,263-64 (§ 88.2); the assurance and certification requirements, *id.* at 23,269-70 (§ 88.4); the compliance requirements, *id.* at 23,270-71 (§ 88.6);

and the agency's enforcement scheme, *id.* at 23,271-72 (§ 88.7)—should be invalidated under the APA, the Constitution, or both. As Plaintiffs have explained, Pls.' SJ Mem. 54-55, the remaining, ancillary provisions cannot function on their own. *See MD/DC/DE Broad. Ass'n v. FCC*, 236 F.3d 13, 22 (D.C. Cir. 2001) (severability depends on "whether the remainder of the regulation could function sensibly without the stricken provision"). Invalidation of any one of the core provisions challenged in this litigation would "severely distort" the agency's intended rulemaking and "produce a rule strikingly different from any the [agency] has ever considered or promulgated." *Id.* at 23. It would therefore "be untenable to require [agency] employees to parse through pieces of regulations disembodied from their animating purpose." *Flores v. Barr*, No. 85-cv-4544, 2019 WL 4781312, at *15 (C.D. Cal. Sept. 27, 2019).

Apart from the *ipse dixit* that "portions of the rule can clearly operate independently from each other," Defs.' Reply 49, Defendants' severability argument appears to rest entirely on the fact that HHS "explained that it intended for the constituent parts to survive independently." *Id.* But "a severability clause is an aid merely; not an inexorable command." *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2319 (2016) (internal quotation marks omitted); *see also Flores*, 2019 WL 4781312, at *15 (permanently enjoining agency regulation and rejecting defendants' severability argument that was based on a "*pro forma* severability clause"). Defendants have provided no reason for the Court to depart from the normal relief of vacatur for regulations held to be invalid under the APA. 5 U.S.C. § 706(2); *see Fed. Election Comm'n v. Akins*, 524 U.S. 11, 25 (1998); *Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1110 (D.C. Cir. 2014).

With regard to Defendants' contention that any relief "must be limited to the specific Plaintiffs before the Court," Defs.' Reply 49-50, the statute provides otherwise. 5 U.S.C.

§ 706(2) (the reviewing court "shall" "hold unlawful and set aside" defective agency action); *see also Harmon v. Thornburgh*, 878 F.2d 484, 495 n.21 (D.C. Cir. 1989). In rejecting just last week the same argument regarding the scope of relief that Defendants proffer here, the U.S. District Court for the District of Columbia explained:

> In sum, and sternly put, the argument that an administrative agency should be permitted to side-step the required result of a fair-fought fight about well-established statutory constraints on agency action is a terrible proposal that is patently inconsistent with the dictates of the law. Additionally, it reeks of bad faith, demonstrates contempt for the authority that the Constitution's Framers have vested in the judicial branch, and, ultimately, deprives successful plaintiffs of the full measure of the remedy to which they are entitled.

Make the Road N.Y., 2019 WL 4738070, at *44; *see also id.* ("[I]n this case, as elsewhere, [the agency] appears to be engaged in a concerted effort to establish a precedent for judicial acquiescence to an agency's continued application of rules that courts have invalidated."). This Court should likewise reject Defendants' invitation to establish this precedent.[15]

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.

[15] Defendants cite *Gill v. Whitford*, 138 S. Ct. 1916 (2018) for the proposition that a remedy "must be tailored to redress the plaintiff's particular injury." Defs.' Reply. 49-50. But as the U.S. District Court for the District of Columbia explained in rejecting this very argument, vacating an improper rule "actually does redress the injury that an APA plaintiff presents." *Make the Road N.Y.*, 2019 WL 4738070, at *46 ("The agency simply parrots the Supreme Court's general statement (made in another context) that '[a] plaintiff's remedy must be tailored to redress the plaintiff's particular injury.'").

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Respectfully submitted,

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