Nos. 19-4254(L), 20-31, 20-32, 20-41

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

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

Plaintiffs-Appellees,

(Caption continued on inside cover)

On Appeal from the United States District Court
for the Southern District of New York

REPLY BRIEF FOR DEFENDANTS-APPELLANTS UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR, II; AND UNITED STATES OF AMERICA, AND CONSOLIDATED-DEFENDANTS-APPELLANTS ROGER T. SEVERINO AND OFFICE FOR CIVIL RIGHTS, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

ETHAN P. DAVIS
Acting Assistant Attorney General

MICHAEL S. RAAB
LOWELL V. STURGILL JR.
SARAH CARROLL
LEIF OVERVOLD
Attorneys, Appellate Staff
Civil Division, Room 7226
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 532-4631

Of Counsel:

ROBERT P. CHARROW
General Counsel

SEAN R. KEVENEY
Deputy General Counsel

U.S. Department of Health & Human Services

PLANNED PARENTHOOD FEDERATION OF AMERICA, INC., PLANNED PARENTHOOD OF NORTHERN NEW ENGLAND, INC., NATIONAL FAMILY PLANNING AND REPRODUCTIVE HEALTH ASSOCIATION, AND PUBLIC HEALTH SOLUTIONS, INC.

Consolidated-Plaintiffs-Appellees,

v.

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

Defendants-Appellants,

DR. REGINA FROST AND CHRISTIAN MEDICAL AND DENTAL ASSOCIATIONS,

Intervenors-Defendants-Appellants,

ROGER T. SEVERINO, in his official capacity as Director, Office for Civil Rights, United States Department of Health and Human Services, and OFFICE FOR CIVIL RIGHTS, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Consolidated-Defendants-Appellants.

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INTRODUCTION AND SUMMARY

HHS's provider conscience rule collects conscience-related statutory requirements applicable to HHS funds, offers the best reading of key statutory terms, and clarifies procedures for ensuring statutory compliance. The Rule is within HHS's authority and consistent with the Administrative Procedure Act (APA) and other statutes, the separation of powers, and the Spending Clause. Erroneously assuming the Rule expands on the conscience statutes' protections, plaintiffs fail to persuasively defend the district court's criticisms. At minimum, the court lacked authority to vacate the Rule beyond the parties to this suit and the aspects of the Rule the court found invalid.

ARGUMENT

I. The Rule Is Within HHS's Authority

Plaintiffs' attack on HHS's authority to issue the Rule elides the core inquiry: whether the challenged aspects of the Rule are substantive, rather than interpretive or internal housekeeping measures. Properly understood, none is substantive; HHS plainly has authority to issue a Rule outlining its procedures for enforcing the conscience statutes, ensuring statutory compliance through certification requirements, and interpreting statutory terms.

A. The Rule's Enforcement Provisions Permissibly Set Out Actions HHS May Take To Respond To Noncompliance With The Conscience Statutes

Pursuant to HHS's housekeeping authority, the Rule's enforcement provisions outline HHS's existing authority to take action to enforce the conscience statutes. *See* Appellants' Opening Brief (AOB) 20-24. Plaintiffs do not dispute that HHS may enforce these statutes, indeed conceding that HHS may terminate an award tied to a particular conscience statute, when "appropriate," if that statute is violated. PP Br. 28.

Under its unchallenged grant and contract administration authority, HHS may thus "terminate the Federal award," 45 C.F.R. § 75.371, or "terminate the contract completely or partially," 48 C.F.R. §§ 49.402-1, 52.249-8, if a recipient violates applicable requirements. Plaintiffs fault the Rule for authorizing termination of a recipient's "funding" rather than its "award" or "contract" (PP Br. 28), but that distinction makes no difference when, for example, a recipient only receives funds subject to a statutory requirement and then violates that requirement. *See* AOB 23. Nor do plaintiffs identify anything in the HHS Uniform Administrative Requirements (HHS UAR) or Federal Acquisition Regulation that would preclude a recipient-wide funding termination where a violation extends to each award received.

Government plaintiffs suggest a subparagraph of the Rule—stating that HHS may effect compliance with the conscience statutes by "[t]erminating Federal financial assistance or other Federal funds from the Department, in whole or in part," 45

C.F.R. § 88.7(i)(3)—provides "on its face" that a "single violation of a discrete provision of the Church Amendment would permit HHS to terminate or withhold all of a State's federal health care funding." NY Br. 52. That assertion is untethered from the provision's text, which presents termination of HHS funding as one of a range of remedies HHS "may" take in response to the gamut of violations HHS may encounter. *See* AOB 21; *cf. Munsell v. USDA*, 509 F.3d 572, 587 (D.C. Cir. 2007) (noting, where challenged directive listed several discretionary enforcement actions, "it is unclear if, when or how the agency will employ it" (quotation marks omitted)). The preamble makes clear, moreover, that a conscience-statute violation threatens only "the funding streams that such statutes directly implicate." 84 Fed. Reg. 23,170, 23,223 (May 21, 2019). At minimum, including this provision among a range of remedies is not facially invalid.

Government plaintiffs complain that the Rule's enforcement provisions do not incorporate certain funding-termination procedures from the HHS UAR or applicable to particular grant programs. NY Br. 54-55. But the Rule does not supplant the UAR, *see* 84 Fed. Reg. at 23,184, and requires HHS to act "pursuant to statutes and regulations" governing its funding arrangements. 45 C.F.R. § 88.7(i)(3). Plaintiffs also fault the Rule for providing that, where the subrecipient of Federal funds violates a conscience statute, the recipient "may be subject" to "funding restrictions or any appropriate remedies available," 45 C.F.R. § 88.6(a). NY Br. 55. Again, however, the text of this provision, which simply allows HHS to impose "appropriate remedies," 84

Fed. Reg. at 23,220, does not support speculation that a subrecipient's violation would cause a recipient to lose unrelated funding and comports with existing authorities

B. The Rule's Certification Requirements Permissibly Ensure Compliance With The Conscience Statutes

Plaintiffs do not dispute that HHS can require that recipients certify compliance with applicable conscience statutes. *See* 45 C.F.R. § 75.300(a); 48 C.F.R. § 1.301(a)(1). Rather, they fault HHS for requiring compliance with both the statutes and the Rule. *See* PP Br. 25. But the Rule provides the best reading of statutory terms and collects relevant statutory requirements, imposing no duties beyond the statutes. *See infra* section I.C.

Plaintiffs do not meaningfully contest that *Perales v. Sullivan*, 948 F.2d 1348 (2d Cir. 1991), on which the district court relied to find the certification requirements substantive, is inapposite. Unlike in *Perales*, plaintiffs are on notice of the challenged requirements, which reflect existing duties that the conscience statutes impose on HHS and its funding recipients. While requiring compliance with the statutes and the Rule may represent a belt-and-suspenders approach, that does not render the provision "substantive" under *Perales* or otherwise outside HHS's undisputed authority to ensure statutory compliance.

C. The Rule's Definitional Provisions Clarify Duties Imposed By The Conscience Statutes

Plaintiffs contend that the Rule's definitional provisions render it substantive. But a substantive rule "create[s] new law, rights, or duties," *White v. Shalala*, 7 F.3d

296, 303 (2d Cir. 1993), with "effect[s] *completely independent* of the [relevant] statute," *Mejia-Ruiz v. INS*, 51 F.3d 358, 364 (2d Cir. 1995) (first brackets in original). The definitional provisions are interpretive, not substantive, because they create no new rights or duties but rather clarify those the statutes impose. *Cf. City & Cty. of San Francisco v. Azar*, 411 F. Supp. 3d 1001, 1011 (N.D. Cal. 2019), *appeal filed*, Nos. 20-15398 et al. (9th Cir. Mar. 6, 2020) (recognizing Rule is, with "minor exceptions," "purely an interpretive rule").

1. The validity of the Rule's definitions "stands or falls on the correctness of the agency's interpretation of [the statutory] provisions," *United Techs. Corp. v. EPA*, 821 F.2d 714, 719-20 (D.C. Cir. 1987), the hallmark of an interpretive rule. Plaintiffs do not meaningfully defend the district court's erroneous focus on whether the Rule "shapes the primary conduct of regulated entities," SA 48, echoing that language without addressing this Court's recognition that interpretive rules may have substantive effects. *See* PP Br. 58; *White*, 7 F.3d at 303.

Plaintiffs attempt (PP Br. 23) to factually distinguish cases articulating the interpretive-rule standard without confronting the key analysis. *United Technologies*, for example, involved a contested definition, but what mattered was whether the rule represented "an attempt to construe specific statutory provisions." 821 F.2d at 720-21*; see also Health Ins. Ass'n of Am., Inc. v. Shalala*, 23 F.3d 412, 423 (D.C. Cir. 1994) (interpretive rule "do[es] not rest on" statute's "delegation of legislative authority" but reflects agency's "elucidation of rights and duties created by Congress"). In

developing the challenged definitions, HHS relied on terms' ordinary meaning and statutory context. *See infra* section I.C.2. That is interpretive activity and not, for example, providing content to a vague statutory term like "appropriate" in a manner that "cannot readily be derived by judicial reasoning." *Catholic Health Initiatives v. Sebelius*, 617 F.3d 490, 495 (D.C. Cir. 2010).

Plaintiffs argue that the Rule is legislative because the definitions use "prescriptive terms." PP Br. 22. But the definitional section uses "shall not" once—stating that an entity "shall not be regarded as having engaged in discrimination" where it offers and a protected entity accepts an effective accommodation. 45 C.F.R. § 88.2—and that provision has no prescriptive effect on regulated entities. Likewise, "may only" appears once, indicating a limit on HHS's understanding of the reach of "discrimination," and does not render that provision (or the section as a whole) prescriptive. The argument that the Rule's definitional section gives content to the "Requirements" section (PP Br. 22) misses the point, since 45 C.F.R. § 88.3 simply collects statutory requirements, and the definitions offer the best reading of terms in those statutes.

Contrary to plaintiffs' assertion (PP Br. 21), *NYC Employees' Retirement System v. SEC*, 45 F.3d 7, 13-14 (2d Cir. 1995), did not hold publication in the Code of Federal Regulations (C.F.R.) "sufficient" to render a rule substantive; that case did not involve C.F.R. publication and held the agency action at issue not substantive. C.F.R. publication is not "anything more than a snippet of evidence of agency intent." *Sweet*

v. Sheahan, 235 F.3d 80, 91 n.8 (2d Cir. 2000) (quotation marks omitted). And while this Court has read a grant of authority to "implement" a statute to authorize substantive rulemaking, *United States v. Lott*, 750 F.3d 214, 218 (2d Cir. 2014), and viewed notice-and-comment rulemaking as one indication that a statute authorized and an agency exercised legislative rulemaking authority, *Sweet*, 235 F.3d at 93, plaintiffs cite no case suggesting an agency's voluntary use of notice-and-comment procedures or a rule's passing reference to "implementation" of statutes, *see* 45 C.F.R. § 88.1 (Rule's "Purpose" section), renders substantive a rule that does not add to relevant statutory requirements.

Plaintiffs cite an exchange before the district court regarding the Rule's purportedly substantive nature (PP Br. 18), but the question, as demonstrated above, is whether the Rule adds to the obligations the statutes impose. It does not. And if the "agency's characterization of a rule is the starting point" in labeling it substantive or interpretive, *Mejia-Ruiz*, 51 F.3d at 365, the Rule's preamble makes HHS's characterization clear: the Rule "does not substantively alter or amend the obligations of the respective statutes." 84 Fed. Reg. at 23,185. Finally, while the government invoked *Chevron* deference in its district court briefing, the briefing also emphasized that the Rule simply reiterated statutory requirements and set forth HHS's internal processes for enforcing the statutes. JA 1423-24, 2408-09.

2. Plaintiffs' arguments regarding the Rule's definitions themselves likewise lack merit.

a. Plaintiffs do not dispute the dictionary definitions of key terms in the statutory phrase "assist in the performance." *See* PP Br. 39-40; NY Br. 43-44. Plaintiffs insist, however, that the "assist[ance]" this term covers is "limited to actions that support the actual execution of a particular medical procedure," NY Br. 43, or occur the day a procedure is performed, PP Br. 40. They identify no textual basis in the conscience statutes for either limitation, and ignore Congress's decision to extend the Church Amendments to both "performance" and "assist[ance] in the performance." 42 U.S.C. § 300a-7(c)(1)-(2), (d); *see also id.* § 300a-7(b)(2)(A) (protecting hospitals, whose participation is necessarily indirect and involves "mak[ing] facilities available" for a procedure). The Rule's definition accordingly does not read "performance" out of the statute (NY Br. 44) but instead gives effect to the separate inclusion of "*assist* in the performance."

Congress sensibly chose to expand this protection, as religious or moral objections to complicity in acts believed to be immoral are not limited to direct support. *See* AOB 30. Contrary to provider plaintiffs' suggestion (PP Br. 41-42), the potential breadth of conscience-based objections was recognized long before Congress enacted the Church Amendments. *Cf. United States v. Seeger*, 380 U.S. 163, 177-78 (1965) (reflecting congressional consideration of those with "religious scruples against rendering military service in its various degrees" in enacting conscientious-objection statute).

Government plaintiffs note (NY Br. 45-46) that a separate Church Amendments provision references "counsel[ing]," "suggest[ing]," and "recommend[ing]" abortions or sterilizations, *see* 42 U.S.C. § 300a-7(e). They do not explain, however, why Congress's choice to expressly cover such aid in that provision, added separately in 1979, requires a narrower understanding of "assist[ance]" in distinct provisions, nor attempt to explain why Congress would provide broader protection to applicants for training or study than to those covered by other Church Amendments provisions. *See* 84 Fed Reg. at 23,188. Plaintiffs likewise do not explain why the statutory language should exclude an action that would otherwise qualify as assistance if the procedure ultimately does not occur for unrelated reasons. *See* PP Br. 40. A conscientious objector may reasonably object to performing preparatory tasks for a procedure, for example, even though that procedure may not ultimately occur.

The legislative-history colloquies on which government plaintiffs (NY Br. 43) rely indicate only that the Church Amendments were not intended to protect a "frivolous objection from someone unconnected with the procedure" or someone with "no responsibility, directly or indirectly with regard to [its] performance." 119 Cong. Rec. 9597 (1973). That is consistent with the Rule's requirement that an action have a "specific, reasonable, and articulable connection" to furthering a procedure and its recognition that assistance may be provided in numerous ways. 45 C.F.R. § 88.2. In any case, plaintiffs have no response to the Supreme Court's admonition that individual legislators' floor statements warrant little weight, *see, e.g.*, *NLRB v. SW*

Gen., Inc., 137 S. Ct. 929, 943 (2017), and cannot support reading an atextual limitation into the statute.

b. Plaintiffs do not dispute that actions catalogued in paragraphs (1)-(3) of the Rule's definition of "discriminate or discrimination" comport with the terms' ordinary definition. Government plaintiffs suggest the definition's inclusion of the catch-all phrase "any adverse treatment" conflicts with certain Title VII decisions requiring that an employment action be "materially adverse." NY Br. 40. But nothing in the conscience statutes requires express incorporation of this Title VII jurisprudence, and in any event the Rule simply provides a non-exhaustive list of actions that *may* constitute discrimination, 45 C.F.R. § 88.2. Plaintiffs note (PP Br. 36) that the plaintiffs in a case challenging the Weldon Amendment failed to identify instances in which the government had construed reassignment based on refusal to provide abortion counseling as discrimination. *NFPRHA v. Gonzales*, 468 F.3d 826, 829-30 (D.C. Cir. 2006). But that does not suggest a reassignment for impermissible reasons could not constitute discrimination if, for example, it represents the "exclu[sion] from" employment described in the Rule's definition. 45 C.F.R. § 88.2; *see also* 73 Fed. Reg. 78,072, 78,077 (Dec. 19, 2008) (rejecting suggestion that reassigning objecting employee can never constitute discrimination).

Though plaintiffs claim that the Rule should incorporate Title VII's undue-hardship and reasonable-accommodation defenses, the conscience statutes do not implicitly import these defenses (or related requirements regarding, for example, an

employee's duty to inform an employer of religious needs to be accommodated, *see* NY Br. 41). *See infra* section II.A.1. That this Court "does not sit as a super-personnel department" in employment-discrimination cases, *Scaria v. Rubin*, 117 F.3d 652, 655 (2d Cir. 1997) (per curiam), is irrelevant here for the same reason, and plaintiffs in any event have not shown that the Rule would require courts to assume such a role. Plaintiffs also suggest any action that "is *not* permitted" by paragraphs (4)-(6) of the definition necessarily "*is* discrimination" under paragraphs (1)-(3). PP Br. 34. That conduct falls outside paragraphs (4)-(6) does not, however, necessarily mean it falls within paragraphs (1)-(3), which describe actions that may constitute discrimination "as applicable to, and to the extent permitted by," a given conscience statute. 45 C.F.R. § 88.2.

Finally, plaintiffs suggest that the Rule's definition impermissibly applies when an applicant is unwilling, based on a conscience objection, to "perform the essential functions of a job." NY Br. 41; PP Br. 36. HHS specifically declined to resolve how the Rule would apply in such circumstances, however, because "the Department is not aware of any instances in which individuals with religious or moral objections to [covered] practices have sought out such jobs." 84 Fed. Reg. at 23,192. And while HHS did not, for example, authorize rural hospitals to discriminate where the statutes would prohibit it (and had no textual basis for doing so) (*see* PP Br. 35), it also did not decide how other hypothetical scenarios would be resolved given the inquiry's undisputedly fact-dependent nature.

c. Plaintiffs object to the inclusion of "pharmacist[s]," "pharmac[ies]," and "medical laborator[ies]" in the Rule's Coats-Snowe-specific definition of "health care entity" because those entities are not connected to "medical residency training," NY Br. 47, or are not "involved in abortion training," PP Br. 45. But the statutory text covers the broader category of "participant[s] in a program of training in the health professions," 42 U.S.C. § 238n(c)(2), and extends protections beyond the training context, *id.* § 238n(a)(1). Plaintiffs do not dispute that the additional categories the Rule's definition covers are "health care entities" under any ordinary understanding of the term.

Nor does the *ejusdem generis* canon require a narrower reading. *See* PP Br. 44-45. That canon does not displace a statutory term's plain meaning, particularly when the specific examples the statute "includes" are nonexhaustive (which is undisputed here). *See United States v. DiCristina*, 726 F.3d 92, 99-100 & n.8 (2d Cir. 2013). Even if the "defining essence" (PP Br. 45) of the statute's examples were relevant, that "essence" is health-care entities potentially involved in abortion, through training and other means. Although plaintiffs highlight the statutory section's purportedly limiting title, a statutory caption "cannot undo or limit that which the statute's text makes plain." *Intel Corp. v. Advanced Micro Devices, Inc.*, 542 U.S. 241, 256 (2004) (brackets and quotation marks omitted).

For Weldon and the Patient Protection and Affordable Care Act (ACA), plaintiffs do not dispute that plan sponsors and third-party administrators listed in the

Rule's "health care entity" definition provide or administer health-care coverage. They suggest the statutory term applies only to "direct participants in the health care industry," NY Br. 48, but that limitation has no basis in the statutory text. Even where plaintiffs recognize that the entities listed as examples in the statutory definition are "involved in the provision of health care" (PP Br. 45), they assert without justification that the manner in which plan sponsors and third-party administrators are involved in providing health care means they somehow do not qualify. Here too, *ejusdem generis* cannot displace the term's plain meaning, and the entities included in the Rule's definition are in any case similar to those the statutes enumerate because of their role in delivering health care. *See* AOB 34. And while plaintiffs highlight the same statement from Representative Weldon that the district court cited (SA 54), they provide no further reason to think it limits the statutory text. *See* AOB 35.

d. Plaintiffs do not rebut the government's showing that the Rule's definition of "refer or referral" comports with the terms' ordinary understanding. *See* AOB 36. They claim the definition is too broad (PP Br. 43), but fail to explain why providing information, where it will reasonably foreseeably aid a person in obtaining a procedure, does not "send or direct" a person for that procedure. Plaintiffs again rely on legislative history, but the cited statement indicates the Weldon Amendment will not affect "the provision of abortion-related information or services *by willing providers*." *See* PP Br. 43-44 (citing 150 Cong. Rec. 25,044-45 (2004)) (emphasis added; other emphasis omitted). That simply reflects that the provision protects objecting

providers, rather than restricting services or information offered willingly, underscoring that declining to provide information *is* protected.

Plaintiffs argue that "refer" or "referral" should be defined by reference to the definition of "referral" in certain Medicare provisions, NY Br. 49-50 (citing 42 U.S.C. § 1395nn(h)(5)(A)-(B)), or the term's asserted term-of-art usage in the medical context, NY Br. 50. But the Medicare provisions do not define "referral" for purposes of that statute as a whole, much less for distinct provisions like Coats-Snowe and Weldon. *See* 42 U.S.C. § 1395nn(h) (defining terms only "[f]or purposes of this section"). The presumption "that identical words used in different parts of the same act are intended to have the same meaning," *Utility Air Regulatory Grp. v. EPA*, 573 U.S. 302, 319 (2014), thus has no bearing here. Nor do plaintiffs attempt to reconcile their proposed meaning with, for example, Coats-Snowe's protections relating to referring "for" abortion generally or referrals for abortion-related *training*. 42 U.S.C. § 238n(a)(1).[1]

[1] Plaintiffs suggest (PP Br. 43 n.14) that HHS argued for a narrower understanding of "referral" in other litigation, but the cited brief simply contrasted "nondirective pregnancy counseling" with "referrals" in the context of a particular appropriations rider addressing Title X. *Cf. California v. Azar*, 950 F.3d 1067, 1086 (9th Cir. 2020) (contrasting "counseling" with "referral" in that context); *see* 84 Fed. Reg. at 23,191.

II. Plaintiffs' Other Criticisms Of The Rule Lack Merit

A. The Rule Is Not Contrary To Law

1. The Rule Is Consistent With Title VII

The Rule does not conflict with Title VII because it does not include Title VII's reasonable-accommodation or undue-hardship defenses. Title VII does not require that those defenses be applied in this context, and the later-enacted conscience statutes do not include them. *See* AOB 37-39.

Plaintiffs provide no textual basis for reading the Title VII defenses into the conscience statutes. Plaintiffs' concerns about patient safety cannot justify departure from the statutory terms Congress enacted, and plaintiffs are wrong in any event to assume hospitals cannot recognize statutorily protected conscience objections while also providing adequate patient care. *See infra* section II.B.

Plaintiffs derive no support from *Jackson v. Birmingham Board of Education*, 544 U.S. 167 (2005), which held that Title IX's prohibition of sex discrimination by recipients of federal education funding bars retaliation, even though Title IX does not specifically mention retaliation. *See id.* at 174. Title IX's text required that conclusion because retaliation is by definition a form of discrimination—the complainant is being subjected to differential treatment. *See id.* at 173-74. Here, by contrast, the conscience statutes' text provides no basis for reading in Title VII's reasonable-accommodation and undue-hardship defenses.

Plaintiffs also contend (PP Br. 38) that Congress must have intended to incorporate Title VII defenses *sub silentio* because the Church Amendments were enacted one year after Congress added those defenses to Title VII (albeit in the statutory definition of "religion"). That extra-textual speculation is no ground for reading missing language into a statute, and if anything, Congress's omission of those defenses from the later-enacted Church Amendments confirms that Congress deliberately chose *not* to include them. *See DHS v. MacLean*, 135 S. Ct. 913, 920-21 (2015).

2. The Rule Is Consistent With EMTALA

The district court erred by holding that the Rule facially conflicts with the Emergency Treatment and Active Labor Act (EMTALA), which requires hospitals with emergency rooms either to (1) stabilize a presenting patient's emergency medical condition "within the staff and facilities available at the hospital," or (2) transfer the patient to another medical facility as permitted by EMTALA. 42 U.S.C. § 1395dd(b)(1); *see* AOB 39-42.

Plaintiffs' administrative-record citations (PP Br. 50 n.17), which purport to identify conscience-related emergency-care deficiencies in a few limited contexts, do not justify invalidating the Rule in *all* potential applications. "The possibility that [a] rule, in uncommon particular applications," might be subject to as-applied challenge "does not warrant judicial condemnation of the rule in its entirety." *EPA v. Eme Homer City Generation, L.P.*, 572 U.S. 489, 524 (2014).

Plaintiffs also distort how the Rule would work in practice. Whether "a paramedic transporting a patient with a life-threatening complication that may require an emergency abortion" (PP Br. 47) is "assist[ing] in the performance" of the procedure will, for example, "depend on the facts and circumstances." 84 Fed. Reg. at 23,188. The lawfulness of a rule that depends on facts and circumstances is properly adjudicated through an as-applied, not a facial, challenge, to the extent one would arise in this context. *See American Hosp. Ass'n v. NLRB*, 499 U.S. 606, 609 (1991) ("point[ing] to a hypothetical case in which the rule might lead to an arbitrary result does not render the rule" facially invalid); *see also* Intervenor-Defendants-Appellants' Opening Br. 31 n.7 (noting record contains no evidence that any faith group prohibits adherents from treating an ectopic pregnancy).

Plaintiffs speculate (PP Br. 47) that a hospital would have to "double-staff" to comply with the Rule, but ignore a hospital's ability to require that employees inform it of conscience objections when there is a reasonable likelihood that they would engage in such activities. 45 C.F.R. § 88.2.

The Rule also does not conflict with EMTALA because, under conscience statutes other than the ACA, hospital employees' statutorily protected conscience objections can affect what staff are "available at the hospital." AOB 40-41. Plaintiffs argue (PP Br. 49-50) that the Fourth Circuit rejected that understanding of EMTALA in *In re Baby K*, 16 F.3d 590 (4th Cir. 1994), but that case did not involve an asserted federal statutory right. *See id.* at 597.

Plaintiffs fail to explain why the plain meaning of "within the staff and facilities available" should not include employee unavailability due to conscience objections; plaintiffs attempt (PP Br. 48) to find support in EMTALA's legislative history thus is unavailing. *See SW Gen.*, 137 S. Ct. at 943. Contrary to plaintiffs' contention (PP Br. 49), Congress's inclusion of an express EMTALA exception in the ACA's conscience provision does not suggest an implied exception should be grafted on the other conscience statutes but rather underscores that they do not contain any such exception. *See* AOB 41 (citing *MacLean*, 135 S. Ct. at 920-21).

Finally, plaintiffs' suggestion (PP Br. 50) that our understanding of EMTALA conflicts with HHS's regulatory definition of "availability" also lacks merit, as they cite a regulation that merely quotes the relevant statutory language "within the capabilities of the staff and facilities available," 42 C.F.R. § 489.24(d)(1), and a Centers for Medicare & Medicaid Services guidance document defining the term "capabilities," not "available," PP Br. 50 & n.18.

3. The Rule Is Consistent With Medicare and Medicaid Informed-Consent Requirements

Addressing a matter the district court did not reach, plaintiffs also contend (NY Br. 56) that the Rule violates an aspect of conscience provisions in the Medicare and Medicaid statutes. These statutes include informed-consent provisions prohibiting covered managed-care organizations from restricting communications between patients and covered health-care professionals. 42 U.S.C. §§ 1395w-22(j)(3)(A),

1396u-2(b)(3)(A). A rule of construction indicates that these provisions shall not be construed to require organizations to provide certain services to which they have conscience objections. *Id.* §§ 1395w-22(j)(3)(B), 1396u-2(b)(3)(B). The clauses plaintiffs cite, in turn, limit this rule of construction, stating that it shall not "be construed to affect disclosure requirements under State law" or the Employee Retirement Income Security Act of 1974. *Id.* §§ 1395w-22(j)(3)(C), 1396u-2(b)(3)(B).

Plaintiffs contend that the Rule would violate this limitation by preempting state disclosure laws if those laws required health-care entities to engage in activities to which they object. Plaintiffs, however, do not identify any state laws that relate to communications covered by these provisions that would in turn be affected by the relevant rule of construction. This as-applied objection is thus entirely hypothetical and meritless.

B. The Rule Is Not Arbitrary And Capricious

1. Plaintiffs do not dispute that the APA's arbitrary-and-capricious standard is "deferential" and "narrow," *Department of Commerce v. New York*, 139 S. Ct. 2551, 2569 (2019) (quotation marks omitted), and that consistency with statutory language is itself adequate justification for an agency's choice, *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2127 (2016). The Rule's definitional provisions reflect the best reading of the conscience statutes, providing significant public benefits of notice and clarity. While plaintiffs allege that enforcement of the statutes imposes various costs, Congress, not HHS, was responsible for weighing those considerations.

Plaintiffs' reliance (PP Br. 52) on *Perez v. Mortgage Bankers Association*, 575 U.S. 92, 105-06 (2015), misses the point. The government does not claim interpretive rules are exempt from arbitrary-and-capricious review; rather, a rule that provides the best reading of statutory terms simply reflects congressional intent and cannot be arbitrary and capricious as a result.

2. Plaintiffs' criticisms also lack merit on their own terms. Plaintiffs complain that one of HHS's reasons for promulgating the Rule was a "significant increase" in complaints alleging conscience violations. NY Br 58; PP Br. 53. As the Rule explains and plaintiffs do not dispute, OCR received "approximately 1.25 complaints per year alleging such violations during the eight years preceding the change in Administration." 84 Fed. Reg. at 23,245. By contrast, even on the district court's view of the record, OCR received "20 or 21 complaints implicat[ing] the Conscience Provisions" in a single fiscal year shortly before the Rule was promulgated. SA 80-82. That increase would indisputably be "significant" even if the district court's total were correct.

Plaintiffs, like the district court, focus on a few statements in the Rule's preamble that HHS received 343 complaints alleging conscience violations in one recent fiscal year. NY Br. 58-59; PP Br. 53-54. But plaintiffs are wrong to claim that the Rule is "premised" on any "specific number" of meritorious complaints. NY Br. 61; *cf. Islander E. Pipeline Co., LLC v. McCarthy*, 525 F.3d 141, 161 (2d Cir. 2008) (upholding agency action even where agency relied on "mathematically flawed" study

because action was "rationally supported by other findings" grounded in the record). Indeed, even the fact of an *increase* in complaints, which is indisputable even assuming the absolute *number* of complaints is not, was only "one of the many metrics used to demonstrate [the Rule's] importance." 84 Fed. Reg. at 23,229; *see id.* at 23,175-78 (discussing other support). Plaintiffs' observation (PP Br. 55) that complaints increased after HHS issued its notice of proposed rulemaking (NPRM) does not undermine the Rule; if anything, it supports HHS's conclusion that the public was unfamiliar with the conscience statutes and the Rule would help raise awareness.

Plaintiffs also dispute HHS's conclusions that a public lack of awareness of the conscience statutes and inadequate existing enforcement tools supported the Rule's promulgation. *See* NY Br. 62-65. That plaintiffs spend numerous pages of their briefs attempting to rebut HHS's analysis of these points, *see id.*, underscores that these are not issues HHS "entirely failed to consider," but merely issues as to which plaintiffs might have reached a different conclusion if they were the decisionmakers. *New York v. Department of Justice*, 951 F.3d 84, 122 (2d Cir. 2020). Contrary to plaintiffs' claim (NY Br. 62) that there is no "concrete evidence" of confusion, HHS received comments stating that, for example, health professionals' careers were "jeopardized because entities [were] completely unaware or willfully dismissive of applicable" conscience statutes. 84 Fed. Reg. at 23,228-29; *see id.* at 23,178-79. HHS likewise believed some conscience statutes might never have been enforced because HHS "ha[d] devoted no meaningful attention to [them], ha[d] not conducted outreach to

the public on them, and ha[d] not adopted regulations with enforcement procedures for them." *Id.* at 23,183.

3. Plaintiffs also mistakenly contend that the Rule made unexplained changes to HHS's position. Government plaintiffs assert that HHS was required to address more specifically a statement in the 2011 Rule that the 2008 Rule "may negatively affect the ability of patients to access care." NY Br. 66 (quoting 76 Fed. Reg. 9968, 9974 (Feb. 23, 2011)). As HHS explained, however, *see* 84 Fed. Reg. at 23,181-82, any effect on access to care originates from the conscience statutes themselves, not the Rule, and HHS has consistently (including in the 2011 Rule) required regulated entities to comply with the statutes. *See, e.g.*, 76 Fed. Reg. at 9972. Whether the Rule's definitions are the best reading of those statutes is a question of statutory construction, not a matter of factual findings or agency discretion. In any event, HHS explained its expectation that the Rule would likely *increase* access to care and its discounting of contrary predictions. *See* AOB 47.

It is difficult to understand plaintiffs' claim that the Rule's "discrimination" definition constitutes an unexplained change, NY Br. 66-67; PP Br. 57-58, given that HHS had not previously defined that term, *see* 73 Fed. Reg. at 78,077 (explaining HHS's 2008 decision not to do so). Though plaintiffs suggest the Rule contravenes HHS's 2008 observation that "significant federal case law exists" regarding the meaning of "discrimination," *id.*, the current Rule, too, "draw[s] substantially from definitions and interpretations of 'discrimination' found in other anti-discrimination

statutes and case law," 84 Fed. Reg. at 23,192. Contrary to plaintiffs' suggestion that the 2011 Rule incorporated Title VII defenses, *see* NY Br. 67; PP Br. 57-58, the 2011 Rule expressly declared "[t]he relationship between the protections contained under the [conscience statutes] and the protections afforded under Title VII" to be "outside" that rule's "scope." 76 Fed. Reg. at 9973; *see also* 73 Fed. Reg. at 78,084 (finding it not "necessary or appropriate to incorporate elements of Title VII jurisprudence into" 2008 Rule). Plaintiffs are therefore wrong to suggest the Rule substitutes an "entirely new framework" for Title VII. PP Br. 58.

4. Plaintiffs fault HHS for supposedly inadequately considering various matters. But even a legislative rule "may be overturned as arbitrary and capricious [only] if the agency *entirely failed* to consider an important aspect of the problem," *New York*, 951 F.3d at 122 (emphasis added; quotation marks omitted), and the Rule's extensive analysis would easily clear that bar even assuming it applied.

Contrary to plaintiffs' contention (NY Br. 68-70), the Rule did not upend legitimate reliance interests. In the 2011 Rule, HHS cautioned that "Departmental funding recipients must continue to comply with the" conscience statutes and stated that "individual investigations w[ould] provide the best means of answering questions about the application of the statutes in particular circumstances." 76 Fed. Reg. at 9972-74. The 2011 Rule therefore did not set standards of conduct on which regulated entities might rely, nor do plaintiffs identify any other relevant agency pronouncement. Far from making a "policy" change of the sort addressed in *Encino*

Motorcars, 136 S. Ct. at 2126, the Rule merely provides notice of the best reading of statutes to which plaintiffs have always known they are subject.

Plaintiffs and amici contend that HHS inadequately grappled with various harms they claim the Rule will cause. NY Br. 70-74; PP Br. 60-62. Putting aside HHS's careful analysis of the issues plaintiffs raise, this Court has made clear that an agency cannot "excuse" a regulated entity from complying with federal law based "on a finding that the detrimental effects of compliance outweigh the benefits." *New York*, 951 F.3d at 122. Because the Rule simply provides notice of the conscience statutes' meaning, even a complete "failure to discuss detrimental effects" would not "show that [HHS] arbitrarily or capriciously" promulgated the Rule. *Id.* at 122-23; *see also Catskill Mountains Chapter of Trout Unlimited, Inc. v. EPA*, 846 F.3d 492, 523 (2d Cir. 2017) ("[A]gencies are not obligated to conduct detailed fact-finding or cost-benefit analyses when interpreting a statute.").

In any event, HHS carefully considered all the issues plaintiffs and amici raise here. *See, e.g.*, 84 Fed. Reg. at 23,180-82, 23,246-48, 23,250-54 (access to care, including in rural communities); *id.* at 23,182-83, 23,188, 23,224 (emergency care and EMTALA); *id.* at 23,189, 23,200 (informed consent and medical ethics); *id.* at 23,191 (interaction with Title VII); *id.* at 23,191-92, 23,217, 23,219, 23,239-46 (alleged burdens on hospitals); *id.* at 23,239 (potential for litigation involving providers); *id.* at 23,251-54 (underserved communities). At bottom, plaintiffs are left to label HHS's analysis insufficiently "serious." NY Br. 74. But HHS considered the issues plaintiffs

raise, and agency action is not arbitrary and capricious simply because plaintiffs or a reviewing court might disagree with the agency's conclusions. *See Islander*, 525 F.3d at 153 (upholding agency action even where "evidence raise[d] legitimate questions," as the agency "accorded it little weight" rather than "ignore[d]" it).[2]

C. The Rule Satisfies The APA's Notice-And-Comment Requirement

Plaintiffs do not dispute that, if the Rule is interpretive rather than legislative, it need not be a "logical outgrowth" of the NPRM. *See* 5 U.S.C. § 553(b)(3)(A) (APA notice-and-comment requirement does not apply to interpretive rules); *Fertilizer Inst. v. EPA*, 935 F.2d 1303, 1308 (D.C. Cir. 1991). Plaintiffs' logical-outgrowth argument (PP Br. 62) fails for that reason.

Their argument also fails for additional reasons. *See* AOB 49-52. To begin, the NPRM plainly disclosed HHS's recognition that Title VII's reasonable-accommodation and undue-hardship defenses were unavailable, as the NPRM's definition included *no* defenses. Cases premised on the absence of notice are thus inapposite. *See, e.g.*, *Environmental Integrity Project v. EPA*, 425 F.3d 992, 995 (D.C. Cir. 2005) (involving rule that "switched course and adopted the opposite position" from

[2] Plaintiffs complain that HHS relied on anecdotal evidence supporting its conclusions, while rejecting anecdotal evidence of potential harm to certain communities. PP Br. 60-62. HHS considered this evidence and concluded that the accounts of harm did not establish that conscience statutes had "played any causal role in the discrimination experienced," 84 Fed. Reg. at 23,252, a determination well within HHS's broad discretion to "determine which evidence [is] most persuasive and what weight it deserve[s]." *Islander*, 525 F.3d at 154.

that proposed in the NPRM). HHS's final rule adhered to the NPRM's non-inclusion of Title VII's reasonable-accommodation and undue-hardship defenses, commenters understood the proposal that way, and HHS specifically addressed objections on that point. *See* 84 Fed. Reg. at 23,189-92

Plaintiffs contend that the most they could glean from the NPRM was that it was "unclear if HHS meant to adhere to the reasonable accommodation/undue hardship standard." PP Br. 63. Even accepting that contention, plaintiffs "should have anticipated" (as some plaintiffs did, *see* AOB 50) that HHS might adhere to the NPRM's non-inclusion of those defenses, *Environmental Integrity*, 425 F.3d at 996, and objected to that decision.

Plaintiffs also argue (PP Br. 64) that the NPRM, by referring to Title VI's "disparate impact" analysis, led regulated entities to assume HHS was planning to include Title VII's reasonable-accommodation and undue-hardship defenses. That contention finds no support in the NPRM's definition of "discrimination," however, and inaccurately describes the NPRM, which stated only that HHS was "solicit[ing] comment on whether disparate impact analysis is appropriate" in this context. 83 Fed. Reg. 3880, 3893 (Jan. 26, 2018).

Plaintiffs also cannot effectively defend the district court's holding that the NPRM failed to anticipate paragraphs (4)-(6) of the Rule's discrimination definition. Plaintiffs offer no response to the argument (AOB 50) that they lack standing to raise that contention because those paragraphs give employers *more* protections than the

proposed rule. *See* AOB 50-51 (noting that, for the same reason, those paragraphs do not cause plaintiffs any prejudice). And their argument (PP Br. 62-63) that those paragraphs prevent employers from "ensuring they hire applicants willing to perform [a] job's core functions" ignores that the Rule allows employers to inquire about conscience objections, *inter alia*, when "supported by a persuasive justification." 45 C.F.R. § 88.2.

D. The Rule Is Constitutional

The government plaintiffs fail to demonstrate that their Spending Clause claims are ripe or that either set of constitutional claims is meritorious.

1. The Rule Is Consistent With The Separation Of Powers

Plaintiffs do not dispute that their separation-of-powers claim depends on the district court's holding that the Rule's enforcement provisions exceed HHS's authority. Because that conclusion cannot be sustained, as discussed *supra*, their constitutional claim fails as well. They further fail even to attempt to demonstrate that they satisfy the second element of this claim, namely that agency action was "not only unauthorized but also intrusive on power constitutionally committed to a coordinate branch." *New York*, 951 F.3d at 101; *see also Dalton v. Specter*, 511 U.S. 462, 472 & n.6 (1994). This claim consequently should be rejected.

2. Plaintiffs' Spending Clause Challenge Is Unripe And Meritless

a. Ripeness depends on "(1) whether the issues presented to the district court are fit for review, and (2) what hardship the parties will suffer in the absence of review." *Connecticut v. Duncan*, 612 F.3d 107, 113 (2d Cir. 2010). On the first prong, plaintiffs do not deny that a Spending Clause claim premised on the possibility that HHS might terminate all of a State's funding under the Rule depends on a chain of speculative hypotheticals, and a concrete enforcement action and further administrative proceedings would facilitate the Court's review of the legal question. *See id.* at 114-15. Plaintiffs suggest that any future administrative proceedings may not involve notice to the parties. NY Br. 76-77. The Rule provides, however, that, where HHS identifies statutory noncompliance, it "will so inform the relevant parties." 45 C.F.R. § 88.7(i)(2). HHS may take other actions while attempting informal resolution, but must do so "pursuant to statutes and regulations which govern the administration of" the relevant funding arrangement. *Id.* § 88.7(i)(3). In any event, that plaintiffs' response identifies a hypothetical defect in administrative proceedings that have not occurred underscores that further proceedings would facilitate the Court's review.

On the second prong, plaintiffs seek to distinguish previous decisions rejecting challenges to Weldon based on the Rule's asserted compliance burdens, but the risk of funding termination that underlay the district court's constitutional holding here is the same in those cases. *See NFPRHA*, 468 F.3d at 829-31; *California v. United States*, No.

05-00328, 2008 WL 744840, at *3 (N.D. Cal. Mar. 18, 2008). And the availability of future administrative proceedings distinguishes the sole case on which plaintiffs rely, notwithstanding their hypothetical objections to such proceedings. *See Connecticut*, 612 F.3d at 115 (distinguishing *Thomas v. City of New York*, 143 F.3d 31, 36 (2d Cir. 1998)).

b. Plaintiffs' Spending Clause claims also lack merit. First, they assert that the Rule violates the clear-notice requirement of *Pennhurst State School & Hospital v. Halderman*, 451 U.S. 1 (1981), not because the conscience statutes or the Rule are ambiguous or impose retroactive conditions, but because plaintiffs believe the Rule reflects funding conditions imposed by HHS rather than Congress. NY Br. 77. As discussed, the Rule does not change plaintiffs' substantive obligations or alter HHS's enforcement authority under the statutes, and it certainly does not "transform[]" an existing program into a new program as described in *NFIB v. Sebelius*, 567 U.S. 519, 584 (2012). In any event, this Court rejected plaintiffs' precise argument in *New York*, 951 F.3d at 110, which plaintiffs fail to cite much less distinguish. HHS may permissibly supply clarifying interpretations grounded in the conscience statutes, *see id.*, and there is no question that the Rule gives plaintiffs notice of the funding conditions HHS understands the conscience statutes to impose.

Second, while plaintiffs assert that the Rule is unconstitutionally coercive, the Rule does not change HHS's ability to terminate funding due to a violation of the conscience statutes. As under the unchallenged statutes, the Rule places at risk only the funding implicated by a violation. And the Rule operates differently from the

Medicaid expansion at issue in *NFIB*: it does not make termination of funding the default penalty and threatens only funds associated with the particular condition a State violates, such that there is no effort to use such a threat to induce States to participate in a "new health care program." 567 U.S. at 584; *see* AOB 59-60. The Rule simply provides for the enforcement of statutes that have long governed funds plaintiffs received, raising no Spending Clause concern.

III. The District Court Erroneously Vacated The Rule In Its Entirety And Against All Persons

A. Any Relief Should Be Limited to Plaintiffs

Article III standing principles require that any remedy ordered by a federal court "be limited to the inadequacy that produced the injury in fact that the plaintiff has established," *Gill v. Whitford*, 138 S. Ct. 1916, 1931 (2018), and equitable principles likewise require that any relief "be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs," *Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 765 (1994). In addition, nationwide relief is inappropriate where it may "override contrary decisions from co-equal and appellate courts." *New York v. DHS*, Nos. 19-3591, 19-3595, 2020 WL 4457951, at *31 (2d Cir. Aug. 4, 2020) (modifying nationwide injunction by limiting it to New York, Connecticut, and Vermont); *see also Casa de Maryland, Inc. v. Trump*, No. 19-2222, 2020 WL 4664820, at *23-29 (4th Cir. Aug. 5, 2020) (holding district court erred by entering nationwide injunction under the APA). The district court violated those principles and others (*see*

AOB 60-63) by vacating the Rule as to all potential parties, rather than rendering it inapplicable to plaintiffs.

Plaintiffs argue (NY Br. 64) that the cited principles do not apply to vacatur in an APA case, but that is incorrect. Article III standing is jurisdictional, and applies to all forms of federal court relief. *See Gill*, 138 S. Ct. at 1931. As the Fourth Circuit recently held, the APA does not "even authorize[], much less compel[], nationwide injunctions." *Casa de Maryland*, 2020 WL 4664820, at *28 n.8; *see Virginia Soc'y for Human Life, Inc. v. FEC*, 263 F.3d 379, 394 (4th Cir. 2001) ("Nothing in the language of the APA" requires that a regulation be "set[] aside . . . for the entire country.") Indeed, the APA's provisions confirm that "equitable defenses may be interposed," *Abbott Labs. v. Gardner*, 387 U.S. 136, 155 (1967); *see* 5 U.S.C. §§ 702(1), 703, reinforcing that Congress did not intend to authorize vacatur *beyond* the parties unless necessary to provide the parties with full relief or otherwise to depart from longstanding principles of equity. *See* AOB 63-64; Amicus Brief for Nicholas Bagley and Samuel L. Bray, *Trump v. Pennsylvania*, No. 19-454, 2020 WL 1433996, at *11-17 (2017) (Mar. 9, 2020) (noting APA left traditional equity practice undisturbed).[3]

[3] Nothing in *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139 (2010), or *American Bioscience, Inc. v. Thompson*, 269 F.3d 1077 (D.C. Cir. 2001), is to the contrary, and *American Bioscience* expressly noted that vacatur of a rule under the APA is permissible only "[i]f an appellant has standing." *Id.* at 1084. In addition, plaintiffs cite various cases, *see, e.g.*, *DHS v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891 (2020), that contain no discussion of whether the rules at issue were voidable beyond the parties. "[D]rive-by jurisdictional rulings" are entitled to "no precedential effect." *Arbaugh v. Y & H Corp.*, 546 U.S. 500, 511 (2006).

Provider plaintiffs contend (PP Br. 67) that nationwide vacatur is necessary to provide them with full relief because their members "are often sub-recipients of HHS funds" and could lose funding if HHS is permitted to enforce the Rule against non-parties. The district court did not so find, however, and nothing prevents the non-parties directly affected from seeking redress for their own injuries. *See Warth v. Seldin*, 422 U.S. 490, 499 (1975).

B. Any Relief Should Be Limited To Specific Provisions

By vacating the Rule in its entirety, the district court violated its "duty" "to maintain the [regulation] in so far as it is valid." *Regan v. Time, Inc.*, 468 U.S. 641, 652 (1984). The court's error is underscored by the Rule's express severability clause, *see* 45 C.F.R. § 88.10; 84 Fed. Reg. at 23,226, which creates a "presumption of severability," *FEC v. Survival Educ. Fund, Inc.,* 65 F.3d 285, 297 (2d Cir. 1995), and the court's recognition that "some aspects of the Rule are within HHS's authority," SA 42, *see also*, *e.g.*, SA 57.

Plaintiffs argue that no part of the Rule is valid because "HHS's rationale for issuing the Rule in the first place was arbitrary and capricious." PP Br. 67 (emphasis omitted). The Rule is not arbitrary and capricious, however, much less in a way that invalidates *all* of its provisions. *See supra* section II.B. Plaintiffs also contend (PP Br. 68; NY Br. 82) that severing any provisions would "severely distort" the Rule, but fail to explain why valid portions of the Rule could not function apart from any provisions held unlawful. Even if one or more definitional provisions were

invalidated, for example, the other definitions could continue to function. Plaintiffs also suggest (PP Br. 68-69) that HHS could "commenc[e] a new rulemaking" for anything the agency believes is valid, but that would invert the applicable presumption of severability, requiring full vacatur and new rulemaking whenever *any* part of any rule is held invalid. That is not the law.

CONCLUSION

For the foregoing reasons and the reasons stated in the federal government's opening brief, the judgment of the district court should be reversed.

Respectfully submitted,

ETHAN P. DAVIS
Acting Assistant Attorney General
MICHAEL S. RAAB

s/ Leif Overvold
LOWELL V. STURGILL JR.
SARAH CARROLL
LEIF OVERVOLD
Attorneys, Appellate Staff
Civil Division, Room 7226
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 532-4631
leif.overvold2@usdoj.gov

Of Counsel:

ROBERT P. CHARROW
General Counsel
SEAN R. KEVENEY
Deputy General Counsel
U.S. Department of Health & Human Services

AUGUST 2020

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing Reply Brief for Defendants-Appellants contains 7,969 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f), consistent with the word limit requested in the Appellants' Unopposed Motion To Extend Word Limit filed August 14, 2020. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word 2016 in Garamond 14-point font, a proportionally spaced typeface.

s/ Leif Overvold
Leif Overvold

CERTIFICATE OF SERVICE

I hereby certify that on August 31, 2020, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Second Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

s/ Leif Overvold
Leif Overvold