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Via Federal eRulemaking Portal

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Melanie Fontes Rainer
Director
U.S. Department of Health and Human Services
Office for Civil Rights
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: "Safeguarding the Rights of Conscience as Protected by Federal Statutes" Notice of Proposed Rulemaking (RIN 0945-AA18)

Dear Secretary Becerra and Director Fontes Rainer:

The undersigned State Attorneys General of California, New York, Arizona, Connecticut, Delaware, the District of Columbia, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, North Carolina, Oregon, Pennsylvania, Rhode Island, Vermont, and Washington (the States) write in support of the Notice of Proposed Rulemaking issued by the U.S. Department of Health and Human Services (HHS) and Office for Civil Rights (OCR) entitled "Safeguarding the Rights of Conscience as Protected by Federal Statutes" (the "Proposed Rule"). The Proposed Rule rescinds portions of the previous rulemaking (84 Fed. Reg. 23,170 (2019) ("2019 Rule")) that are redundant, confusing, or have been deemed illegal by district court opinions in litigation brought by many of the States, as well as local governments and healthcare providers. The 2019 Rule—which never took effect due to multiple court injunctions—marked a sweeping change to the carefully crafted balance between an individual's right to object based on conscience and a patient's right to access basic healthcare, including emergency care and family planning services. In upending this balance, the 2019 Rule placed the health of millions in extreme jeopardy and threatened to terminate hundreds of billions of dollars in essential federal healthcare funding to the States.

For the reasons set forth below, we welcome the changes made in the Proposed Rule, which appropriately restore the balance of respecting individual conscience rights with assuring healthcare access, and we address specific points on which HHS requests comment. *See* 88 Fed. Reg. 826–27 (Jan. 5, 2023).

A. THE 2019 RULE AND SUBSEQUENT LITIGATION

Numerous federal statutory provisions aim, in specified contexts, to accommodate religious and moral objections to healthcare services provided by recipients of federal funds. These provisions (the "federal conscience provisions") principally address objections by healthcare entities—like doctors, nurses, and hospitals—to providing abortion, sterilization, and assisted suicide services, in addition to counseling and referrals related to these services. *See* 84 Fed. Reg. at 23,170. These provisions include the Church Amendments, 42 U.S.C. § 300a-7; the Coats-Snowe Amendment, *id*. § 238n(a); the Weldon Amendment, i.e., Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2019, Pub. L. No. 115-245, Div. B., § 507(d), 132 Stat. 2981, 3118 (2018); the Conscience Provisions in the Patient Protection and Affordable Care Act ("ACA") of 2010, 42 U.S.C. §§ 14406(1), 18023(b)(1)(A) and (b)(4), 18113; and the Medicaid and Medicare Advantage Conscience Provisions, 42 U.S.C. §§ 1395w-22(j)(3)(B), 1396u-2(b)(3)(B).

Beginning in 2008, HHS engaged in various rounds of rulemaking around the federal conscience provisions. Ultimately, in 2011, HHS rescinded several definitions imposed by its 2008 rule and, under its general housekeeping authority, maintained the 2008 rule's designation of OCR as the agency to receive and coordinate handling of complaints regarding conscience violations. 76 Fed. Reg. at 9977. Between 2008 and January 2018, OCR received only 44 complaints based on moral or religious objections. 83 Fed. Reg. 3880, 3886 (Jan. 26, 2018). Yet in January 2018, HHS issued a Notice of Proposed Rulemaking to vastly expand the reach and scope of nearly 30 narrowly drawn federal conscience laws. *Id*. HHS published a largely identical final rule in May 2019.

The 2019 Rule imposed a new regime that broadened the rights of religious objectors at the expense of providers, physicians, and the safety of patients. It did this by, among other things, defining key statutory terms more broadly and applying them generally, rather than in the limited contexts specified by Congress (Section 88.2 of the 2019 Rule). The 2019 Rule also expanded OCR's powers to enforce violations of the conscience provisions by terminating, denying, or withholding all HHS federal funding following a single violation (Section 88.7 of the 2019 Rule).

Shortly after HHS issued the 2019 Rule, it was challenged in federal lawsuits filed in California, Washington, and New York. On May 21, 2019, California filed a lawsuit in federal district court alleging that the 2019 Rule violates the Administrative Procedure Act, the Spending Clause, and the Establishment Clause. This lawsuit proceeded with simultaneously-filed actions by the City of San Francisco and the County of Santa Clara. On November 19, 2019, the district

court granted California's motion for summary judgment and vacated the 2019 Rule. *California v. Azar*, 411 F. Supp. 3d 1001 (N.D. Cal. 2019). The court concluded that HHS violated the APA because the regulation's "new definitions conflict with the underlying statutes," "impos[e] draconian . . . penalties," and are contrary to law. *Id*. at 1022, 1024. The court did not reach the parties' arbitrary and capricious APA claim or the constitutional claims. HHS appealed to the Ninth Circuit.[1]

On May 21, 2019, New York, along with the City of New York, Colorado, Connecticut, Delaware, District of Columbia, Hawai'i, Illinois, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, Oregon, Pennsylvania, Rhode Island, Vermont, Virginia, Wisconsin, City of Chicago, and Cook County, Illinois, filed a lawsuit challenging the 2019 Rule.[2] On November 6, 2019, the district court granted New York's motion for summary judgment, concluding that the 2019 Rule (1) exceeded HHS's rulemaking authority, (2) exceeded HHS's enforcement authority; (3) was contrary to Title VII; (4) was contrary to the Emergency Medical Treatment and Labor Act (EMTALA); (5) was arbitrary and capricious; (6) was not a logical outgrowth of the notice of proposed rulemaking; (7) violated Separation of Powers; and (8) violated the Spending Clause. *New York v. U.S. Dep't of Health & Hum. Servs.*, 414 F. Supp. 3d 475 (S.D.N.Y. 2019).[3] HHS appealed the court's summary judgment order to the Second Circuit.

The Ninth Circuit appeal has been held in abeyance pending HHS's issuance of the Proposed Rule. The Second Circuit appeals had been held abeyance, but as of December 8, 2022, they have been dismissed without prejudice to reinstatement after the completion of this rulemaking.

B. THE PROPOSED RULE'S RESCISSION OF THE 2019 RULE IS APPROPRIATE

The States welcome HHS's rescission of parts of the 2019 Rule. The rulemaking responds to the reasoning in the orders issued by courts in the prior litigation. That litigation demonstrated the 2019 Rule's negative effects on access to healthcare and raised substantial questions about the lawfulness of the 2019 Rule, including whether the Rule exceeded the scope of HHS's authority, was arbitrary and capricious, was contrary to law, and was unconstitutional. The States address these issues below in response to the Proposed Rule's specific requests for comment. *See* 88 Fed. Reg. at 826.

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[1] In the Eastern District of Washington, the Washington Attorney General filed suit contesting the 2019 Rule. The district court granted summary judgment to Washington and likewise vacated the 2019 Rule in its entirety. *Washington v. Azar*, 426 F. Supp. 3d 704 (E.D. Wash. 2019). That appeal was consolidated with the appeal of the California litigation.

[2] Several health care providers also filed suit, and this challenge was argued and decided together with New York's case.

[3] The court did not reach the parties' Title X, Section 1554 of the Affordable Care Act, or Medicaid informed consent provisions claims.

1. The 2019 Rule Would Have Hindered Access to Information and Healthcare Services

HHS requests information "including specific examples where feasible" supporting or refuting allegations that the 2019 Rule "hindered, or would have hindered, access to information and health care services, particularly sexual and reproductive health care and other preventative services." 88 Fed. Reg. at 826.

As the prior litigation amply demonstrated, the 2019 Rule would have threatened significant harm to the States' residents in need of emergency reproductive healthcare. For example, during the prior litigation, HHS conceded that the 2019 Rule would allow a paramedic to refuse to transport a patient with a life-threatening complication that could require an emergency abortion and also represented that, under the Rule, OCR "could potentially impose liability" on an employer for insisting the paramedic provide transport. *See New York*, 414 F. Supp. 3d at 539.[4] These representations alone reflect how the 2019 Rule would have denied access to reproductive care during a life-or-death medical emergency.

There is additional evidence that providers across the country have invoked personal beliefs to deny patients the emergency care they need. In one case, for example, a Michigan woman was denied treatment that would have prevented severe infection and pain when she experienced a miscarriage at 18 weeks of pregnancy. *Means v. United States Conference of Catholic Bishops*, 836 F. 3d 643, 646 (6th Cir. 2016).[5] In another case, a Catholic hospital in Arkansas refused to provide a sterilization procedure based on "religious-based prohibitions on sterilization procedures" to a woman who requested one at the time she delivered her baby because "becoming pregnant again presented a danger to her health." Nat'l Women's L. Ctr., *Refusals to Provide Health Care Threaten the Health and Lives of Patients Nationwide* (August 2017).[6] And in another case, an HIV-positive patient was repeatedly denied emergency room treatment after suffering seizures, leading to his hospitalization for gastrointestinal hemorrhaging, pneumonia, a staph infection, and AIDS. *Id.* More recently, a Minnesota woman was forced to travel over 100 miles to receive emergency contraception after a local pharmacist refused to fill her prescription on the basis of his religious beliefs.[7] While many of the States

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[4] Citing Transcript of Oral Argument ("Tr.") at 116–20, New York v. U.S. Dep't of Health & Hum. Servs., 414 F. Supp. 3d 475 (S.D.N.Y. 2019) (No. 19-cv-4676).

[5] "Despite the gravity of [the woman]'s condition, which created serious risks to herself and her baby" and the certainty that the baby would not survive, the religiously-affiliated hospital "sent her home with some pain medication." *Id.* at 646–47. The woman had to return twice more before she was treated, only when she was experiencing "extremely painful contraction[s]" and had already begun to deliver. *Id.* at 647.

[6] Available at https://nwlc.org/wp-content/uploads/2017/08/Refusal-to-Provide-Care.pdf.

[7] Lindsey Bever, Can a Pharmacist Deny a Patient the Morning-After Pill? A Jury Will Decide, Washington Post (August 3, 2022), available at https://www.washingtonpost.com/nation/2022/08/03/minnesota-pharmacist-contraception-lawsuit/.

have attempted to protect their residents from harm resulting from the denial of care, the 2019 Rule guaranteed that such injuries would proliferate notwithstanding the States' best efforts.

The 2019 Rule threatened to increase the number and types of providers who refuse to provide or facilitate abortion services. But as it is, there are already "significant challenges" in access to "abortion services, particularly for low-income women and women of color." Human Rights Watch, *Letter to U.S. Secretary of Health and Human Services Alex Azar* (Mar. 27, 2018).[8] Studies show that "[p]oor women are five times more likely than higher income women to have an unintended pregnancy, and rates of unintended pregnancy among women of color are more than twice the rates for white women." *Id.* By further restricting access, the 2019 Rule would have exacerbated existing racial and socio-economic health disparities. These disparities have become even more exigent in the wake of the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*.[9]

Other vulnerable populations would have also suffered disproportionate impacts from the 2019 Rule. For example, "LGBTQ populations experience a significant rate of discrimination in health care settings, and also experience negative health outcomes compared with the overall population."[10] Indeed, even before the 2019 Rule, "more than half" of 5,000 LGBT respondents to one survey reported some form of discrimination in care.[11] In another, 33% of transgender patients "reported having at least one negative experience related to being transgender such as verbal harassment, refusal of treatment, or having to teach the health care provider about transgender people to receive appropriate care."[12] These experiences impact patients' decisions to seek necessary medical care. According to a 2022 survey, "more than 1 in 5 LGBTQI+ adults reported postponing or avoiding medical care in the past year due to disrespect or discrimination by providers, including more than 1 in 3 transgender or nonbinary individuals." Ctr. for Am. Progress, *Discrimination and Barriers to Well-Being: The State of the LGBTQI+ Community in 2022* (Jan. 12, 2023).[13]

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[8] Available at https://www.hrw.org/news/2018/03/27/human-rights-watch-letter-us-secretary-health-and-human-services-alex-azar.

[9] Katy Backes Kozhimannil, Asha Hassan, and Rachel Hardeman, Abortion Access as a Racial Justice Issue, 387 New England Journal of Medicine 17 (October 27, 2022), available at https://www.nejm.org/doi/full/10.1056/NEJMp2209737 ("Recent estimates suggest that a nationwide abortion ban would increase maternal mortality by 21% overall and by 33% among Black Americans. Racial and ethnic disparities in reproductive health outcomes follow from inequities in access to care.").

[10] Comment Letter from American Nurses Association to 2019 Rule at 5 (citing studies).

[11] Comment Letter from Lambda Legal to 2019 Rule at 12 (citing Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey on Discrimination Against LGBT People and People Living with HIV* (2010)).

[12] Comment Letter from Ca. Dep't. of Ins. to 2019 Rule at 6 (citing Nat'l Ctr. For Transgender Equality, *Report of the 2015 U.S. Transgender Survey* (2016)).

[13] Available at https://www.americanprogress.org/article/discrimination-and-barriers-to-well-being-the-state-of-the-lgbtqi-community-in-2022/.

The link between refusal provisions and discrimination against LGBTQ individuals is already well documented. In one case, a woman was denied infertility treatment because she is a lesbian, resulting in the California Supreme Court holding that doctors' religious beliefs do not exempt them from California's laws prohibiting discrimination. *N. Coast Women's Care Med. Group, Inc. v. San Diego Cty. Superior Court*, 44 Cal. 4th 1145, 1159–60 (2008). In similar ways, expansive conscience provisions have caused transgender individuals to be denied reproductive services, family members to be prohibited from visiting ill loved ones, same-sex couples to be denied counseling, and individuals living with HIV to be denied medical care.[14] This kind of discrimination involving sexual orientation, gender identity, or HIV status would have only increased in frequency given the broad scope of the 2019 Rule, further exacerbating existing health disparities and undermining the States' efforts to combat those disparities.

2. The Proposed Rule Reinstates the Proper Scope of the Federal Conscience Provisions and OCR's Enforcement Powers

HHS requests comment on "whether the provisions added by the 2019 Rule [were] necessary . . . to serve the statutes' . . . objectives," "whether any statutory terms require additional clarification," and its proposal "to retain portions of the 2019 Final Rule's enforcement provisions." 88 Fed. Reg. 826–27. In rescinding various provisions of the 2019 Rule—in particular the definitions at Section 88.2 and certain enforcement provisions at Section 88.7—the Proposed Rule reinstates the proper scope of federal conscience provisions and OCR's enforcement powers. The APA instructs courts to "hold unlawful and set aside agency action" that is "in excess of statutory . . . authority." 5 U.S.C. § 706(2)(C). The 2019 Rule exceeded its authority in two respects: (1) Congress did not delegate to HHS rulemaking authority to promulgate the substantive components of the 2019 Rule and (2) Congress did not delegate to OCR the ultimate enforcement power to cut off all of a recipient's funding for the breach of a conscience provision.

a. *The 2019 Rule Engaged in Improper Substantive Rulemaking by Vastly Expanding Definitions Set Out by Federal Provisions that Limited Who Could Object Based on Conscience*

As the California district court recognized, a non-substantive, interpretive rule "can never add to or subtract from a statute itself." *City & Cnty. of San Francisco v. Azar*, 411 F. Supp. 3d 1001, 1022 (N.D. Cal. 2019). Yet several parts of the 2019 Rule announced new rights and imposed new duties. *New York*, 414 F. Supp. 3d at 513 n.14 (quoting Tr. at 115 ("The agency does take the position that the rule is substantive, that it does impose obligations on regulated

[14] Comment Letter from Lambda Legal to 2019 Rule at 14–18 (citing survey responses and cases such as *Keeton v. Anderson-Wiley*, 664 F.3d 865 (11th Cir. 2011) (counseling student objected to providing relationship counseling to same-sex couples); *Hyman v. City of Louisville*, 132 F. Supp. 2d 528, 539–540 (W.D. Ky. 2001) (physician sought to screen applicants on the basis of sexual orientation); *Stepp v. Review Bd. of Indiana Emp. Sec. Div.*, 521 N.E.2d 350, 352 (Ind. 1988) (lab technician refused to process lab specimens from persons with HIV)).

entities.")). For example, the 2019 Rule redefined "health care entity" to include dozens of new entities such as employers that provide health benefits, pharmacists, and medical laboratories even though Congress did not include these entities under the definitions of "health care entity" in the Coats-Snowe or Weldon Amendments. 84 Fed. Reg. 23,264 (45 C.F.R. § 88.2); *San Francisco*, 411 F. Supp. 3d at 1015–18; *see also Lawson v. Suwanee Fruit & Steamship Co.*, 336 U.S. 198, 201 (1949) (where a statute expressly defines a term, the "[s]tatutory definitions control the meaning of statutory words"). These entities have "never [previously] appeared in any conscience statute." *San Francisco*, 411 F. Supp. 3d at 1016. Similarly, the 2019 Rule's definitions of "assist in the performance" and "referral" broadened the right to object based on conscience—a right previously limited to clinical staff—to virtually any person employed in the healthcare setting, allowing an expanded group of employees to withhold virtually any action that might help the patient obtain the care at issue. The definition of "discrimination" prescribed unworkable limitations on a provider's ability to ask for and address possible conscience objections among employees, undermining providers' ability to provide undisrupted patient care.

The Proposed Rule appropriately rescinds these definitions in addition to other portions of the 2019 Rule that engaged in substantive rulemaking in excess of HHS's authority under 5 U.S.C. 301.[15]

b. *The 2019 Rule Improperly Expanded OCR's Enforcement Powers by Allowing for Termination of the Entirety of a State's Federal Healthcare Funding*

Eliminating portions of Section 88.7 of the 2019 Rule harmonizes the Proposed Rule with the federal conscience provisions. The 2019 Rule allowed for the termination of *all* federal healthcare funding for a violation of the conscience statutes. *See* 45 C.F.R. § 88.7(i)(3)(iv) (OCR may "[t]erminat[e] Federal financial assistance or other Federal funds from the Department, in whole or in part"). But Congress did not delegate to HHS the power to cut off all of a recipient's funding for a breach of a conscience provision—no law authorizes this drastic enforcement power. *See New York*, 414 F. Supp. 3d at 534. The Church, Coats-Snowe, and Weldon Amendments are silent as to remedy. *See id*. at 533. The 2019 Rule relied on the Uniform Administrative Requirements (UAR) to authorize the enforcement provisions. 84 Fed. Reg. 23,184; *see also New York*, 414 F. Supp. 3d at 515. During the prior litigation, however, HHS conceded that the UAR does not authorize the wholesale termination of funding. *See New York*, 414 F. Supp. 3d at 516 (citing Tr. at 81 ("THE COURT: Do the funding statutes authorize you to adopt a rule that on its face threatens the entirety of HHS funding for a single violation? [. . .] MR. BATES: "So first point, your Honor, is that the regulation would not do that. For the

[15] 88 Fed. Reg. 825; *see also* Tr. at 75 (conceding Church, Weldon, and Coats-Snowe Amendments contain no express delegation of authority for HHS to promote regulations). The 2019 Rule's "Purpose" Section 88.1 sought to provide for the "implementation" of the federal conscience statutes (an act of substantive rulemaking) and the "Assurance and Certification" requirements in Section 88.4 imposed new obligations and duties on employers and providers that did not appear in the federal statutes. *New York*, 414 F. Supp. 3d at 523, 526-27.

purposes—for the terms of the UAR, my understanding is that the UAR would not do that either.")).

The States applaud HHS's decision to rescind the enforcement provisions of Section 88.7 that exceeded Congress's delegated authority. The Proposed Rule seeks to maintain from the 2019 Rule several procedural provisions that apply to OCR's enforcement powers, such as OCR's broadened investigatory powers, which include the authority to conduct interviews and issue "written data or discovery requests." 88 Fed. Reg. at 829–30. HHS states these modified provisions "address concerns by many of the commenters—and echoed in federal district court decisions—about the Department's underlying rulemaking authority." 88 Fed. Reg. 825. The States are neutral as to this aspect of the Proposed Rule, although HHS may be better-served by a more detailed justification. In the Final Rule, HHS should provide more specificity, including specific comments received and portions from the federal district court decisions, explaining the reasoned basis for its decision to retain procedural elements of the 2019 Rule's Section 88.7.

3. The Proposed Rule Avoids Conflicts and Inconsistencies With EMTALA, Title VII, and Other Federal Laws

HHS seeks generally comments as to rescission in whole or in part of the 2019 Rule. 88 Fed. Reg. 826. In rescinding the definitions contained in Section 88.2 of the 2019 Rule, the Proposed Rule avoids the 2019 Rule's conflicts with existing laws, particularly the Emergency Medical Treatment and Active Labor Act (EMTALA) and Title VII of the Civil Rights Act of 1964. *See also* 5 U.S.C. § 706(2)(A) (requiring courts "hold unlawful and set aside agency action" that is "not in accordance with law").

Since 1986, EMTALA has required hospitals that receive federal funds and have emergency departments to provide emergency care to any patient suffering from an emergency medical condition, which includes providing medical screening and stabilizing treatment or a medical transfer. *See* 42 U.S.C. § 1395dd(a)–(b)(1). EMTALA does not include any exception for religious or moral refusals to provide emergency care and courts have not read such exceptions into EMTALA's mandate. *See, e.g.*, *Matter of Baby K*, 16 F.3d 590, 597 (4th Cir. 1994) ("EMTALA does not provide an exception for stabilizing treatment physicians may deem medically or ethically inappropriate."); *Burditt v. U.S. Dep't of Health & Human Servs.*, 934 F.2d 1362, 1375 (5th Cir. 1991). The 2019 Rule, however, applied even in emergency-care situations. Its definition of "discrimination," for example, exposed employers to liability for failure to accommodate an employee's conscience objection in emergency circumstances. Indeed, HHS even conceded during the prior litigation that the 2019 Rule could potentially impose liability on an employer for insisting that an ambulance driver complete a mission of transporting a patient to a hospital for an emergency procedure. *See New York*, 414 F. Supp. 3d at 539 (citing Tr. at 116–20 (addressing scenario in which a driver, in Central Park transverse en route to hospital, ceased driving upon learning that patient sought emergency care for ectopic pregnancy)).

Similarly, the 2019 Rule's definition for "discrimination" departed from the well-understood definition of "discrimination" in the Title VII context, which has defined the duties of employers with respect to religious objections in the employment context since 1967 by EEOC rule, and since 1972 by statute. Title VII requires employers to make "reasonable accommodations" for an employee's religious practice where such accommodations can be made "without undue hardship" to the employer, meaning no "more than a de minimis cost." *Trans World Airlines, Inc. v. Hardison*, 432 U.S. 63, 84 (1977). This "reasonable accommodation" framework is well-established under Title VII but the 2019 Rule departed from it without a statutory basis. The 2019 Rule forbid regulated entities from inquiring in advance of hiring about a prospective employee's objections. Instead, an employer "may," only after hiring, and no more than once per calendar year thereafter except with "persuasive justification," require an employee to inform the employer of any conscience objections. 84 Fed. Reg. at 23,263. Employers would thus have been put in an untenable position of hiring individuals who would refuse to perform the core duties of the position. The 2019 Rule also disposed of the "reasonable accommodation" framework by requiring "effective accommodation" (i.e., accommodation that the objecting employee accepts), 45 C.F.R. § 88.2(4), or an accommodation that does not require "additional action" by the employee, does not exclude the employee from her "field[ ] of practice," and does not constitute an "adverse action," *id*. § 88.2(6). This new framework represented a major, substantive departure from the well-settled understanding of discrimination in the employment context and would have upended decades of practice concerning healthcare delivery, thus significantly endangering patients' health. For example, HHS conceded that under the 2019 Rule, but not under Title VII, an employer would be prohibited from terminating a nurse who refused to perform emergency treatment on pregnant women and who also refused transfer to another hospital unit. *See New York*, 414 F. Supp. 3d at 514 (citing Tr. at 113-115). The 2019 Rule failed to explain how that was an outcome intended by Congress.

The Proposed Rule rescinds the most problematic aspects of the 2019 Rule—including the definition of "discrimination" and an unworkable expansion of accommodation obligations—and thus avoids conflicts and inconsistencies with EMTALA, Title VII, and several other federal statutes that have long co-existed with the federal conscience provisions.[16]

[16] The 2019 Rule also violated Title X, Section 1554 of the Affordable Care Act, and Medicaid informed consent requirements. Title X and Section 1554 include provisions aimed at ensuring patient access to all relevant heath care information. *See* Title X, Public Health Service Act of 1970 § 1001, 42 U.S.C. § 300; Consolidated Appropriations Act of 2017, Pub. L. No. 115-31, 131 Stat. 135, 521 (2017); 42 C.F.R. § 59.5(a)(5); 23 42 U.S.C. § 18114. Medicaid's informed consent provision requires Medicaid managed care providers to comply with state laws that require the disclosure of policies denying coverage of services on religious grounds. 42 U.S.C. § 1396u-2(b)(3)(B). The 2019 Rule interfered with each of these informed consent requirements. Finally, the 2019 Rule raised potential conflicts with Title III of the American Disabilities Act, which includes provisions that prohibit health care providers from discriminating against patients with disabilities, including those with HIV and AIDS. *See* Title III, Americans with Disabilities Act of 1990, 104 Stat. 355, 42 U.S.C. § 12182.

4. The 2019 Rule Was Arbitrary and Capricious Because There Had Not Been a Significant Increase in Complaints Regarding Conscience Violations and the 2019 Rule Failed to Consider the Safety of Patients

HHS seeks comment on whether HHS "accurately evaluated the need for additional regulation in the 2019 Rule . . . ." 88 Fed. Reg. 826. If an agency has "offered an explanation for its decision that runs counter to the evidence before the agency," the regulation is considered arbitrary and capricious and must be set aside. 5 U.S.C. § 706(2)(A); *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983); *see also Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016) (an agency "must give adequate reasons for its decisions").

In promulgating the 2019 Rule, HHS cited "a significant increase" in complaints that "alleg[e] violations" of the conscience provisions as demonstrating the need for agency action. 84 Fed. Reg. at 23,175; *see also* 83 Fed. Reg. at 3,903 (proposed rule seeks to address problem of confusion "leading to increased complaints"). But this assertion was "demonstrably false." *New York*, 414 F. Supp. 3d at 541. The 2019 Rule stated that OCR had received 343 complaints during fiscal year 2018. 84 Fed. Reg. at 23,229. But during the prior litigation, HHS conceded that it received only 20 complaints that actually implicated the federal conscience provisions. *New York*, 414 F. Supp. 3d at 542 ("THE COURT: Yes or no: Are we down to about 20 that actually implicate these statutes as opposed to other problems? MR. BATES: Yes. In that ballpark.") (quoting Tr. at 94). As one of the district courts held, "HHS's reliance even 'in part on the basis of' these patently inapposite complaints is enough to render the Rule arbitrary and capricious." *Id*. at 546.

Similarly, HHS attempted to justify the 2019 Rule by stating that the significant increase in complaints "underscore[d] the need for the Department to have proper enforcement tools available to appropriately enforce" the federal conscience provisions. 84 Fed. Reg. at 23,175. But nothing in the record showed that HHS lacked the capacity to enforce the provisions or supported the need for expanding definitions, such as expanding "assist in the performance" to include non-clinical healthcare staff. *See, e.g.*, *New York*, 414 F. Supp. 3d at 545 ("THE COURT: Is the agency aware of any receptionist, ambulance driver, elevator repairman, anybody, who ever [sic] complained that their ancillary work, other than on the day of the procedure, was violating their conscience rights? MR. BATES: Not that I'm aware of, Your Honor.") (quoting Tr. at 127).

Agency action is also considered arbitrary and capricious where the agency "entirely failed to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43, 103 S.Ct. 2856. As described in previous sections of this letter, HHS failed to consider the 2019 Rule's impact on patient safety and how the 2019 Rule would apply in medical emergencies or in the context of the pre-existing Title VII framework.

HHS further failed to consider the 2019 Rule's interference with state and local laws, which are carefully calibrated to address existing obligations under federal law and to ensure the health and safety of their citizens. For example, many of the States have laws addressing the provision of care in emergency situations. New York requires that mandatory emergency care include the provision of emergency contraceptives to sexual assault survivors, *see* N.Y. Pub. Health Law § 2805-p, and prohibits medical professionals from abandoning patients without providing for continued care. *See* N.Y. Codes R. & Regs. tit. 8, § 29.2. Both mandates would be significantly eroded under the 2019 Rule.

Furthermore, HHS's analysis of the costs and benefits of the 2019 Rule was woefully inadequate and counter to evidence before the agency. HHS refused to address the potential costs to healthcare access, the magnitude of which was previously discussed, and instead implemented the rule "without regard to whether data exists on the competing contentions about its effect on access to services." 84 Fed. Reg. at 23,182. HHS claimed the 2019 Rule would confer various benefits, but relied on insufficient, outdated, and irrelevant evidence in support of these claims. For example, HHS claimed the 2019 Rule would reduce the departure from the field by healthcare providers who cited religious reasons, but relied on a source that contained no support for the assertion. 84 Fed. Reg. at 23,247 n.322.

Given HHS's concessions during the prior litigation and omissions in HHS's considerations, the States do not believe that HHS accurately evaluated the need for additional regulation in promulgating the 2019 Rule.[17]

5. The Proposed Rule Addresses Constitutional Issues[18]

HHS requests comment on the proposal to retain portions of the 2019 Rule's enforcement provisions. 88 Fed. Reg. 827. In rescinding portions of the 2019 Rule's Section 88.7 that allowed HHS to terminate, deny, or withhold billions in federal funds, the Proposed Rule avoids Spending Clause violations. Under the Spending Clause, U.S. Const., art. I, § 8, cl. 1, Congress may not impose conditions on federal funds that are so coercive as to compel States to comply,

[17] To the extent the Proposed Rule relies on the cost and benefit analysis conducted for the 2019 Rule, that analysis may be incomplete. The States believe it would be prudent for HHS to provide a more complete analysis that adequately takes into account the harms and disruptions in patient care discussed above, and that HHS include additional support and evidence for that analysis. Such an analysis would further strengthen the basis for the proposed revocation of the 2019 Rule.

[18] Apart from the Spending Clause, the 2019 Rule violated the constitutional Separation of Powers and raised serious Establishment Clause concerns. By claiming for HHS the authority to completely terminate funding for a violation of a federal conscious provision, the 2019 Rule "aggrandize[d] the Executive Branch at Congress's expense…inconsistent with the separation of powers." *New York*, 414 F. Supp. 3d at 562. The 2019 Rule also raised Establishment Clause concerns by requiring employers to accommodate employee religious beliefs to the detriment of all other considerations. *See Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703, 709 (1985).

ambiguous, retroactive, or unrelated to the federal interest in a particular program. *Nat'l Fed'n of Indep. Bus. v. Sebelius* (*NFIB*), 567 U.S. 519, 575–82 (2012).

The 2019 Rule was unconstitutionally coercive, forcing a "gun to the head" of States and local governments that depend on federal funds. *NFIB*, 567 U.S. at 581. For California, a violation of the 2019 Rule put in jeopardy $77.6 billion in federal funding to its Health & Human Services Agency, almost half of its annual budget, including $63 billion to provide healthcare services for one-third of Californians.[19] For New York, the 2019 Rule threatened the loss of over $42 billion in Medicaid funding alone.[20] The 2019 Rule further coerced States and localities into abandoning the "intricate statutory and administrative regimes" they had developed in reliance on long-established federal conscience provisions by requiring States to develop a costly system for tracking compliance by sub-recipients of federal funding. *NFIB*, 567 U.S. at 581. [21]

The 2019 Rule also imposed conditions on funding that were ambiguous and retroactive. As described above, the 2019 Rule expanded the scope of the conscience provisions by, among other things, broadly defining "health care entity" far beyond the limits of the statutory text. *See Clovis Unified Sch. Dist. v. Cal. Office of Admin. Hr'g*, 903 F.2d 635, 646 (9th Cir. 1990) ("[B]road interpretations of ambiguous language" in a funding condition are fundamentally unfair and violate the Spending Clause). The 2019 Rule provided no guidance on how States and other regulated entities were supposed to harmonize the 2019 Rule with federal laws such as EMTALA. *New York*, 414 F. Supp. 3d at 568.[22] And the 2019 Rule was unclear as to what funding streams could be terminated for a violation. 84 Fed. Reg. at 23,272 (to be codified at 45 C.F.R. pt. 88.7(i)(3)); *San Francisco*, 411 F. Supp. 3d at 1023. Meanwhile, public entities such as California had already accepted federal funding with the expectation that they would receive the funds under existing agreements and conditions set forth by the conscience

[19] *See* Declarations of Ghaly at ¶¶ 5, 8, 13–14 and Cantwell at ¶¶ 2, 5, 8 filed in City & Cnty. of San Francisco et al. v. Azar et al., No. 20-16045 (9th Cir. Oct. 12, 2020), ECF Nos. 32-4 to 32-7. Other funding at risk: approximately half of the annual budget for the California Department of Public Health, including $1.5 billion for emergency preparedness, chronic and infectious disease prevention, and healthcare facility licensing programs (*id*., Nunes Decl. ¶¶ 5, 9–12, 16; Ghaly Decl. ¶¶ 17–20); and approximately one-quarter of the budget for the California Department of Social Services, including $10.8 billion for child welfare and in-home care for seniors and people with disabilities (*id.*, Ghaly Decl. ¶ 15; Cervinka Decl. ¶¶ 7–16)).

[20] *See* Declaration of Howard Zucker at ¶ 94, New York v. U.S. Dep't of Health & Hum. Servs., No. 19-cv-04676 (S.D.N.Y. June 14, 2019), ECF No. 43-48. At risk in New York was funding to a vast array of programs and services, including: campus sexual assault prevention education, rape crisis centers, child abuse prevention training, reproductive health services for low-income, uninsured, and underinsured men and women, early intervention services for over 68,000 infants and toddlers, and services for persons at risk for and living with HIV, hepatitis C, and STDs. *See id*. at ¶¶ 96–128.

[21] *See* Declarations of Ghaly at ¶ 10 and Cantwell at ¶ 7 filed in *City & Cnty. of San Francisco et al. v. Azar et al*., No. 20-16045 (9th Cir. Oct. 12, 2020), ECF Nos. 32-4 to 32-7.

[22] *Id.*, Colwell Decl. ¶¶ 8, 11–12.

provisions.[23] But the 2019 Rule upended this planning by requiring entities to immediately comply with its new provisions or risk the entirety of their HHS funding. *New York*, 414 F. Supp. 3d at 567 (quoting *NFIB*, 567 U.S. at 583–84) ("alter[ed] the conditions attached to [federal] funds so significantly as to 'accomplish[] a shift in kind, not merely degree[,]'" thus "surprising participating States with post-acceptance or 'retroactive' conditions.").[24]

These concerns are not just hypothetical. On January 24, 2020, OCR issued a "Notice of Violation" to California, concluding that its Department of Managed Health Care "has discriminated, in violation of the Weldon Amendment, against health care plans and issuers," due to its requirement that health plans not limit or exclude coverage for abortion.[25] On December 16, 2020, OCR issued a press release announcing that, commencing January 2021, "HHS will disallow $200 million in federal Medicaid funds going to California in the upcoming quarter due to the state illegally mandating that all health care plans . . . cover abortion without exclusion or limitation."[26] A disallowance letter followed on January 15, 2021. California submitted a request for reconsideration based on, among other things, its successful challenge to the 2019 Rule, specifically as to the term "health care entity."[27] When the Biden Administration took office, OCR withdrew the disallowance letter finding that none of the entities that had filed complaints against California—all employers who sponsored health plans, not the health plans

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[23] *Id.*, Ghaly Decl. ¶¶ 9–10; Sturges Decl. ¶¶ 6–7; Price Decl. ¶ 16; Parmelee Decl. ¶ 7; Nunes Decl. ¶ 11.

[24] The 2019 Rule also placed at risk federal funds "entirely unrelated to health care"—such as those from the Department of Labor and Department of Education. *Washington v. Azar*, 426 F. Supp. 3d 704, 720 (E.D. Wash. 2019); Appropriations Act at § 507(d) ("None of the funds made available in *this Act* . . .") (emphasis added); 84 Fed. Reg. at 23,172 (referencing funds in "Labor, HHS, and Education appropriations act"); *see also* Declarations of Sturges ¶¶ 5–9, Palma, Ex. A, Parmelee ¶¶ 4–9, and Buchman ¶ 11 filed in *City & Cnty. of San Francisco et al. v. Azar et al.*, No. 20-16045 (9th Cir. Oct. 12, 2020), ECF Nos. 32-4 to 32-7.

[25] Letter from Roger T. Severino, Dir., Office for Civil Rights, U.S. Dep't of Health & Human Servs. to the Honorable Xavier Becerra, California Att'y Gen. at 4-5 (Jan. 24, 2020), https://www.hhs.gov/sites/default/files/ca-notice-of-violation-abortion-insurance-cases-01-24-2020.pdf. This letter reopened a prior OCR investigation that had been decided in California's favor and closed in 2016, finding that the State had not violated Weldon because the health plans that received the letter requiring them to provide plans that had coverage for abortions had not objected to providing such coverage on religious or moral grounds. *See* Letter from Jocelyn Samuels, Dir., Office for Civil Rights, U.S. Dep't of Health & Human Servs. to Complainants (June 21, 2016), https://perma.cc/G4WP-V69V. The 2016 letter also stated that this decision would avoid a potential violation of the Spending Clause. *Id.*

[26] *See* "HHS to Disallow $200M in California Medicaid Funds Due to Unlawful Abortion Insurance Mandate; Refers Vermont Medical Center to DOJ for Lawsuit Over Conscience Violations," HHS.gov, https://www.hhs.gov/about/news/2020/12/16/hhs-disallow-200m-california-medicaid-funds-due-unlawful-abortion-insurance-mandate.html.

[27] Letter from Jacey Cooper, State Medicaid Director, to Karen M. Shields, Deputy Director Center for Medicaid & CHIP Services (March 15, 2021).

themselves—had met the definition of "health care entity" under the Weldon Amendment.[28] While the disallowance was resolved in California's favor, it demonstrates the catastrophic financial consequences that could befall a State under the vastly expanded definitions and enforcement provisions of the 2019 Rule. The Proposed Rule rescinds these portions and, as such, addresses these constitutional issues.

C. CONCLUSION

The States applaud HHS for rescinding aspects of the 2019 Rule so as to maintain the balance Congress struck between safeguarding conscience rights and protecting patients' access to healthcare while acknowledging court decisions that unanimously vacated the 2019 Rule. For the reasons stated in this letter, we urge the federal government to finalize the Proposed Rule.

Sincerely,

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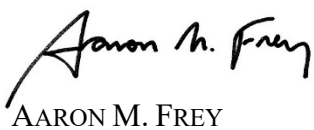
[28] Letter from Robinsue Frohboese, Acting Dir., Office for Civil Rights, U.S. Dep't of Health & Human Servs. to the Honorable Rob Bonta, California Att'y Gen. (Aug. 31, 2021), https://www.hhs.gov/conscience/conscience-protections/ca-letter/index.html.



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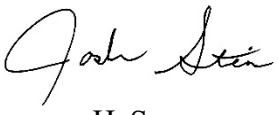

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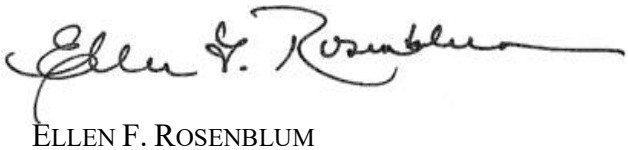

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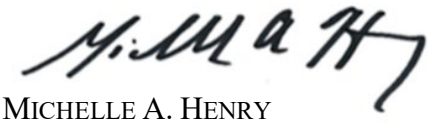

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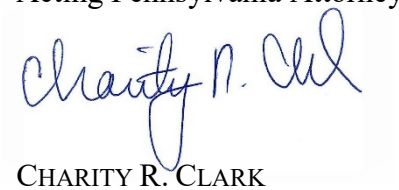

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