APPENDIX

APPENDIX A

FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

STATE OF CALIFORNIA; STATE OF DELAWARE; COMMONWEALTH OF VIRGINIA; STATE OF MARYLAND; STATE OF NEW YORK, *Plaintiffs-Appellees*, v. ALEX M. AZAR II, Secretary of the United States Department of Health and Human Services; U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES; R. ALEXANDER ACOSTA, in his official capacity as Secretary of the U.S. Department of Labor; U.S. DEPARTMENT OF LABOR; STEVEN TERNER MNUCHIN, in his official capacity as Secretary of the U.S. Department of the Treasury; U.S. DEPARTMENT OF THE TREASURY, *Defendants*, and THE LITTLE SISTERS OF THE POOR JEANNE JUGAN RESIDENCE, *Intervenor-Defendant-Appellant*.	No. 18-15144 D.C. No. 4:17-cv-05783-HSG

STATE OF CALIFORNIA; STATE OF DELAWARE; COMMONWEALTH OF VIRGINIA; STATE OF MARYLAND; STATE OF NEW YORK,

Plaintiffs-Appellees,

v.

ALEX M. AZAR II, Secretary of the United States Department of Health and Human Services; U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES; R. ALEXANDER ACOSTA, in his official capacity as Secretary of the U.S. Department of Labor; U.S. DEPARTMENT OF LABOR; STEVEN TERNER MNUCHIN, in his official capacity as Secretary of the U.S. Department of the Treasury; U.S. DEPARTMENT OF THE TREASURY,

Defendants,

and

MARCH FOR LIFE EDUCATION AND DEFENSE FUND,

Intervenor-Defendant-Appellant.

No. 18-15166
D.C. No.
4:17-cv-05783-
HSG

Appeals from the United States District Court for the Northern District of California

Haywood S. Gilliam, Jr., District Judge, Presiding

Argued and Submitted October 19, 2018 San Francisco, California

Filed December 13, 2018

Before: J. Clifford Wallace, Andrew J. Kleinfeld, and Susan P. Graber, Circuit Judges.

Opinion by Judge Wallace;
Dissent by Judge Kleinfeld

SUMMARY[*]

Affordable Care Act

The panel affirmed in part and vacated in part the district court's nationwide preliminary injunction in an action brought by a number of states, including California and New York, challenging two interim federal agency rules that exempted certain employers with religious and moral objections from the Affordable Care Act's requirement that group health plans cover contraceptive care.

The Affordable Care Act and the regulations implementing it require group health plans to cover contraceptive care without cost sharing. Federal agencies issued two interim rules that exempted employers with religious and moral objections from this requirement. In response, California, Delaware, Maryland, New York, and Virginia sued the federal agencies and their secretaries in the Northern District

[*] This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

of California alleging that the interim rules were invalid under the Administrative Procedure Act, the Fifth Amendment equal protection component of the Due Process Clause, and the First Amendment Establishment Clause. The district court determined that the states were likely to succeed on their Administrative Procedure Act claim – that the rules were procedurally invalid for failing to follow notice and comment rulemaking.

The panel first held that the case was not moot even though the federal agencies had published final versions of the religious and moral exemptions that are due to go into effect on January 14, 2019. The panel held that mootness was not an issue until the final rules supersede the interim rules, as expected on January 14, 2019.

The panel held that venue was proper in the Northern District of California. The panel further held that states had standing to sue on their Administrative Procedure Act claim because they showed with reasonable probability that the interim rules will lead to women losing employer-sponsored contraceptive coverage, which will then result in economic harm to the states. The panel held that the record supported the states' theory that women who would lose coverage would seek contraceptive care through state-run programs or programs that the states are responsible for reimbursing.

The panel affirmed the preliminary injunction insofar as it barred enforcement of the interim rules in the plaintiff states, but otherwise vacated the portion of the injunction barring enforcement of the rules in other states. The panel agreed with the district court that the states were likely to succeed on the merits of

their Administrative Procedure Act claim. The panel held that based on the totality of the circumstances, the agencies likely did not have good cause, nor statutory authority for bypassing notice and comment, and that bypassing notice and comment likely was not harmless. The panel further held that the states had shown that they were likely to suffer irreparable harm absent an injunction and that the district court did not abuse its discretion in finding that the balance of equities and the public interest weighted in favor of granting the preliminary injunction.

The panel held that the scope of the injunction was overbroad. The panel noted that while the record before the district court was voluminous on the harm to the plaintiff states, it was not developed as to the economic impact on other states. The panel held that district judges must require a showing of nationwide impact or sufficient similarity to the plaintiff states to foreclose litigation in other districts, from Alaska to Puerto Rico to Maine to Guam. The panel therefore vacated the portion of the injunction barring enforcement of the interim rules in other states and remanded to the district court. The panel retained jurisdiction over any subsequent appeals arising from this case.

Dissenting, Judge Kleinfeld stated that the plaintiff state governments lacked standing to bring this case in federal court, and therefore the district court lacked jurisdiction. Judge Kleinfeld wrote that the states lacked standing because their injury was self-inflicted and arose solely from their legislative decisions to spend money to provide contraception benefits.

COUNSEL

Lowell V. Sturgill, Jr. (argued), Karen Schoen, Jaynie Lilley, Catherine H. Dorsey, Matthew M. Collette, and Sharon Swingle, Appellate Staff; Hashim M. Mooppan, Deputy Assistant Attorney General; Alex G. Tse, Acting United States Attorney; Joseph H. Hunt, Assistant Attorney General; Civil Division, United States Department of Justice, Washington, D.C.; for Defendants-Appellants.

Gregory S. Baylor (argued) and Christen M. Price, Alliance Defending Freedom, Washington, D.C.; Kenneth J. Connelly, Kevin H. Theriot, and David A. Cortman, Alliance Defending Freedom, Scottsdale, Arizona; Brian R. Chavez-Ochoa, Chavez-Ochoa Law Offices Inc., Valley Springs, California; for Intervenor-Defendant-Appellant March for Life.

Mark L. Rienzi (argued), Daniel Ortner, Diana M. Verm, Lori H. Windham, Eric C. Rassbach, and Chase T. Harrington, The Becket Fund for Religious Liberty, Washington, D.C., for Intervenor-Defendant-Appellant

Karli Eisenberg (argued) and R. Matthew Wise, Deputy Attorneys General; Max Carter-Oberstone, Associate Deputy Solicitor General; Kathleen Boergers, Supervising Deputy Attorney General; Julie Weng-Gutierrez, Senior Assistant Attorney General; Xavier Becerra, Attorney General; Office of the Attorney General, Sacramento, California; David J. Lyons and Jessica M. Willey, Deputy Attorneys General; Ilona Kirshon, Deputy State Solicitor; Matthew P. Denn, Attorney General; Delaware Department of Justice, Wilmington, Delaware; Kimberly S. Cammarata, Director, Health Education

& Advocacy; Steven M. Sullivan, Solicitor General; Carolyn A. Quattrocki, Deputy

Attorney General; Brian E. Frosh, Attorney General; Attorney General's Office, Baltimore, Maryland; Elizabeth Chesler, Assistant Attorney General; Sara Haviva Mark, Special Counsel; Ester Murdukhayeva, Assistant Solicitor General; Steven C. Wu, Deputy Solicitor General; Lisa Landau, Bureau Chief, Health Care Bureau; Barbara D. Underwood, Acting Attorney General; Office of the Attorney General, New York, New York; Samuel T. Towell, Deputy Attorney General; Mark R. Herring, Attorney General; Office of the Attorney General, Richmond, Virginia; for Plaintiffs-Appellees.

Dwight G. Duncan, Colbe Mazzarella, North Dartmouth, Massachusetts, for Amici Curiae Residents and Families of Residents at Homes of the Little Sisters of the Poor.

William J. Haun, Washington, D.C., for Amici Curiae Constitutional Law Scholars.

Robert E. Dunn and Paul Collins, Gibson Dunn & Crutcher LLP, Palo Alto, California; Daniel L. Chen, Gibson Dunn & Crutcher LLP, San Francisco, California; for Amicus Curiae Religious Sisters of Mercy.

Stephanie N. Taub and Lea E. Patterson, First Liberty Institute, Plano, Texas, for Amicus Curiae First Liberty Institute.

Jamie A. Levitt, Andrea M. Kozak-Oxnard, and Rhiannon N. Batchelder, Morrison & Foerster LLP, New York, New York, for Amici Curiae American Association of University Women; Service Employees

International Union; and 12 Additional Professional, Labor, and Student Associations.

Jeffrey Blumenfeld, Lowenstein Sandler LLP, Washington, D.C.; Michelle Banker, Sunu Chandy, Gretchen Borchelt, and Fatima Goss Graves, National Women's Law Center, Washington, D.C.; Sawyeh Esmaili, National Latina Institute for Reproductive Health, Washington, D.C.; Carolyn Calhoun and Sequoia Ayala, Sisterlove Inc., Atlanta, Georgia; Jane Liu, National Asian Pacific American Women's Forum, Washington, D.C.; Naomi D. Barrowclough, Lowenstein Sandler LLP, Roseland, New Jersey; for Amici Curiae National Women's Law Center, National Latina Institute for Reproductive Health, Sisterlove Inc., and National Asian Pacific American Women's Forum.

Diana Kasdan, Joel Dodge, and Julie Rikelman, Center for Reproductive Rights, New York, New York; Phylicia H. Hill, Katrina L. Goodjoint, Dorian L. Spence, Dariely Rodriguez, and Jon M. Greenbaum, Lawyers' Committee for Civil Rights Under Law, Washington, D.C.; for Amici Curiae Center for Reproductive Rights, Lawyers' Committee for Civil Rights Under Law, and Seven Civil Rights Organizations.

Adriana L. Benedict, Laura S. Trice, and Greta S. Hansen, Deputy County Counsel, San Jose, California; Donna R. Ziegler, County Counsel, County of Alameda, Oakland, California; Andre M. Davis, City Solicitor, Baltimore, Maryland; Farimah Brown, City Attorney, Berkeley, California; Kimberly M. Foxx, State's Attorney for Cook County, Chicago, Illinois; Michael N. Feuer, City Attorney, Los Angeles, California; Mary Wickham, County Counsel, County of Los Angeles, Los

Angeles, California; Susan L. Segal, City Attorney, Minneapolis, Minnesota; Charles J. McKee, County Counsel, County of Monterey, Salinas, California; Zachary W. Carter, City Corporation Counsel, New York, New York; Marcel S. Pratt, City Solicitor, Philadelphia, Pennsylvania; Jeffrey Dana, City Solicitor, Providence, Rhode Island; Dennis J. Herrera, City Attorney, San Francisco, California; Peter S. Holmes, City Attorney, Seattle, Washington; Michael Jenkins, City Attorney, City of West Hollywood, Manhattan Beach, California; for Amici Curiae 17 Cities, Counties, and Local Agencies.

Richard B. Katskee, Alison Tanner, Kelly M. Percival, and Alex J. Luchenitser, Americans United for Separate of Church and State, Washington, D.C.; Nimra Azmi, Sirine Shebaya, and Johnathan Smith, Muslim Advocates, Washington, D.C.; Giselle Klapper, Julian Darwall, and Amrith Kaur, Sikh Coalition, New York, New York; for Amici Curiae Americans United for Separation of Church And State; Bend the Arc: A Jewish Partnership for Justice; Hadassah, The Women's Zionist Organization of America, Inc.; Heart Women & Girls; Interfaith Alliance Foundation; Jewish Women International; Methodist Federation for Social Action; Muslim Advocates; National Council of Jewish Women, Inc.; People for the American Way Foundation; Reconstructing Judaism; Reconstructionist Rabbinical Association; and Sikh Coalition.

Elizabeth O. Gill and Katherine Lin, ACLU Foundation of Northern California, San Francisco, California; Melissa Goodman, ACLU Foundation of Southern California, Los Angeles, California; Brigitte Amiri, ACLU Foundation, New York, New York; David

Loy, ACLU Foundation of San Diego & Imperial Counties, San Diego, California; for Amici Curiae American Civil Liberties Union, ACLU of Northern California, ACLU of Southern California, ACLU of San Diego and Imperial Counties, Anti-Defamation League, Leadership Conference on Civil and Human Rights, and National Urban League.

Allan Arffa, Malina M. Meneguin Layerenza, Elizabeth J. Grossman, and Crystal Johnson, Paul Weiss Rifkind Wharton & Garrison LLP, New York, New York, for Amici Curiae Planned Parenthood Federation of America, National Health Law Program, and National Family Planning and Reproductive Health Association.

Bruce H. Schneider, Gilana Keller, and Michele L. Pahmer, Stroock & Stroock & Lavan LLP, New York, New York, for Amici Curiae Health Professional Organizations The American Nurses Association, The American College of Obstetricians and Gynecologists, The American Academy of Nursing, The American Academy of Pediatrics, Physicians for Reproductive Health, and The California Medical Association.

Genevieve Nadeau, Julia E. Kobick, Jon Burke, and Jonathan B. Miller, Assistant Attorneys General; Elizabeth Carnes Flynn, Special Assistant Attorney General; Office of the Attorney General, Boston, Massachusetts; George Jepsen, Attorney General, Hartford, Connecticut; Karl A. Racine, Attorney General, Washington, D.C.; Russell A. Suzuki, Attorney General, Honolulu, Hawaii; Lisa Madigan, Attorney General, Chicago, Illinois; Tom Miller, Attorney General, Des Moines, Iowa; Janet T. Mills, Attorney General, Augusta, Maine; Lori Swanson, Attorney General, St. Paul, Minnesota; Gurbir S.

Grewal, Attorney General, Trenton, New Jersey; Hector Balderas, Attorney General, Santa Fe, New Mexico; Joshua H. Stein, Attorney General, Raleigh, North Carolina; Ellen F. Rosenblum, Attorney General, Salem, Oregon; Josh Shapiro, Attorney General, Harrisburg, Pennsylvania; Peter F. Kilmartin, Attorney General, Providence, Rhode Island; Thomas J. Donovan Jr., Attorney General, Montpelier, Vermont; Robert W. Ferguson, Attorney General, Olympia, Washington; for Amici Curiae States of Massachusetts, Connecticut, Hawaii, Illinois, Iowa, Maine, Minnesota, North Carolina, New Jersey, New Mexico, Oregon, Pennsylvania, Rhode Island, Vermont, and Washington, and District of Columbia.

Elliot Schulder, Covington & Burling LLP, Washington, D.C.; Seth Davis, Irvine, California; for Amici Curiae Administrative Law Professors.

Alan S. Gilbert, Jacqueline A. Giannini, Cicely R. Miltich, and Leah R. Bruno, Dentons US LLP, Chicago, Illinois, for Amici Curiae U.S. Women's Chamber of Commerce, National Association for Female Executives, and Businesses in Support of Plaintiffs-Appellees.

OPINION

WALLACE, Circuit Judge:

The Affordable Care Act (ACA) and the regulations implementing it require group health plans to cover contraceptive care without cost sharing. Federal agencies issued two interim final rules (IFRs) exempting employers with religious and moral objections from this requirement. Several states sued to enjoin the enforcement of the IFRs, and the district court issued a nationwide preliminary injunction. We

have jurisdiction under 28 U.S.C. § 1292, and we affirm in part, vacate in part, and remand.

I.

A.

To contextualize the issues raised on appeal, we briefly recount the history of the ACA's contraceptive coverage requirement. The ACA provides that:

> a group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for * * * with respect to women, such additional preventive care and screenings * * * as provided for in comprehensive guidelines supported by the Health Resources and Services Administration [HRSA] * * * .

42 U.S.C. § 300gg-13(a)(4). HRSA established guidelines for women's preventive services that include any "[FDA] approved contraceptive methods, sterilization procedures, and patient education and counseling." Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 77 Fed. Reg. 8,725-01, 8,725 (Feb. 15, 2012). The three agencies responsible for implementing the ACA—the Department of Health and Human Services, the Department of Labor, and the Department of the Treasury (collectively, agencies)—issued regulations requiring coverage of all preventive services contained in HRSA's guidelines. See, e.g., 45 C.F.R. § 147.130(a)(1)(iv) (DHSS regulation).

The agencies also recognized that religious organizations may object to the use of contraceptive care and offering health insurance that covers such care. For those organizations, the agencies provided two avenues. First, group health plans of certain religious employers, such as churches, are categorically exempt from the contraceptive coverage requirement. Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. 39,870, 39,874 (July 2, 2013). Second, nonprofit "eligible organizations" that are not categorically exempt can opt out of having to "contract, arrange, pay, or refer for contraceptive coverage." *Id*. To be eligible, the organization must file a self-certification form stating (1) that it "opposes providing coverage for some or all of any contraceptive services required to be covered under [the regulation] on account of religious objections," (2) that it "is organized and operates as a nonprofit entity," and (3) that it "holds itself out as a religious organization." *Id*. at 39,892. The organization sends a copy of the form to its insurance provider, which must then provide contraceptive coverage for the organization's employees and cannot impose any charges related to the coverage. *Id*. at 39,876. The regulations refer to this second avenue as the "accommodation," and it was designed to avoid imposing on organizations' beliefs that paying for or facilitating coverage for contraceptive care violates their religion. *Id*. at 39,874.

The agencies subsequently amended the accommodation in response to several legal challenges. First, certain closely-held for-profit organizations became eligible for the accommodation. Coverage of Certain Preventive Services Under the Affordable

Care Act, 80 Fed. Reg. 41,318-01, 41,343 (July 14, 2015); *see also Burwell* v. *Hobby Lobby Stores*, Inc., 134 S. Ct. 2751, 2785 (2014). Second, instead of directly sending a copy of the self-certification form to the insurance provider, an eligible organization could simply notify the Department of Health and Human Services in writing, and the agencies then would inform the provider of its regulatory obligations. 80 Fed. Reg. at 41,323; *see also Wheaton Coll.* v. *Burwell*, 134 S. Ct. 2806, 2807 (2014).

Various employers then challenged the amended accommodation as a violation of the Religious Freedom Restoration Act (RFRA). *Zubik* v. *Burwell*, 136 S. Ct. 1557, 1559 (2016) (per curiam). The actions reached the Supreme Court, but, instead of deciding the merits of the claims, the Supreme Court vacated and remanded to afford the parties "an opportunity to arrive at an approach going forward that accommodates petitioners' religious exercise while at the same time ensuring that women covered by petitioners' health plans receive full and equal health coverage, including contraceptive coverage." *Id*. (internal quotation marks and citation omitted). The agencies solicited comments on the accommodation in light of *Zubik*, but ultimately declined to make further changes to the accommodation. Dep't of Labor, FAQs About Affordable Care Act Implementation Part 36, at 4, www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activiti es/resource-center/faqs/aca-part-36.pdf.

B.

On May 4, 2017, the President issued an executive order directing the secretaries of the agencies to "consider issuing amended regulations, consistent with applicable law, to address conscience-based objections

to" the ACA's contraceptive coverage requirement. Promoting Free Speech and Religious Liberty, Exec. Order No. 13,798, 82 Fed. Reg. 21,675, 21,675 (May 4, 2017). On October 6, 2017, the agencies effectuated the two IFRs challenged here, without prior notice and comment. The religious exemption IFR expanded the categorical exemption to all entities "with sincerely held religious beliefs objecting to contraceptive or sterilization coverage" and made the accommodation optional for such entities. Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,792, 47,807–08 (Oct. 13, 2017). The moral exemption IFR expanded the categorical exemption to "include additional entities and persons that object based on sincerely held moral convictions." Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,838, 47,849 (Oct. 13, 2017). It also "expand[ed] eligibility for the accommodation to include organizations with sincerely held moral convictions concerning contraceptive coverage" and made the accommodation optional for those entities. *Id.*

California, Delaware, Maryland, New York, and Virginia sued the agencies and their secretaries in the Northern District of California. The states sought to enjoin the enforcement of the IFRs, alleging that they are invalid under the Administrative Procedure Act (APA), the Fifth Amendment equal protection component of the Due Process Clause, and the First Amendment Establishment Clause. The district court held that venue was proper and that the states had standing to challenge the IFRs. The district court then

issued a nationwide preliminary injunction based on the states' likelihood of success on their APA claim—that the IFRs were procedurally invalid for failing to follow notice and comment rulemaking. After issuing the injunction, the district court allowed Little Sisters of the Poor, Jeanne Jugan Residence (Little Sisters) and March for Life Education and Defense Fund (March for Life) to intervene in the case.

The agencies, Little Sisters, and March for Life appeal from the district court's order on venue, standing, and nationwide preliminary injunction.

II.

Venue is reviewed de novo. *Immigrant Assistance Project of the L.A. Cty. Fed'n of Labor (AFL-CIO)* v. *INS*, 306 F.3d 842, 868 (9th Cir. 2002). Standing is also reviewed de novo. *Am.-Arab Anti-Discrimination Comm.* v. *Thornburgh*, 970 F.2d 501, 506 (9th Cir. 1991). Findings of fact used to support standing are reviewed for clear error. *Id.*

A preliminary injunction is reviewed for abuse of discretion. *Pimentel* v. *Dreyfus*, 670 F.3d 1096, 1105 (9th Cir. 2012). In reviewing the injunction, we apply a two-part test. First, we "determine de novo whether the trial court identified the correct legal rule to apply to the relief requested." *Id.* (quoting *Cal. Pharmacists Ass'n* v. *Maxwell-Jolly*, 596 F.3d 1098, 1104 (9th Cir. 2010). Second, we determine "if the district court's application of the correct legal standard was (1) illogical, (2) implausible, or (3) without support in inferences that may be drawn from the facts in the record." *Id.* (quoting *Cal. Pharmacists*, 596 F.3d at 1104). The scope of the preliminary injunction, such as its nationwide effect, is also reviewed for abuse of

discretion. *United States* v. *Schiff*, 379 F.3d 621, 625 (9th Cir. 2004).

III.

A.

We first address whether the appeal is moot. We have authority only to decide live controversies, and because mootness is a jurisdictional issue, we are obliged to raise it sua sponte. *Gator.com Corp.* v. *L.L. Bean, Inc.*, 398 F.3d 1125, 1129 (9th Cir. 2005) (en banc). We determine "questions of mootness in light of the present circumstances where injunctions are involved." *Mitchell* v. *Dupnik*, 75 F.3d 517, 528 (9th Cir. 1996). More specifically, the question before us is "whether changes in circumstances that prevailed at the beginning of litigation have forestalled any occasion for meaningful relief." *Gator.com*, 398 F.3d at 1129 (quoting *West* v. *Sec'y of the Dep't of Transp.*, 206 F.3d 920, 925 n.4 (9th Cir. 2000)).

On November 15, 2018, the agencies published final versions of the religious and moral exemption IFRs. *See* Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,536 (Nov. 15, 2018); Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,592 (Nov. 15, 2018). The final rules are set to supersede the IFRs and become effective on January 14, 2019. *Id*. The district court's preliminary injunction rested solely on its conclusion that the IFRs are likely to be procedurally invalid under the APA. If the final rules become effective as planned on January 14, there will be no justiciable controversy regarding the procedural

defects of IFRs that no longer exist. Indeed, we have previously dismissed a procedural challenge to an interim rule as moot after the rule expired. *Safari Aviation Inc.* v. *Garvey*, 300 F.3d 1144, 1150 (9th Cir. 2002); *see also NRDC* v. *U.S. Nuclear Regulatory Comm'n*, 680 F.2d 810, 814–15 (D.C. Cir. 1982) (holding that procedural challenge to a regulation promulgated in violation of notice and comment requirements was rendered moot by re-promulgation of rule with prior notice and comment); *The Gulf of Me. Fishermen's All.* v. *Daley*, 292 F.3d 84, 88 (1st Cir. 2002) ("[P]romulgation of new regulations and amendment of old regulations are among such intervening events as can moot a challenge to the regulation in its original form").

However, it is not yet January 14. We agree with the parties that mootness is not an issue until the final rules supersede the IFRs as expected on January 14, 2019. The IFRs have not been superseded yet, and the procedural validity of the IFRs is a live controversy. We can still grant the parties effective relief. Mootness, if at all, will arise only after our decision has issued. Accordingly, we have jurisdiction to decide this appeal.

B.

We hold that venue is proper in the Northern District of California. A civil action against an officer of the United States in his or her official capacity may "be brought in any judicial district in which * * * the plaintiff resides if no real property is involved in the action." 28 U.S.C. § 1391(e)(1). There is no real property involved here. The inquiry thus turns on which judicial district(s)—for a state with multiple districts like California—a state is considered to

reside. This is a question of first impression in this circuit.

The agencies argue that California resides only in the Eastern District of California, where the state capital is located. The agencies cite 28 U.S.C. § 1391(c), which defines residency for "a natural person," "an entity," and "a defendant not resident in the United States." Relevant here, "an entity with the capacity to sue and be sued * * * whether or not incorporated" is deemed to reside "only in the judicial district in which it maintains its principal place of business." *Id.* § 1391(c)(2). The agencies argue that California is an "entity" and that its capital Sacramento, located in the Eastern District of California, is the principal place of business for the state.

The agencies' argument is unconvincing. We must "interpret [the] statut[e] as a whole, giving effect to each word and making every effort not to interpret a provision in a manner that renders other provisions of the same statute inconsistent, meaningless or superfluous." *United States* v. *Thomsen*, 830 F.3d 1049, 1057 (9th Cir. 2016) (citation omitted and alterations in original). The venue statute explicitly refers to the incorporation status of the "entity," indicating that the term refers to some organization, not a state. *See* 28 U..S.C. § 1391(c)(2) ("an entity * * * whether or not incorporated"). The legislative history confirms this interpretation. According to the House Report underlying section 1391(c)(2), the section is a response to "division in authority as to the venue treatment of unincorporated associations" and that the section, as stated, would treat equally corporations and unincorporated associations like partnerships and labor unions. *See* H.R. Rep. No. 112-10, at 21 (2011).

These types of entities do not encompass sovereign states. Finally, we highlight that the statute explicitly distinguishes between states and entities. 28 U.S.C. § 1391(d); *see also Spencer Enters., Inc.* v. *United States*, 345 F.3d 683, 689 (9th Cir. 2003) ("[U]se of different words or terms within a statute demonstrates that Congress intended to convey a different meaning for those words"). The agencies therefore improperly assume, without support from the text or legislative history, that "entity" encompasses a state acting as a plaintiff.

Instead, we interpret the statute based on its plain language. A state is ubiquitous throughout its sovereign borders. The text of the statute therefore dictates that a state with multiple judicial districts "resides" in every district within its borders. *See Alabama* v. *U.S. Army Corps of Eng'rs*, 382 F. Supp. 2d 1301, 1329 (N.D. Ala. 2005) (holding that, for purposes of 28 U.S.C. § 1391(e), "common sense dictates that a state resides throughout its sovereign borders"); *see also Atlanta & F.R. Co.* v. *W. Ry. Co. of Ala.*, 50 F. 790, 791 (5th Cir. 1892) (discussing that "the state government * * * resides at every point within the boundaries of the state"). Any other interpretation limiting residency to a single district in the state would defy common sense. *See Silvers* v. *Sony Pictures Entm't, Inc.*, 402 F.3d 881, 900 (9th Cir. 2005) ("[C]ourts will not interpret a statute in a way that results in an absurd or unreasonable result"). Venue is thus proper in the Northern District of California.

C.

We hold that the states have standing to sue. The states bear the burden of establishing "the irreducible constitutional minimum" of standing. *Spokeo, Inc.* v.

Robins, 136 S. Ct. 1540, 1547 (2016) (internal quotation marks omitted). The states must have suffered an injury-in-fact that is fairly traceable to the challenged conduct and that is likely to be redressed by a favorable judicial decision. *Id*. The states must also demonstrate standing for each claim they seek to press. *DaimlerChrysler Corp.* v. *Cuno*, 547 U.S. 332, 352 (2006). Standing as to one claim does not "suffice for all claims arising from the same 'nucleus of operative fact.'" *Id*.

The district court held that the states had standing to assert their procedural APA claim. To establish an injury-in-fact, a plaintiff challenging the violation of a procedural right must demonstrate (1) that he has a procedural right that, if exercised, could have protected his concrete interests, (2) that the procedures in question are designed to protect those concrete interests, and (3) that the challenged action's threat to the plaintiff's concrete interests is reasonably probable. *Citizens for Better Forestry* v. *U.S. Dep't of Agric.*, 341 F.3d 961, 969–70 (9th Cir. 2003); *see also Spokeo*, 136 S. Ct. at 1540 (describing the applicable standards for Article III standing in the context of statutory procedural rights). "[D]eprivation of a procedural right without some concrete interest that is affected by the deprivation * * * is insufficient to create Article III standing." *Summers* v. *Earth Island Inst.*, 555 U.S. 488, 496 (2009). Relaxed standards apply to the traceability and redressability requirements. See *NRDC* v. *Jewell*, 749 F.3d 776, 782–83 (9th Cir. 2014) (en banc) ("One who challenges the violation of 'a procedural right to protect his concrete interests can assert that right without meeting all the normal standards' for traceability and redressibility." (quoting

Lujan v. *Defs. of Wildlife*, 504 U.S. 555, 572 n.7 (1992))). The plaintiff need not prove that the substantive result would have been different had he received proper procedure; all that is necessary is to show that proper procedure could have done so. *Citizens for Better Forestry*, 341 F.3d at 976.

The states argue that the agencies issued the religious and moral exemption IFRs without notice and comment as required under the APA. They argue that the deprivation of this procedural right affected their economic interests. According to the states, the IFRs expanded the number of employers categorically exempt from the ACA's contraceptive coverage requirement, and states will incur significant costs as a result of their residents' reduced access to contraceptive care. The states specifically identify three ways in which the IFRs will economically harm them. First, women who lose coverage will seek contraceptive care through state-run programs or programs that the states are responsible for reimbursing. Second, women who do not qualify for or cannot afford such programs will be at risk for unintended pregnancies, which impose financial costs on the state. Third, reduced access to contraceptive care will negatively affect women's educational attainment and ability to participate in the labor force, affecting their contributions as taxpayers. Because we conclude that the record supports the first theory, we do not reach the alternative theories. See, e.g., *Washington* v. *Trump*, 847 F.3d 1151, 1161 & n.5 (9th Cir. 2017) (per curiam) (holding that the plaintiffs had standing and declining to reach alternative theories of standing).

Appellants do not dispute that the states were denied notice and opportunity to comment on the IFRs prior to their effective date. They do not dispute that the notice and comment process could have protected and was designed to protect the states' economic interests. Instead, the appellants dispute whether the threat to the states' economic interests is reasonably probable. They argue that the allegations of economic injury are based on a speculative chain of events unlikely to occur. *Cf. Clapper* v. *Amnesty Int'l USA*, 568 U.S. 398, 414 (2013) (rejecting standing where "respondents' speculative chain of possibilities does not establish that injury * * * is certainly impending or is fairly traceable"). Appellants highlight how the states have failed to prove (1) that employers will take advantage of the expanded religious and moral exemptions, (2) that women will lose contraceptive coverage as a result, and (3) that states will then incur economic costs.

We hold that the states have standing to sue on their procedural APA claim. The states show, with reasonable probability, that the IFRs will first lead to women losing employer-sponsored contraceptive coverage, which will then result in economic harm to the states. *See Citizens for Better Forestry*, 341 F.3d at 969. Just because a causal chain links the states to the harm does not foreclose standing. *See Maya* v. *Centex Corp.*, 658 F.3d 1060, 1070 (9th Cir. 2011) ("A causal chain does not fail simply because it has several 'links,' provided those links are not hypothetical or tenuous" (internal quotation marks and citation omitted)). The states need not have already suffered economic harm. *See City of Sausalito* v. *O'Neill*, 386 F.3d 1186, 1197 (9th Cir. 2004) (requiring only that the protected

concrete interest be "threatened"). There is also no requirement that the economic harm be of a certain magnitude. *See United States* v. *Students Challenging Regulatory Agency Procedures (SCRAP)*, 412 U.S. 669, 689 n.14 (1973) (explaining that injuries of only a few dollars can establish standing).

First, it is reasonably probable that women in the plaintiff states will lose some or all employer-sponsored contraceptive coverage due to the IFRs. The agencies' own regulatory impact analysis (RIA)—which explains the anticipated costs, benefits, and effects of the IFRs— estimates that between 31,700 and 120,000 women nationwide will lose some coverage. *See* 82 Fed. Reg. at 47,821, 47,823. Importantly, when making these estimates, the agencies accounted for key factors likely to skew the estimate, including that some objecting employers will continue to use the accommodation instead of the new, expanded exemptions. *See id*. at 47,818 (estimating that 109 entities—of the 209 entities who have litigated the contraceptive care requirement and are currently using the accommodation process—would seek exemption); *id*. ("We expect the 122 nonprofit entities that specifically challenged the accommodation in court to use the expanded exemption"). The record also includes names of specific employers identified by the RIA as likely to use the expanded exemptions, including those operating in the plaintiff states like Hobby Lobby Stores, Inc. Appellants fault the states for failing to identify a specific woman likely to lose coverage. Such identification is not necessary to establish standing. For example, in *Sierra Forest Legacy* v. *Sherman*, California challenged a forest-management plan that

changed the standards governing logging on a parcel of land. 646 F.3d 1161, 1171–72 (9th Cir. 2011). The state's standing to do so was based on future injury resulting from any logging under the plan. *Id*. at 1178 (maj. op. of Fisher, J.). We emphasized that the state's standing to challenge the plan "is not defeated by its not having submitted affidavits establishing approval of specific logging projects under" the plan because "there is no real possibility that the [relevant agency] will * * * decline to adopt" any project under the plan. *Id*. at 1179. The same is true here. Evidence supports that, with reasonable probability, some women residing in the plaintiff states will lose coverage due to the IFRs.

Second, it is reasonably probable that loss of coverage will inflict economic harm to the states. The RIA estimates the direct cost of filling the coverage loss as $18.5 or $63.8 million per year, depending on the method of estimating. 82 Fed. Reg. at 47,821, 47,824. More importantly, the RIA identifies that state and local programs "provide free or subsidized contraceptives for low-income women" and concludes that this "existing inter-governmental structure for obtaining contraceptives significantly diminishes" the impact of the expanded exemptions. *Id*. at 47,803. The RIA itself thus assumed that state and local governments will bear additional economic costs.

The declarations submitted by the states further show that women losing coverage from their employers will turn to state-based programs or programs reimbursed by the state. For example, California offers the Family Planning, Access, Care, and Treatment (Family PACT) program to provide contraceptive care to those below 200% of the federal poverty level. As

attested to by program administrators, loss of coverage due to the IFRs will result in increased enrollment to Family PACT. Increased enrollment translates into, for example, the state reimbursing Planned Parenthood about $74.96 for each enrollee who receives contraceptive care. The states provided similar evidence for New York, Maryland, Delaware, and Virginia, which all have state-funded family planning programs.

Appellants dispute various factual findings underlying standing, but they do not explain how those findings are clearly erroneous. Appellants also argue that four of the plaintiff states—California, Delaware, Maryland, and New York—will not suffer harm because they have state laws that independently require certain employer-provided plans to cover contraceptive care. Those state laws do not apply to self-insured (also called self-funded) plans. See 29 U.S.C. § 1144(a) (preempting "any and all state laws" on this subject). Evidence shows that millions of people are covered, in each of the four states, under self-insured plans. For example, Hobby Lobby Stores, Inc. covers its employees through self-insured plans. *Hobby Lobby Stores, Inc.* v. *Sebelius*, 723 F.3d 1114, 1124 (10th Cir. 2013), *aff'd sub nom. Burwell* v. *Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014). Appellants' argument does not even apply to Virginia, which does not have any state law requiring coverage for contraceptive care.

Accordingly, the states have shown that the threat to their economic interest is reasonably probable, and they have established a procedural injury. *Cf. East Bay Sanctuary Covenant* v. *Trump*, No. 18-17274, 2018 WL 6428204, at *12 n.8 (9th Cir. Dec. 7, 2018) (order)

(holding that the plaintiffs "have adequately identified concrete interests impaired by the Rule and thus have standing to challenge the absence of notice-and-comment procedures in promulgating it"). "[T]he causation and redressability requirements are relaxed" once a plaintiff has established a procedural injury, *Citizens for Better Forestry*, 341 F.3d at 975 (quoting *Pub. Citizen* v. *Dep't of Transp.*, 316 F.3d 1002, 1016 (9th Cir. 2003)), and both requirements are met here. The injury asserted is traceable to the agencies' issuing the IFRs allegedly in violation of the APA's requirements, and granting an injunction would prohibit enforcement of the IFRs. The states have thus established standing.[1]

The dissent raises a theory not advanced by any party. According to the dissent, the states' economic injuries, if any, will be self-inflicted because the states voluntarily chose to provide money for contraceptive care to its residents through state programs. The dissent argues that the states lack standing because such "self-inflicted" injuries are not traceable to the agencies' conduct, citing *Pennsylvania* v. *New Jersey*, 426 U.S. 660 (1976) (per curiam). In *Pennsylvania*, the plaintiff states challenged other states' laws that

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[1] In addition to establishing constitutional standing, "[a] plaintiff must also satisfy the non-constitutional standing requirements of the statute under which [it] seeks to bring suit." *City of Sausalito*, 386 F.3d at 1199. In a single sentence, Little Sisters argues that the states lack statutory standing. This argument is waived. *See Greenwood* v. *FAA*, 28 F.3d 971, 977 (9th Cir. 1994) ("We review only issues which are argued specifically and distinctly in a party's opening brief * * * [and a] bare assertion does not preserve a claim" (citation omitted)); *Bilyeu* v. *Morgan Stanley Long Term Disability Plan*, 683 F.3d 1083, 1090 (9th Cir. 2012) (holding that "statutory standing may be waived").

increased taxes on nonresident income. 426 U.S. at 662–63. The plaintiff states provided tax credits to their residents for taxes paid to other states. *Id.* at 662. Accordingly, the defendant states' tax increases also increased the amount of tax credits provided by the plaintiff states, and the plaintiff states lost revenue. *Id.* In denying leave to file bills of complaint invoking the Supreme Court's original jurisdiction, the Court held that the plaintiff states could not "demonstrate that the injury for which [they sought] redress was directly caused by the actions of another State" because the injuries to the plaintiff states' fiscs "were self-inflicted * * * and nothing prevents [them] from withdrawing [the] credit for taxes paid to [defendant states]." *Id.* at 664.

We question whether the holding of *Pennsylvania* applies outside the specific requirements for the invocation of the Supreme Court's original jurisdiction. Courts regularly entertain actions brought by states and municipalities that face economic injury, even though those governmental entities theoretically could avoid the injury by enacting new legislation. *See, e.g., South Dakota* v. *Dole*, 483 U.S. 203 (1987) (addressing South Dakota's challenge to highway funding conditioned on a minimum drinking age, even though South Dakota could have avoided the injury by changing its minimum drinking age); *Gladstone Realtors* v. *Village of Bellwood*, 441 U.S. 91, 110–11 (1979) (holding that a municipality suffered an injury from a reduction in its property tax base, even though nothing required the municipality to impose property taxes). But we need not decide whether *Pennsylvania*'s "self-infliction" doctrine applies to the ordinary injury-in-fact requirement of Article III standing because, as

explained below, the injury here is not "self-inflicted" within the meaning of *Pennsylvania*.

The Supreme Court later held, in *Wyoming* v. *Oklahoma*, that Wyoming had standing to challenge an Oklahoma statute that decreased Wyoming's revenue—from tax on coal mined in Wyoming—by requiring Oklahoma power plants to burn at least 10% Oklahoma-mined coal. 502 U.S. 437, 447–48 (1992). The Court highlighted that Wyoming suffered a "direct injury in the form of a loss of specific tax revenues" from the reduced demand for Wyoming coal caused by the Oklahoma statute. *Id*. at 448.

Both *Pennsylvania* and *Wyoming* involved harm to the plaintiff states' fiscs that were, as described by the dissent, "self-inflicted." What distinguishes the two cases, and what caused the Supreme Court to reach different results, is that the plaintiff states' laws in *Pennsylvania* directly and explicitly tied the states' finances (revenue loss caused by tax credit) to another sovereign's laws (other states' taxes on nonresident income). *See Maryland* v. *Louisiana*, 451 U.S. 725, 742 n.18 (1981) ("In *Pennsylvania*, the only reason that the complaining States were denied tax revenues was because their legislatures had determined to give a credit for taxes paid to other States, and, to this extent, any injury was voluntarily suffered"). *Wyoming* did not involve such state laws; the tax on Wyoming-mined coal was not so tethered to the legislative decisions of other sovereigns. The same is true of the contraceptive coverage laws of the plaintiff states here. Accordingly, we are not convinced that Pennsylvania controls in this case. *Cf. Texas* v. *United States*, 809 F.3d 134, 158–59 (5th Cir. 2015), *as revised* (Nov. 25, 2015); *Texas* v. *United States*, 787 F.3d 733, 749 n.34 (5th Cir. 2015).

D.

We affirm the preliminary injunction insofar as it bars enforcement of the IFRs in the plaintiff states, but we otherwise vacate the portion of the injunction barring enforcement in other states. The scope of the injunction is overbroad.

A preliminary injunction is a matter of equitable discretion and is "an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter* v. *NRDC*, 555 U.S. 7, 22 (2008) (citation omitted). "A party can obtain a preliminary injunction by showing that (1) it is 'likely to succeed on the merits,' (2) it is 'likely to suffer irreparable harm in the absence of preliminary relief,' (3) 'the balance of equities tips in [its] favor,' and (4) 'an injunction is in the public interest.'" *Disney Enters., Inc.* v. *VidAngel, Inc.*, 869 F.3d 848, 856 (9th Cir. 2017) (alteration in original) (quoting *Winter*, 555 U.S. at 20). When the government is a party, the last two factors merge. *Drakes Bay Oyster Co.* v. *Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014).

1.

Likelihood of success on the merits is "the most important" factor; if a movant fails to meet this "threshold inquiry," we need not consider the other factors. *Disney*, 869 F.3d at 856 (citation omitted). The district court held that the states are likely to succeed on the merits of their APA claim. We agree.

The APA requires that, prior to promulgating rules, an agency must issue a general notice of proposed rulemaking, 5 U.S.C. § 553(b), and "give interested persons an opportunity to participate in the rule making through submission of written data, views or

arguments," *id.* § 553(c). A court must set aside rules made "without observance of [this] procedure." *Id.* § 706(2)(D). Again, the parties do not dispute that the religious and moral exemption IFRs were issued without notice and comment. The only remaining issue is whether prior notice and comment was not required because an exception to this rule applied.

Exceptions to notice and comment rulemaking "are not lightly to be presumed." *Marcello* v. *Bonds*, 349 U.S. 302, 310 (1955). "[I]t is antithetical to the structure and purpose of the APA for an agency to implement a rule first, and then seek comment later." *Paulsen* v. *Daniels*, 413 F.3d 999, 1005 (9th Cir. 2005). Failure to follow notice and comment rulemaking may be excused when good cause exists, 5 U.S.C. § 553(b)(B); when a subsequent statute authorizes it, *id.* § 559; and when it is harmless, *id.* § 706. Appellants argue that each of these three exceptions applies here.

We begin by examining whether the agencies had good cause for bypassing notice and comment. An agency may "for good cause find[]* * * that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(B). "[T]he good cause exception goes only as far as its name implies: It authorizes departures from the APA's requirements only when compliance would interfere with the agency's ability to carry out its mission." *Riverbend Farms, Inc.* v. *Madigan*, 958 F.2d 1479, 1485 (9th Cir. 1992). Good cause is to be "narrowly construed and only reluctantly countenanced." *Alcaraz* v. *Block*, 746 F.2d 593, 612 (9th Cir. 1984) (citation omitted). As such, the good cause exception is usually invoked in emergencies, and an agency must "overcome a high bar" to do so. *United*

States v. *Valverde*, 628 F.3d 1159, 1164–65 (9th Cir. 2010). Because good cause is determined on a "case-by-case" basis, based on "the totality of the factors at play," *Valverde*, 628 F.3d at 1164 (quoting *Alcaraz*, 746, F.2d at 612), prior invocations of good cause to justify different IFRs—the legality of which are not challenged here—have no relevance.[2]

In the past, we have acknowledged good cause where the agency cannot "both follow section 553 and execute its statutory duties." *Riverbend*, 958 F.2d at 1484 n.2 (quoting *Levesque* v. *Block*, 723 F.2d 175, 184 (1st Cir. 1983)). We have also acknowledged good cause where "'delay would do real harm' to life, property, or public safety." *East Bay Sanctuary Covenant*, 2018 WL 6428204, at *20 (quoting *Valverde*, 628 F.3d at 1165); see also *Haw. Helicopter Operators Ass'n* v. *FAA*, 51 F.3d 212, 214 (9th Cir. 1995) (good cause shown based on threat reflected in an increasing number of helicopter accidents); *Jifry* v. *FAA*, 370 F.3d 1174, 1179 (D.C. Cir. 2004) (upholding good cause determination that the rule was "necessary to prevent a possible imminent hazard to aircraft, persons, and property within the United States").

The agencies here determined that "it would be impracticable and contrary to the public interest to engage in full notice and comment rulemaking before putting these [IFRs] into effect." *See, e.g.,* 82 Fed. Reg.

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[2] The Little Sisters argue that if the court invalidates the IFRs here, the court must also invalidate prior ones related to the exemption and accommodation. This argument is unpersuasive. Whether or not those IFRs were promulgated with good cause, they are not before us at this time.

at 47,815; see also 82 Fed. Reg. at 47,856. They recited the immediate need to (1) reduce the legal and regulatory uncertainty regarding the accommodation in the wake of *Zubik*, (2) eliminate RFRA violations by reducing the burden on religious beliefs of objecting employers, and (3) reduce the costs of health insurance.[3] 82 Fed. Reg. at 47,813–15; 82 Fed. Reg. at 47,855–56. These general policy justifications are insufficient to establish good cause.

First, an agency's desire to eliminate more quickly legal and regulatory uncertainty is not by itself good cause. *See Valverde*, 628 F.3d at 1167 (concluding that an agency's "interest in eliminating uncertainty does not justify its having sought to forego notice and comment"). "If 'good cause' could be satisfied by an Agency's assertion that 'normal procedures were not followed because of the need to provide immediate guidance and information[,] * * * then an exception to the notice requirement would be created that would swallow the rule.'" *Id*. (alterations in original) (quoting *Zhang* v. *Slattery*, 55 F.3d 732, 746 (2d Cir. 1995)); see also *Envtl. Def. Fund, Inc.* v. *EPA*, 716 F.2d 915, 920–21 (D.C. Cir. 1983) ("[I]t was not at all reasonable for [the agency] to rely on the good cause exception" simply because of "an alleged pressing need to avoid industry compliance with regulations that were to be eliminated"). Furthermore, the agencies' request for

[3] Little Sisters argues that the agencies had good cause because the prior regulatory regime violated the Free Exercise Clause and the Establishment Clause. This assertion was not part of the agencies' original good cause findings, and we may not consider it now. *See Motor Vehicle Mfrs. Ass'n of U.S., Inc.* v. *State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983) ("[A]n agency's action must be upheld, if at all, on the basis articulated by the agency itself").

post-promulgation comments in issuing the IFRs "casts further doubt upon the authenticity and efficacy of the asserted need to clear up potential uncertainty," *Valverde*, 628 F.3d at 1166, because allowing for post-promulgation comments implicitly suggests that the rules will be reconsidered and that the "level of uncertainty is, at best, unchanged," *United States* v. *Reynolds*, 710 F.3d 498, 510 (3d Cir. 2013) (citing *United States* v. *Johnson*, 632 F.3d 912, 929 (5th Cir. 2011)). This explanation therefore fails. It is always the case that an agency can regulate—or in this case, de-regulate—faster by issuing an IFR without notice and comment.

Second, we of course acknowledge that eliminating RFRA violations by reducing the burden on religious beliefs is an important consideration for the agencies. Any delay in rectifying violations of statutory rights has the potential to do real harm. *See Buschmann* v. *Schweiker*, 676 F.2d 352, 357 (9th Cir. 1982) ("The notice and comment procedures in Section 553 should be waived only when delay would do real harm"). Whether the accommodation actually violates RFRA is a question left open by the Supreme Court.[4] *See Zubik*, 136 S. Ct. at 1560. But we need not determine whether there is a RFRA violation here because, even if immediately remedying the RFRA violation constituted good cause, the agencies' reliance on this justification was not a reasoned decision based on

[4] Before *Zubik*, eight courts of appeals (of the nine to have considered the issue) have found that the regulatory regime in place prior to the IFRs did not impose a substantial burden on religious exercise under RFRA. *See, e.g., E. Tex. Baptist Univ.* v. *Burwell*, 793 F.3d 449 (5th Cir. 2015), vacated, *Zubik*, 136 S. Ct. at 1561.

findings in the record. See *Valverde*, 628 F.3d at 1165, 1168 (agencies must provide "rational justification" and identify "rational connection between the facts found and the choice made to promulgate the interim rule" (internal quotation marks and citation omitted)). In January 2017, the agencies explicitly declined to change the accommodation in light of *Zubik* and RFRA. They then let nine months go by and failed to specify what developments necessitated the agencies to change their position and determine, in October 2017, that RFRA violations existed. *Cf. id*. at 1166 (reasoning that agency finding of urgent need was inadequate when agency had allowed seven months to pass without action). The agencies provided no explanation, legal or otherwise, for their changed understanding. *Cf. Encino Motorcars, LLC* v. *Navarro*, 136 S. Ct. 2117, 2125–26 (2016) (holding that an agency's unexplained change in position does not warrant deference); *East Bay Sanctuary Covenant*, 2018 WL 6428204, at *20 (concluding that "speculative" reasoning is insufficient to support good cause). The IFRs are devoid of any findings related to the issue. Indeed, the agencies cited no intervening legal authority for their justification, in contrast to when they issued an IFR in light of Wheaton. Given these failures, the agency action cannot be upheld on unexplained about-face.

The agencies further argue that the new IFRs will decrease insurance costs for entities remaining on more expensive grandfathered plans—which are exempt from the contraceptive coverage requirement—to avoid becoming subject to the requirement. 82 Fed. Reg. at 47,815; 82 Fed. Reg. at 47,855–56. This is speculation unsupported by the administrative record and is not sufficient to constitute good cause. *See*

Valverde, 628 F.3d at 1167 ("[C]onclusory speculative harms the [agency] cites are not sufficient" (citation omitted)).

We also highlight that there was no urgent deadline to issue the IFRs that interfered with the agencies from complying with the APA.[5] Congress had not imposed a deadline here on agency decisionmaking that interfered with compliance. The President's executive order merely asks the agencies to "consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate." 82 Fed. Reg. at 21,675. Neither did the Supreme Court mandate any deadline when it remanded the last challenge to the accommodation in order to give parties "an opportunity to arrive at an approach going forward." *Zubik*, 136 S. Ct. at 1560.

The agencies cite two cases in support of their good cause claim: *Priests For Life* v. *U.S. Dep't of Health & Human Servs.*, 772 F.3d 229 (D.C. Cir. 2014), *vacated and remanded sub nom. Zubik*, 136 S. Ct. at 1557; and *Serv. Employees Int'l Union, Local 102* v. *Cty. of San Diego*, 60 F.3d 1346 (9th Cir. 1994). Both are distinguishable. The D.C. Circuit in *Priests for Life* rejected the plaintiffs' argument that the government lacked good cause to promulgate IFRs without notice and comment. 772 F.3d at 276–77. In so holding, it emphasized that the IFRs modified existing

[5] We also point out that the agencies have not displayed urgency in reaching final resolution of this case. After filing this appeal from the district court's order granting a preliminary injunction, the agencies filed a stipulation staying further district court proceedings pending resolution of the appeal. Before the district court, this case has remained in abeyance for nearly a year.

regulations that "were recently enacted pursuant to notice and comment rulemaking, and presented virtually identical issues" as the challenged IFRs. *Id.* at 276 (emphasis added); see also *id.* (describing the modifications in the new IFRs as "minor"). The IFRs here do not present minor changes. They substantially expanded the categorical exemption and effectively made accommodations voluntary. The IFRs also introduced an entirely new moral exemption that had never been the subject of previous regulations. These substantial changes came after the agencies previously determined that no change to the religious accommodation process was needed in light of RFRA. In *Serv. Employees Int'l Union*, we held that resolving uncertainty caused by conflicting judicial decisions is sufficient good cause. 60 F.3d at 1352 n.3. In that case, resolving uncertainty was sufficient because the agencies found that conflicting decisions were poised to cause "enormous" and "unforeseen" financial liability "threaten[ing] [the] fiscal integrity" of state and local governments. *Id.* When issuing the IFRs here, the agencies cited no such comparable financial threat.

Accordingly, based on the totality of the circumstances, the agencies likely did not have good cause for bypassing notice and comment.

We next turn to whether the agencies had statutory authority for bypassing notice and comment. The APA cautions "that no subsequent statute shall be deemed to modify it 'except to the extent that it does so expressly.'" *Castillo-Villagra* v. *INS*, 972 F.2d 1017, 1025 (9th Cir. 1992) (quoting 5 U.S.C. § 559); *see also Asiana Airlines* v. *FAA*, 134 F.3d 393, 397 (D.C. Cir. 1998) (defining the inquiry as "whether Congress has established procedures so clearly different from those

required by the APA that it must have intended to displace the norm"). The agencies point to three statutory provisions enacted as part of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). These provisions specify:

> The Secretary, consistent with section 104 of the Health [Insurance] Portability and Accountability Act of 1996, may promulgate such regulations as may be necessary or appropriate to carry out the provisions of this subchapter. The Secretary may promulgate any interim final rules as the Secretary determines are appropriate to carry out this subchapter.

26 U.S.C. § 9833; 29 U.S.C. § 1191c; 42 U.S.C. § 300gg-92. When enacting the ACA, Congress codified the contraceptive coverage requirement in the same chapters of the United States Code as those provisions. The agencies argue that the provisions authorize them to issue IFRs implementing the ACA without notice and comment.

Their argument likely fails. The identified provisions authorize agencies to issue IFRs, but they are silent as to any required procedure for issuing an IFR. They do not provide that notice and comment is supplanted or that good cause is no longer required. They neither contain express language exempting agencies from the APA nor provide alternative procedures that could reasonably be understood as departing from the APA. *See Castillo-Villagra*, 972 F.2d at 1025 (holding that a subsequent statute must "expressly" modify the APA). These provisions thus stand in contrast to other provisions that we have found to be express abdications of the APA. *See, e.g.*, *id*. (holding that APA was supplanted by statute that

stated "the procedure so prescribed shall be the sole and exclusive procedure for determining the deportability of an alien under this section" (internal quotation marks omitted)); *Methodist Hosp. of Sacramento* v. *Shalala*, 38 F.3d 1225, 1236 n.18 (D.C. Cir. 1994) (holding that APA was supplanted by statute that stated "[t]he Secretary shall cause to be published in the Federal Register a notice of the interim final DRG prospective payment rates" (emphasis added)).

The agencies insist that we must read HIPAA's use of the word "interim" as singlehandedly authorizing the agencies to issue IFRs without notice and comment whenever the agencies deem it appropriate. Otherwise, the agencies warn, we will be rendering superfluous the second sentence of the quoted provisions. We disagree.

The first sentence of the quoted provisions authorizes the issuance of regulations "consistent with section 104 of the Health [Insurance] Portability and Accountability Act of 1996." Section 104 of HIPAA, entitled "Assuring Coordination," generally requires the three Secretaries to coordinate their regulations and policies.[6] Notably, the second sentence of the

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[6] Section 104 states:

> The Secretary of the Treasury, the Secretary of Health and Human Services, and the Secretary of Labor shall ensure, through the execution of an interagency memorandum of understanding among such Secretaries, that—
>
> (1) regulations, rulings, and interpretations issued by such Secretaries relating to the same matter over which

quoted provisions does not contain the same consistency requirement; each Secretary is authorized to issue IFRs without ensuring consistency with the rules of his or her partner Secretaries. Reading both sentences together, Congress authorized the Secretaries to issue coordinated final rules in the ordinary course; and, if a Secretary met an inter-agency impasse but needed to regulate within his or her own domain temporarily while sorting out the inter-agency conflict, then a Secretary could issue an interim final rule. In this procedural posture, we need not delimit the full scope of the second sentence of the quoted provisions. For present purposes, it suffices to observe that we need not give the second sentence the agencies' expansive interpretation in order for the second sentence to retain independent effect.

Accordingly, the agencies likely did not have statutory authority for bypassing notice and comment.

We last turn to whether bypassing notice and comment was harmless. The court "must exercise great caution in applying the harmless error rule in the administrative rulemaking context." *Riverbend*, 958 F.2d at 1487. "[T]he failure to provide notice and

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two or more such Secretaries have responsibility under this subtitle (and the amendments made by this subtitle and section 401) are administered so as to have the same effect at all times; and

(2) coordination of policies relating to enforcing the same requirements through such Secretaries in order to have a coordinated enforcement strategy that avoids duplication of enforcement efforts and assigns priorities in enforcement. Pub. L. No. 104-191, § 401, 110 Stat. 1976 (1996) (codified at 42 U.S.C. § 300gg-92 note).

comment is harmless only where the agency's mistake 'clearly had no bearing on the procedure used or the substance of decision reached.'" *Id.* (quoting *Sagebrush Rebellion, Inc.* v. *Hodel*, 790 F.2d 760, 764–65 (9th Cir. 1986)).

The circumstances here are similar to those in *Paulsen*, 413 F.3d at 1006. There, the Bureau of Prisons "failed to provide the required notice-and-comment period before effectuating [an] interim regulation, thereby precluding public participation in the rulemaking." *Id*. We held the error not harmless because "petitioners received no notice of any kind until after the Bureau made the * * * interim rule effective." *Id*. at 1007. We further emphasized that "an opportunity to protest an already-effective rule" did not render the violation harmless. *Id*. (emphasis added). We distinguished from prior cases where "interested parties received some notice that sufficiently enabled them to participate in the rulemaking process before the relevant agency adopted the rule." *Id*. (citing cases). The agencies' actions here are analogous. No members of the public received notice of the IFRs or were able to comment prior to their effective dates.

Appellants argue that the states "were afforded multiple opportunities to comment on the scope of the exemption and accommodation during multiple rounds of rulemaking." These "opportunities" refer to public comment on prior rules regarding the religious exemption and accommodation. Appellants' argument does not convince us. As previously discussed, those prior rules were materially different from the IFRs here, which dramatically expanded the scope of the religious exemption and introduced a moral exemption that was not the subject of any previous round of notice

and comment rulemaking. The public had no such notice or opportunity to comment on these potential changes, thus denying it the safeguards of the notice and comment procedure. This denial is comparable to failing to provide prior notice and comment before finalizing a rule that is not a "logical outgrowth" of the proposed rule, which an agency may not do without considering "whether a new round of notice and comment would provide the first opportunity for interested parties to offer comments that could persuade the agency to modify its rule." *NRDC* v. *EPA*, 279 F.3d 1180, 1186 (9th Cir. 2002) (citation omitted); *see also CSX Transp., Inc.* v. *Surface Transp. Bd.*, 584 F.3d 1076, 1081 (D.C. Cir. 2009) (holding that notice of a proposed rule is sufficient to uphold a final rule if interested parties "should have anticipated" the content of the rule). Accordingly, the prior "opportunities" are irrelevant.

The agencies argue that the states have failed to identify any specific comment that they would have submitted. There is no such requirement for harmless error analysis. The agencies also argue that the states had an opportunity to comment on the IFRs post-issuance and that the agencies will consider the comments before issuing final rules. This argument also fails. "The key word in the title 'Interim Final Rule' * * * is not interim, but final. 'Interim' refers only to the Rule's intended duration—not its tentative nature." *Career Coll. Ass'n* v. *Riley*, 74 F.3d 1265, 1268 (D.C. Cir. 1996). We reiterate that "an opportunity to protest an already-effective rule" does not render an APA violation harmless. *Paulsen*, 413 F.3d at 1007 (emphasis added).

Accordingly, bypassing notice and comment likely was not harmless.

2.

A plaintiff seeking preliminary relief must "demonstrate that irreparable injury is likely in the absence of an injunction." *Winter*, 555 U.S. at 22 (emphasis omitted). The analysis focuses on irreparability, "irrespective of the magnitude of the injury." *Simula, Inc.* v. *Autoliv, Inc.*, 175 F.3d 716, 725 (9th Cir. 1999).

The district court concluded that the states are likely to suffer irreparable harm absent an injunction. This decision was not an abuse of discretion. As discussed in our standing analysis, it is reasonably probable that the states will suffer economic harm from the IFRs. Economic harm is not normally considered irreparable. *L.A. Mem'l Coliseum Comm'n* v. *Nat'l Football League*, 634 F.2d 1197, 1202 (9th Cir. 1980). However, such harm is irreparable here because the states will not be able to recover monetary damages connected to the IFRs. *See* 5 U.S.C. § 702 (permitting relief "other than money damages"); *see also Cottonwood Envtl. Law Ctr.* v. *U.S. Forest Serv.*, 789 F.3d 1075, 1091 (9th Cir. 2015) (reaffirming that the harm flowing from a procedural violation can be irreparable). That the states promptly filed an action following the issuance of the IFRs also weighs in their favor. *Cf. Oakland Tribune, Inc.* v. *Chronicle Publ'g Co., Inc.*, 762 F.2d 1374, 1377 (9th Cir. 1985) ("Plaintiff's long delay before seeking a preliminary injunction implies a lack of urgency and irreparable harm").

Again, appellants argue that the economic harm is speculative, which "does not constitute irreparable injury sufficient to warrant granting a preliminary injunction." *See Boardman* v. *Pac. Seafood Grp.*, 822 F.3d 1011, 1022 (9th Cir. 2016) (citation omitted). As we previously explained in our analysis of standing, the harm is not speculative; it is sufficiently concrete and supported by the record. Appellants also dispute the factual findings underlying the district court's holding of irreparable harm, but again fail to explain how the district court erred under our standard of review.

3.

Because the government is a party, we consider the balance of equities and the public interest together. *Jewell*, 747 F.3d at 1092.

The IFRs are an attempt to balance states' interest in "ensuring coverage for contraceptive and sterilization services" with appellants' interest in "provid[ing] conscience protections for individuals and entities with sincerely held religious [or moral] beliefs in certain health care contexts." 82 Fed. Reg. at 47,793. The district court concluded that the balance of equities and the public interest tip in favor of granting the preliminary injunction. The district court did not abuse its discretion.

The public interest is served by compliance with the APA: "The APA creates a statutory scheme for informal or notice-and-comment rulemaking reflecting a judgment by Congress that the public interest is served by a careful and open review of proposed administrative rules and regulations." *Alcaraz*, 746 F.2d at 610 (internal quotation marks and citation

omitted). It does not matter that notice and comment could have changed the substantive result; the public interest is served from proper process itself. *Cf. Citizens for Better Forestry*, 341 F.3d at 976 (stating, in standing context, that "[i]t suffices that the agency's decision could be influenced" by public participation (alterations and citation removed) (emphasis in original)). The district court additionally found that the states face "potentially dire public health and fiscal consequences as a result of a process as to which they had no input" and highlighted the public interest in access to contraceptive care. This finding is sufficiently supported by the record.

We acknowledge that free exercise of religion and conscience is undoubtedly, fundamentally important. Regardless of whether the accommodation violates RFRA, some employers have sincerely-held religious and moral objections to the contraceptive coverage requirement. *Cf. Jolly* v. *Coughlin*, 76 F.3d 468, 482 (2d Cir. 1996) ("[A]lthough the plaintiff's free exercise claim is statutory rather than constitutional, the denial of the plaintiff's right to the free exercise of his religious beliefs is a harm that cannot be adequately compensated monetarily"). Protecting religious liberty and conscience is obviously in the public interest. However, balancing the equities is not an exact science. *See also Youngstown Sheet & Tube Co.* v. *Sawyer*, 343 U.S. 579, 609 (1952) (Frankfurter, J., concurring) ("Balancing the equities * * * is lawyers' jargon for choosing between conflicting public interests"). We do not have a sufficient basis to second guess the district court and to conclude that its decision was illogical, implausible, or without support in the record. Finalizing that issue must await any appeal from the

district court's future determination of whether to issue a permanent injunction.

E.

The district court enjoined enforcement of the IFRs nationwide because the agencies "did not violate the APA just as to Plaintiffs: no member of the public was permitted to participate in the rulemaking process via advance notice and comment." The district court abused its discretion in granting a nationwide injunction. *See Stormans, Inc.* v. *Selecky*, 586 F.3d 1109, 1140 (9th Cir. 2009) ("[A]n overbroad injunction is an abuse of discretion" (quoting *Lamb-Weston, Inc.* v. *McCain Foods, Ltd.*, 941 F.2d 970, 974 (9th Cir. 1991)). We vacate the portion of the injunction barring enforcement of the IFRs in non-plaintiff states.

Crafting a preliminary injunction is "an exercise of discretion and judgment, often dependent as much on the equities of a given case as the substance of the legal issues it presents." *Trump* v. *Int'l Refugee Assistance Project*, 137 S. Ct. 2080, 2087 (2017). "The purpose of such interim equitable relief is not to conclusively determine the rights of the parties but to balance the equities as the litigation moves forward." *Id.* (citation omitted). Although "there is no bar against * * * nationwide relief in federal district court or circuit court," such broad relief must be "necessary to give prevailing parties the relief to which they are entitled." *Bresgal* v. *Brock*, 843 F.2d 1163, 1170–71 (9th Cir. 1987) (emphasis in original removed in part); *see also Califano* v. *Yamasaki*, 442 U.S. 682, 702 (1979) ("[I]njunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs" before the court). This rule applies with special force where there is no class

certification.[7] *See Easyriders Freedom F.I.G.H.T.* v. *Hannigan*, 92 F.3d 1486, 1501 (9th Cir. 1996) ("[I]njunctive relief generally should be limited to apply only to named plaintiffs where there is no class certification").

Before we examine the scope of the injunction here, we highlight several concerns associated with overbroad injunctions, particularly nationwide ones. Our concerns underscore the exercise of prudence before issuing such an injunction. First, "nationwide injunctive relief may be inappropriate where a regulatory challenge involves important or difficult questions of law, which might benefit from development in different factual contexts and in multiple decisions by the various courts of appeals." *L.A. Haven Hospice, Inc.* v. *Sebelius*, 638 F.3d 644, 664 (9th Cir. 2011). The Supreme Court has repeatedly emphasized that nationwide injunctions have detrimental consequences to the development of law and deprive appellate courts of a wider range of perspectives. *See Califano*, 442 U.S. at 702 (highlighting that nationwide injunctions "have a detrimental effect by foreclosing adjudication by a number of different courts and judges"); *United States* v. *Mendoza*, 464 U.S. 154, 160 (1984) (concluding that allowing nonmutual collateral estoppel against the government would "substantially thwart the development of important questions of law by freezing the first final decision rendered on a particular legal

[7] Indeed, Congress has recently proposed a bill that would prohibit injunctions involving non-parties "unless the non-party is represented by a party acting in a representative capacity pursuant to the Federal Rules of Civil Procedure." H.R. 6730, 115th Cong. (2018).

issue" and "deprive [the Supreme] Court of the benefit it receives from permitting several courts of appeals to explore a difficult question before [the Supreme] Court grants certiorari"); *Arizona* v. *Evans*, 514 U.S. 1, 23 n.1 (1995) (Ginsburg, J., dissenting) ("We have in many instances recognized that when frontier legal problems are presented, periods of 'percolation' in, and diverse opinions from, state and federal appellate courts may yield a better informed and more enduring final pronouncement by this Court").

The detrimental consequences of a nationwide injunction are not limited to their effects on judicial decisionmaking. There are also the equities of non-parties who are deprived the right to litigate in other forums. *See* Zayn Siddique, *Nationwide Injunctions*, 117 Colum. L. Rev. 2095, 2125 (2017) ("A plaintiff may be correct that a particular agency action is unlawful or unduly burdensome, but remedying this harm with an overbroad injunction can cause serious harm to nonparties who had no opportunity to argue for more limited relief"). Short of intervening in a case, non-parties are essentially deprived of their ability to participate, and these collateral consequences are not minimal. Nationwide injunctions are also associated with forum shopping, which hinders the equitable administration of laws. *See* Samuel L. Bray, *Multiple Chancellors: Reforming the National Injunction*, 131 Harv. L. Rev. 417, 458–59 (2017) (citing five nationwide injunctions issued by Texas district courts in just over a year).

These consequences are magnified where, as here, the district court stays any effort to prepare the case for trial pending the appeal of a nationwide preliminary injunction. We have repeatedly

admonished district courts not to delay trial preparation to await an interim ruling on a preliminary injunction. *See, e.g.*, *Melendres* v. *Arpaio*, 695 F.3d 990, 1002–03 (9th Cir. 2012); Global *Horizons, Inc.* v. *U.S. Dep't of Labor*, 510 F.3d 1054, 1058 (9th Cir. 2007). "Because of the limited scope of our review of the law applied by the district court and because the fully developed factual record may be materially different from that initially before the district court, our disposition of appeals from most preliminary injunctions may provide little guidance as to the appropriate disposition on the merits." *Id.* at 1003 (quoting *Sports Form, Inc.* v. *United Press Int'l, Inc.*, 686 F.2d 750, 753 (9th Cir. 1982)). The district court here failed to give any particular reason for the stay,[8] and this case could have well proceeded to a disposition on the merits without the delay in processing the interlocutory appeal. "Given the purported urgency of" implementing the IFRs, the agencies and intervenors might "have been better served to pursue aggressively" its defense of the IFRs in the district court, "rather than apparently awaiting the outcome of this appeal." *Global Horizons*, 510 F.3d at 1058.

In light of these concerns, we now address the preliminary injunction issued here. The scope of the remedy must be no broader and no narrower than necessary to redress the injury shown by the plaintiff states. The plaintiff states argue that complete relief to them would require enjoining the IFRs in all of their

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[8] The district court stayed the case pending the outcome of this appeal based on the parties' stipulation. The order staying the case provides no other justification or analysis supporting the stay.

applications nationwide. That is not necessarily the case. *See L.A. Haven Hospice*, 638 F.3d at 665 (vacating the nationwide portion of an injunction barring the enforcement of a facially invalid regulation); *City & Cty. of San Francisco* v. *Trump*, 897 F.3d 1225, 1244–45 (9th Cir. 2018) (vacating nationwide portion of injunction barring enforcement of executive order). The scope of an injunction is "dependent as much on the equities of a given case as the substance of the legal issues it presents," and courts must tailor the scope "to meet the exigencies of the particular case." *Int'l Refugee Assistance Project*, 137 S. Ct. at 2087 (citations omitted). The circumstances of this case dictate a narrower scope.

On the present record, an injunction that applies only to the plaintiff states would provide complete relief to them. It would prevent the economic harm extensively detailed in the record. Indeed, while the record before the district court was voluminous on the harm to the plaintiffs, it was not developed as to the economic impact on other states. *See City & Cty. of San Francisco*, 897 F.3d at 1231, 1244–45 (holding that the district court abused its discretion in issuing a nationwide injunction because the plaintiffs' "tendered evidence is limited to the effect of the Order on their governments and the State of California" and because "the record is not sufficiently developed on the nationwide impact of the Executive Order"). The injunction must be narrowed to redress only the injury shown as to the plaintiff states.[9]

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[9] Appellants did not clearly raise other arguments in support of a narrower injunction, including the potential for "substantial

Accordingly, we conclude that the scope of the preliminary injunction is overbroad and that the district court abused its discretion in that regard. District judges must require a showing of nationwide impact or sufficient similarity to the plaintiff states to foreclose litigation in other districts, from Alaska to Puerto Rico to Maine to Guam.

IV.

We affirm that venue is proper in the Northern District of California. We affirm that the plaintiff states have standing to sue. Although we affirm the preliminary injunction, the record does not support the injunction's nationwide scope. We vacate the portion of the injunction barring enforcement of the IFRs in other states and remand to the district court. This panel will retain jurisdiction for any subsequent appeals arising from this case. Costs on appeal are awarded to Plaintiffs-Appellees. The mandate shall issue forthwith.

AFFIRMED IN PART, VACATED IN PART, and REMANDED.

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interference with another court's sovereignty," *United States* v. *AMC Entm't, Inc.*, 549 F.3d 760, 770 (9th Cir. 2008), and the lack of need for courts to apply the law uniformly. Accordingly, we do not address them.

KLEINFELD, Senior Circuit Judge, dissenting:

I respectfully dissent. The plaintiff state governments lack standing, so the district court lacked jurisdiction. The reason they lack standing is that their injury is what the Supreme Court calls "self-inflicted," because it arises solely from their legislative decisions to pay these moneys. Under the Supreme Court's decision in *Pennsylvania* v. *New Jersey*,[1] we are compelled to reverse.

Pennsylvania sued New Jersey on the theory that a new New Jersey tax law caused the Pennsylvania fisc to collect less money.[2] Pennsylvania granted a tax credit for income taxes paid to other states, and New Jersey under its new tax law had begun taxing the New Jersey-derived income of nonresidents.[3] Maine, Massachusetts, and Vermont sued New Hampshire on similar grounds.[4] The concrete financial injury was plain in all these cases. Like the plaintiff states' injury in the case before us, the reason why was the plaintiff states' laws.[5]

The Court in *Pennsylvania* invoked the long established principle that under *Massachusetts* v. *Missouri*,[6] the injuries for which redress was sought had to be "directly caused" by the defendant states.[7]

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[1] 426 U.S. 660 (1976) (per curiam).
[2] *Id*. at 662.
[3] *Id*. at 663.
[4] *Id*.
[5] *Id*.
[6] 308 U.S. 1, 15 (1939).
[7] *Pennsylvania*, 426 U.S. at 664.

They were held not to be "directly caused" in *Pennsylvania*, because the monetary losses resulted from the plaintiff states' own laws.[8] Though it was undisputed that the defendant states' tax schemes had cost the plaintiff states money, the defendant states were held not to have "inflicted any injury,"[9] because the monetary harms were "self-inflicted:"[10]

The injuries to the plaintiffs' fiscs were self-inflicted, resulting from decisions made by their respective state legislatures. Nothing required Maine, Massachusetts, and Vermont to extend a tax credit to their residents for income taxes paid to New Hampshire, and nothing prevents Pennsylvania from withdrawing that credit for taxes paid to New Jersey. No state can be heard to complain about damage inflicted by its own hand.[11]

California and the other plaintiff states in the case before us have pointed out that their legislative schemes were in place before the federal regulatory change that will cost them money. But *Pennsylvania* does not leave room for such a "first in time, first in right" argument. Vermont's law, for instance, long preceded New Hampshire's, but the court held that any "injury" was "self-inflicted" because Vermont need not have extended tax credits to its residents at all.[12] The states could also have prevented their financial injury by changing their laws.[13] As the concurring opinion put

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[8] *Id.*
[9] *Id.*
[10] *Id.*
[11] *Id.*
[12] *Id.*; *see* 32 V.S.A. § 5825 (1966); N.H. R.S.A. § 77-B:2 (1970).
[13] *Pennsylvania*, 426 U.S. at 664.

it, "[t]he appellants therefore, [we]re really complaining about their own statute[s]."[14]

Pennsylvania differs from the case before us because the dispute was between coequal sovereigns in *Pennsylvania*, heard under the Court's original jurisdiction, and here it is between state governments and the federal government. But *Pennsylvania*'s rejection of "self-inflicted" injury has been applied outside the original jurisdiction context.[15] There is no conflict between the federal and state laws, so the sovereign rights of the plaintiff states cannot establish standing.[16] Though the plaintiff states may under their own laws spend additional money to provide benefits to some women that they would not have had to pay for before the federal change, they remain free to decide whether to do so.

As the majority acknowledges, the "irreducible minimum" for standing is that "the plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable

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[14] *Id*. at 667.

[15] *See Clapper* v. *Amnesty Intern. USA*, 568 U.S. 398, 416 (2013).

[16] *Sturgeon* v. *Masica*, 768 F.3d 1066, 1074 (9th Cir. 2014), *vacated and remanded sub nom. Sturgeon* v. *Frost*, 136 S. Ct. 1061 (2016) (rejecting "standing based simply on purported violations of a state's sovereign rights" and requiring "evidence of actual injury" where state failed to "identify any actual conflict between [federal agency regulations] and its own statutes and regulations"); *Sturgeon* v. *Frost*, 872 F.3d 927, 929 (9th Cir. 2017), *cert. granted*, 138 S. Ct. 2648 (2018). (explaining prior holding as to state standing was "unaffected by the Supreme Court's vacatur of [the] prior opinion"); *Virginia ex rel. Cuccinelli* v. *Sebelius*, 656 F.3d 253, 270 (4th Cir. 2011) (holding state lacked standing where it failed to identify enforcement of state statute that "conflict[ed]" with the individual mandate of the ACA).

to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision."[17] All three minima are perhaps debatable, but causation, that is, "traceability," is controlled by *Pennsylvania*. That case establishes that harm to the fisc of a plaintiff state because of its own statute is "self-inflicted," and therefore not "traceable to the challenged conduct of the defendant."[18] Traceability fails if the expense to the state results from its own law and without that state legislative choice, could be avoided. The federal regulatory change itself imposes no obligation on the states to provide money for contraception. The plaintiff states choose to provide some contraception benefits to employees of employers exempted by the federal insurance requirement, so the narrowing of the federal mandate may lead to the states spending more because some employers may spend less. Nor can the plaintiff states invoke the doctrine of *parens patriae* to gain standing.[19]

I recognize that the Fifth Circuit took a different view in different circumstances in *Texas* v. *United States*.[20] There, the Fifth Circuit held that states did

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[17] *Spokeo, Inc.* v. *Robins*, 136 S. Ct. 1540, 1547 (2016), *as revised* (May 24, 2016).

[18] *Pennsylvania*, 426 U.S. at 664; *Spokeo*, 136 S. Ct. at 1547.

[19] *See Massachusetts* v. *EPA*, 549 U.S. 497, 520 n.17 (2007) (explaining that state actions against the federal government "to protect [its] residents from the operation of federal statutes" are precluded); *Sierra Forest Legacy* v. *Sherman*, 646 F.3d 1161, 1178 (9th Cir. 2011) ("California, like all states, 'does not have standing as *parens patriae* to bring an action against the Federal Government.'" (quoting *Alfred L. Snapp & Son, Inc.* v. *Puerto Rico*, 458 U.S. 592, 610 n.16 (1982))).

[20] 809 F.3d 134 (5th Cir. 2015), *as revised* (Nov. 25, 2015).

indeed have standing to challenge a new federal program relating to immigration.[21] Texas was held to have standing because federal regulatory change on its administration of drivers' licenses – requiring it to issue drivers' licenses to illegal aliens – would cost it money.[22] The Fifth Circuit rejected application of the *Pennsylvania* "self-inflicted injury" rule, but stressed that its decision "is limited to these facts."[23] It is not plain that the Fifth Circuit would extend its view of standing to the quite different facts before us. The regulatory change regarding contraception poses no challenge to the sovereign authority of California to provide contraceptive benefits or not, but the regulatory change in *Texas* did limit the legislative choices Texas could make without "running afoul of preemption or the Equal Protection Clause."[24] Nor can we be sure that *Texas* is good law. The Supreme Court granted certiorari on the question whether "a State that voluntarily provides a subsidy" has standing to challenge a federal change that would expand its subsidy, and other issues.[25] The Court was "equally divided," so the questions were not answered.[26]

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[21] *Id.* at 162.
[22] *Id.* at 155–57.
[23] *Id.* at 154.
[24] *Id.* at 153; *see also Zango, Inc.* v. *Kaspersky Lab, Inc.*, 568 F.3d 1169, 1177 n.8 (9th Cir. 2009) ("An amicus curiae generally cannot raise new arguments on appeal." (citations omitted)).
[25] *United States* v. *Texas*, 136 S. Ct. 906 (2016); Pet. for Writ of Cert. at I, *United States* v. *Texas*, No. 15-674 (U.S. Nov. 20, 2015).
[26] *United States* v. *Texas*, 136 S. Ct. 2271, 2272, *reh'g denied*, 137 S. Ct. 285 (2016).

The majority errs in treating *Wyoming* v. *Oklahoma*[27] as though it overruled *Pennsylvania*.[28] It does not say so. And the Court doubtlessly would have said so had that been its intent. Nor is the self-inflicted injury doctrine even relevant to *Wyoming*, which is doubtless why *Wyoming* does not discuss *Pennsylvania*. In *Pennsylvania*, the plaintiff states could have avoided any lost revenue by changing their own laws granting tax credits for taxes paid to the defendant states. By contrast, Wyoming could not prevent the expense to its fisc by changing its own law.[29] Wyoming lost severance tax revenue because the new Oklahoma law required major Oklahoma coal consumers to replace a substantial part of the Wyoming coal they burned with Oklahoma coal, so less

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[27] 502 U.S. 437 (1992).

[28] Of course, it does not matter when jurisdiction is raised, since we must raise it whenever its absence appears likely. *See Interpipe Contracting, Inc.* v. *Becerra*, 898 F.3d 879, 891 n.9 (9th Cir. 2018) ("Because Article III standing is jurisdictional, we must sua sponte assure ourselves."). And the majority errs in saying that the self-inflicted harm doctrine was not raised by the parties. *See* Reply Br. of March for Life at 29, Dkt. No. 95. Much of the briefing before us addresses standing, and the appellee states were also provided an opportunity to address self-inflicted injury at oral argument. And it does not matter that the self-inflicted injury doctrine arose in the context of a case taken under the Court's original jurisdiction, because it is a straightforward application of the generally applicable causation requirement for standing. *See Clapper*, 568 U.S. at 416 (applying *Pennsylvania*'s "self-inflicted" doctrine outside the original jurisdiction context); *Texas*, 809 F.3d at 158–59 (same).

[29] *Wyoming*, 502 U.S. at 447; *see also Texas*, 809 F.3d at 158 ("Wyoming sought to tax the extraction of coal and had *no way to avoid being affected by other states' laws* that reduced demand for that coal." (emphasis added)).

coal was mined in Wyoming.[30] Since the Wyoming legislature could not change the Oklahoma law, the harm to Wyoming's fisc was not self-inflicted. The Oklahoma law, which expressly targeted Wyoming, caused the injury.[31] In our case, as in *Pennsylvania*, the plaintiff states elected to pay money in certain circumstances, and can avoid the harm to their fiscs by choosing not to pay the money.

I agree with the federal position that the plaintiff states lack standing to bring this case in federal court. Because such a conclusion would preclude us from reaching the other issues in the case, I do not speak to them in this dissent. Nor do I address additional reasons why the plaintiff states may lack standing, since the "self-inflicted injury" disposes of the question without them.

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[30] *Id.* at 443, 445–47.

[31] *Id.* at 443.

[Entered on Docket with Opinion; ECF 136-2]

FAQS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION PART 36

U.S. Department of Labor
Employee Benefits Security Administration
January 9, 2017

Set out below is an additional Frequently Asked Question (FAQ) regarding implementation of the Affordable Care Act. This FAQ has been prepared jointly by the Departments of Labor (DOL), Health and Human Services (HHS), and the Treasury (collectively, the Departments). Like previously issued FAQs (available at www.dol.gov/ebsa/healthreform/ index.html and www.cms.gov/cciio/resources/fact-sheetsand-faqs/index.html), this FAQ answers a question from stakeholders to help people understand the law and benefit from it, as intended.

COVERAGE OF PREVENTIVE SERVICES

Section 2713 of the Public Health Service Act (PHS Act), as added by the Affordable Care Act and incorporated into the Employee Retirement Income Security Act (ERISA) and the Internal Revenue Code (the Code), requires that non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage provide coverage of certain specified preventive services without cost sharing.

As originally drafted, the bill that became the Affordable Care Act would not have covered additional preventive services that "many women's health

advocates and medical professionals believe are critically important" to meeting women's unique health needs. 155 Cong. Rec. 28,841 (2009) (Sen. Boxer). To address that concern, the Senate adopted a "Women's Health Amendment," adding a new category of preventive services specific to women's health. This provision requires coverage without cost sharing of preventive care and screenings for women provided for in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA). Supporters of the Women's Health Amendment emphasized that it would reduce unintended pregnancies by ensuring that women receive coverage for "contraceptive services" without cost-sharing. 155 Cong. Rec. at 29,768 (Sen. Durbin).[1]

On August 1, 2011, the Departments issued amended regulations requiring coverage of women's preventive services provided for in the HRSA guidelines,[2] and HRSA adopted and released such guidelines, which were based on recommendations of the independent organization, the National Academy of Medicine (formerly Institute of Medicine).[3] The preventive services identified in the HRSA guidelines include all Food and Drug Administration (FDA)-approved contraceptives, sterilization procedures, and

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[1] *See also*, *e.g.*, 155 Cong. Rec. at 28,841 (Sen. Boxer) ("family planning services"); *id.* at 28,843 (Sen. Gillibrand) ("family planning"); *id.* at 28,844 (Sen. Mikulski) (same); *id.* at 28,869 (Sen. Franken) ("contraception"); *id.* at 29,070 (Sen. Feinstein) ("family planning services"); *id.* at 29,307 (Sen. Murray) (same).

[2] 26 CFR 54.9815-2713, 29 CFR 2590.715-2713, 45 CFR 147.130.

[3] The 2011 amended regulations were issued and effective on August 1, 2011, and published on August 3, 2011 (76 FR 46621).

patient education and counseling for women with reproductive capacity, as prescribed by a health care provider (collectively, contraceptive services).[4] Under the regulations issued in August 2011 and the contemporaneously issued HRSA guidelines, group health plans of "religious employers" (organizations that are organized and operate as nonprofit entities and are referred to in section 6033(a)(3)(A)(i) or (iii) of the Code) are exempt from the requirement to provide contraceptive coverage. That exemption reflects "the longstanding governmental recognition of a particular sphere of autonomy for houses of worship." 80 FR 41318, 41325 (July 15, 2015); *see* 26 U.S.C. 6033(a)(3)(A)(i) or (iii) (referring to "churches, their integrated auxiliaries, conventions or associations of churches, and the exclusively religious activities of any religious order").

Subsequently, on July 2, 2013, the Departments published regulations that provide an accommodation for eligible organizations[5] that object on religious grounds to providing coverage for contraceptive services, but are not eligible for the exemption for

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[4] On December 20, 2016, HRSA updated the women's preventive services guidelines, which go into effect for non-grandfathered group health plans and health insurance coverage for plan years (in the individual market, policy years) beginning on or after December 20, 2017. The HRSA guidelines exclude services relating to a man's reproductive capacity, such as vasectomies and male condoms.

[5] An eligible organization, which may seek the accommodation based on its sincerely held religious objection to providing contraceptive coverage, is defined at 26 CFR 54.9815-2713A(a), 29 CFR 2590.715-2713A(a), and 45 CFR 147.131(b),

religious employers (78 FR 39870).[6] Under the accommodation, an eligible organization is not required to contract, arrange, pay, or provide a referral for contraceptive coverage. At the same time, the accommodation generally ensures that women enrolled in the health plan established by the eligible organization, like women enrolled in health plans maintained by other employers, receive contraceptive coverage seamlessly— that is, through the same issuers or third party administrators that provide or administer the health coverage furnished by the eligible organization, and without financial, logistical, or administrative obstacles.[7] Minimizing such obstacles is essential to achieving the purpose of the Affordable Care Act's preventive services provision, which seeks to remove barriers to the use of preventive services and to ensure that women receive full and equal health coverage appropriate to their medical needs.

In *Burwell* v. *Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014), which addressed claims brought under the Religious Freedom Restoration Act (RFRA), the Supreme Court held that the contraceptive coverage

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[6] 26 CFR 54.9815-2713A, 29 CFR 2590.715-2713A, 45 CFR 147.131.

[7] An accommodation is also available with respect to student health insurance coverage arranged by eligible organizations that are institutions of higher education. 45 CFR 147.131(f). For ease of use, this FAQ refers only to "employers" with religious objections to the contraceptive-coverage requirement, but references to employers with respect to insured group health plans should also be considered to include institutions of higher education that are eligible organizations with respect to student health insurance coverage.

requirement substantially burdened the religious exercise of the closely held for-profit corporations that had religious objections to providing contraceptive coverage, and that the accommodation was a less restrictive means of providing coverage to their employees. In light of the *Hobby Lobby* decision, the Departments extended the accommodation to closely held for-profit entities.[8]

Under the accommodation, an eligible organization that objects to providing contraceptive coverage for religious reasons may either:

(1) self-certify its objection to its health insurance issuer (to the extent it has an insured plan) or third party administrator (to the extent it has a self-insured plan) using a form provided by the Department of Labor (EBSA Form 700);[9] or

(2) self-certify its objection and provide certain information to HHS without using any particular form.[10]

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[8] 26 CFR 54.9815-2713A(b)(2)(ii); 29 CFR 2590.715-2713A(b)(2)(ii); 45 CFR. 147.131(b)(2)(ii).

[9] The EBSA Form 700 serves as a certification that the organization is an "eligible organization" (as described in 26 CFR 54.9815-2713A(a), 29 CFR 2590.715-2713A(a), and 45 CFR 147.131(b)) that has a religious objection to providing coverage for some or all of any contraceptive services that would otherwise be required to be covered. The EBSA Form 700 is available at: https://www.dol.gov/ebsa/pdf/preventiveserviceseligibleorganizationcertificationform.pdf.

[10] A model notice to HHS that eligible organizations may use, but are not required to use, is available at:

In *Zubik* v. *Burwell*, 136 S. Ct. 1557 (2016), the Supreme Court considered claims by a number of employers that, even with the accommodation provided in the regulations, the contraceptive coverage requirement violates RFRA. Following oral argument, the Court issued an order requesting supplemental briefing from the parties. The Court's order noted that under the existing regulations, an objecting employer with an insured plan that seeks to invoke the accommodation by contacting its issuer must use a form of written notice stating that the employer objects on religious grounds to providing contraceptive coverage.[11] The Court directed the parties to file supplemental briefs addressing "whether contraceptive coverage could be provided to [the objecting employers'] employees, through [the employers'] insurance companies, without any such notice."[12] After consideration of the supplemental briefing, the Supreme Court vacated the judgments of the lower courts and remanded *Zubik* and several other cases raising parallel RFRA challenges to the accommodation. 136 S. Ct. at 1560-1561. The Court emphasized that it "expresse[d] no view on the merits of the cases" and, in particular, that it did not "decide whether [the employers'] religious exercise has been substantially burdened, whether the Government has a compelling interest, or whether the current regulations are the least restrictive means of serving that interest." *Id.* at 1560. The Court, however,

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http://www.cms.gov/cciio/resources/Regulations-and-Guidance/index.html#Prevention.

[11] *Zubik* v. *Burwell*, Nos. 14-1418 et al., 2016 WL 1203818, at *2 (Mar. 29, 2016).

[12] *Id.*

stated that in light of what it viewed as "the substantial clarification and refinement in the positions of the parties" in their supplemental briefs, the parties "should be afforded an opportunity to arrive at an approach going forward that accommodates [the objecting employers'] religious exercise while at the same time ensuring that women covered by [the employers'] health plans 'receive full and equal health coverage, including contraceptive coverage.'" Id. (citation omitted).[13]

On July 22, 2016, the Departments published a request for information (RFI) (81 FR 47741) seeking input from interested parties to determine, as contemplated by the Supreme Court's opinion in *Zubik*, whether modifications to the existing accommodation procedure could resolve the objections asserted by the plaintiffs in the pending RFRA cases, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage.

The Departments explained that they were using the RFI procedure because the issues addressed in the supplemental briefing in *Zubik* affect a wide variety of

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[13] The Supreme Court specified that, while the RFRA litigation remains pending, "the Government may not impose taxes or penalties on [the plaintiffs] for failure to provide the * * * notice" required under the existing accommodation regulations. *Zubik*, 136 S. Ct. at 1561. At the same time, the Court also emphasized that "[n]othing in [its] opinion, or in the opinions or orders of the courts below, is to affect the ability of the Government to ensure that women covered by [plaintiffs'] health plans 'obtain, without cost, the full range of FDA approved contraceptives.'" *Id.* at 1560-1561 (quoting *Wheaton College* v. *Burwell*, 134 S. Ct. 2806, 2807 (2014)).

stakeholders, including many who are not parties to the cases that were before the Supreme Court. Other employers also have brought RFRA challenges to the accommodation, and their views may differ from the views held by the employers in *Zubik* and the consolidated cases. In addition, any change to the accommodation could have implications for the rights and obligations of issuers, group health plans, third party administrators, and women enrolled in health plans established by objecting employers. The RFI was intended to assist the Departments in determining whether there are modifications to the accommodation that would be available under current law and that could resolve the pending RFRA claims brought by objecting organizations. The Departments sought feedback from all interested stakeholders, including objecting organizations, and specifically requested that such organizations address the particular issues outlined in the RFI.

In response to the RFI, the Departments received over 54,000 public comments by the comment closing date of September 20, 2016. Commenters included the plaintiffs in *Zubik* and other religiously affiliated organizations, consumer advocacy groups, women's organizations, health insurance issuers, third party administrators and pharmaceutical benefit managers, other industry representatives, employers, members of the public, and other interested stakeholders.[14] The Departments are issuing this FAQ after consideration of comments submitted by a broad array of stakeholders, including the *Zubik* plaintiffs and

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[14] The public comments are accessible at https://www.regulations.gov/docket?D=CMS-2016-0123.

similar religious organizations, issuers or third party administrators, and commenters representing women's and consumer advocacy organizations.

Q: ARE THE DEPARTMENTS MAKING CHANGES TO THE ACCOMMODATION AT THIS TIME?

No. As described in more detail below, the comments reviewed by the Departments in response to the RFI indicate that no feasible approach has been identified at this time that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage. The comments demonstrate that a process like the one described in the Court's supplemental briefing order would not be acceptable to those with religious objections to the contraceptive-coverage requirement. Further, a number of comments illustrate that the administrative and operational challenges to a process like the one described in the Court's order are more significant than the Departments had previously understood and would potentially undermine women's access to full and equal coverage. For these reasons, the Departments are not modifying the accommodation regulations at this time.

As the government explained in its briefs in *Zubik*, the Departments continue to believe that the existing accommodation regulations are consistent with RFRA for two independent reasons. First, as eight of the nine courts of appeals to consider the issue have held, by virtue of objecting employers' ability to avail themselves of the accommodation, the contraceptive-coverage requirement does not substantially burden their exercise of religion. Second, as some of those

courts have also held, the accommodation is the least restrictive means of furthering the government's compelling interest in ensuring that women receive full and equal health coverage, including contraceptive coverage.

NOTIFICATION TO ISSUERS WITHOUT SELF-CERTIFICATION

In its request for supplemental briefing in *Zubik*, the Supreme Court asked the parties to address "whether and how contraceptive coverage may be obtained by [objecting employers'] employees through [the employers'] insurance companies, but in a way that does not require any involvement of [the employers] beyond their own decision to provide health insurance without contraceptive coverage to their employees."[15] Specifically, the Court described—

> a situation in which [objecting employers] would contract to provide health insurance for their employees, and in the course of obtaining such insurance, inform their insurance company that they do not want their health plan to include contraceptive coverage of the type to which they object on religious grounds. [The employers] would have no legal obligation to provide such contraceptive coverage, would not pay for such coverage, and would not be required to submit any separate notice to their insurer, to the Federal government, or to their employees. At the same time, [the employers'] insurance compan[ies]—aware that [the employers] are not providing certain

[15] *Zubik*, 2016 WL 1203818, at *2.

> contraceptive coverage on religious grounds—would separately notify [the employers'] employees that the insurance company will provide cost-free contraceptive coverage, and that such coverage is not paid for by [the employers] and is not provided through [the employers'] health plan[s].[16]

The Departments sought comments on whether this alternative would be acceptable to objecting organizations, and if not, whether further procedures or systems could resolve their RFRA concerns. The Departments asked if organizations specifically object on RFRA grounds to informing their issuers that they object to contraceptive coverage "on religious grounds," or to a requirement that the request by an eligible organization to its issuer be made in writing or through use of a particular form. The Departments also sought comments on whether it would be feasible for issuers to implement the accommodation without the written notification requirement and what effect this alternative procedure would have on the access of women to seamless contraceptive coverage.

In light of the comments received, the Departments have determined not to amend the regulations at this time. On the one hand, comments from parties before the Supreme Court (and other objecting employers) do not suggest that the change identified by the Supreme Court would resolve their concerns. On the other hand, the Departments received comments stating that eliminating written notification would create significant administrative problems and potential legal liabilities for issuers, and would hinder women's

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[16] *Id.*

access to care. As described in greater detail below, these comments have shown that the elimination of the written notification requirement would raise complications that would undermine the statute's goal of ensuring full and equal health coverage for women, the extent of which were not known to the Departments at the time the government filed its supplemental briefs in *Zubik*.

First, comments on behalf of issuers stated that eliminating written notifications would impose administrative costs by forcing them to create new systems to distinguish and track different employers, employees, and the coverage to be provided.[17] For example, commenters stated that issuers currently rely on the written notifications to track the differences between eligible organizations that are seeking an accommodation due to their religious objections – organizations that the Supreme Court has said are "effectively exempt" from the contraceptive-coverage requirement – and religious employers that are automatically exempt under the HRSA guidelines. These comments asserted that eliminating written notifications would burden issuers with creating new systems to distinguish and track these two categories

[17] Related to these comments with respect to the administrative costs of distinguishing and tracking different coverage to be provided, the Departments note that an eligible organization may seek an accommodation so that it need not contract, arrange, pay, or provide a referral for *all* otherwise required contraceptive services, or any subset of such services. Thus, there could be many different combinations of contraceptive services that an issuer must cover, and within each such combination, some such benefits must be provided by the group health insurance policy, and others for which the issuer must make separate payments.

of employers.

Given the different ways in which issuers must treat and respond to these two types of entities, the Departments understand that issuers must be able to easily and separately track the coverage issued to the plans sponsored by these different organizations. With respect to exempt organizations, issuers merely need to eliminate contraceptive benefits from the group health insurance policy. However, with respect to eligible organizations that avail themselves of the accommodation, issuers must take the additional step of making separate payments for contraceptive services, along with providing notice of the availability of such payments. Furthermore, some eligible organizations may object to covering all forms of contraceptive services in their group health coverage while others may object only to certain types of contraceptive services. The Departments conclude therefore that written notification from employers significantly improves issuers' ability to appropriately identify and administer coverage for each of these two categories of employers. The commenters also said that issuers might be subject to legal risks if written notification were eliminated, because they would have no written record to demonstrate compliance with applicable law and regulations to the extent they relied on an organization's oral representation of its eligibility for the accommodation that was later determined to be incorrect. Such legal risks would be magnified, according to the commenters, in circumstances in which issuers would have to rely on agents and brokers to verify eligibility.

Based on these concerns, comments indicated that, even without a legal requirement to use a required

form, issuers would likely seek written documentation, such as an attestation, from objecting employers to confirm the employer's eligibility as a condition of administering the accommodation. For example, an issuer might demand written documentation as a pre-condition for entering into a contract with an organization seeking the accommodation. The commenters indicated that if the written notification requirement were eliminated, employers might object to providing this type of verification, which is currently commonplace for certain purposes, such as communicating grandfathered status. The Departments note that, under the current accommodation, once an issuer has been provided the documentation specified in the accommodation regulations, it may not require any further documentation from an eligible organization regarding its status as such.[18]

Second, several commenters suggested that the lack of written notice would create confusion and miscommunication, which in turn would lead to disputes between the parties, billing problems, and reduced access to care for women. For example, comments from women's advocacy organizations stated that lack of written notice could have repercussions for processing payments to a provider. This could disrupt continuity of care and burden women seeking to resolve any miscommunication between the objecting entity and the issuer. Further, according to these commenters, it could also impose the additional burden of affected women having to

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[18] 26 CFR 54.8815-2713A(c)(1)(i), 29 CFR 2590.715-2713A(c)(1)(i), 45 CFR 147.131(c)(1)(i).

affirmatively assert their eligibility in situations where an employer has not timely provided its oral objection.

One commenter stated that, without a written notification, an eligible employer's representative may misstate an employer's wishes or incorrectly assert eligibility for the accommodation, resulting in a dispute that delays the process of arranging contraceptive coverage for women.

Several commenters representing women's and consumer advocacy organizations stressed the importance of written documentation for verifying compliance and ensuring that women are able to obtain direct, continuous access to the full range of contraceptive methods without cost. These commenters also suggested that eliminating written documentation could hamper the Departments' oversight and enforcement efforts.

Third, as noted above, the Departments have not identified any comments from objecting employers, including any of the *Zubik* plaintiffs, stating that eliminating the written notification requirement would be sufficient to satisfy their RFRA concerns. For example, one comment indicate that employers would object to "any requirement * * * that has the purpose or effect of providing access to or increasing the use of contraceptive services."

The Departments agree that written documentation establishing that a given employer requested the accommodation, and that it satisfies the definition of an eligible organization, is of value to document the legal responsibilities and rights of employees, issuers, and beneficiaries, as well as to

minimize the number of disputes between employers and issuers regarding the accommodation. In turn, the Departments conclude that, by minimizing such disputes and providing certainty regarding which organizations have and have not requested the accommodation, the written notice requirement minimizes the potential number of employers that will be in violation of the contraceptive-coverage requirement. By helping to define which organizations have and have not availed themselves of the accommodation, written documentation also ensures that women receive timely access to contraceptive coverage, as it will help issuers to quickly and effectively determine the appropriate source of payment for such services, i.e., payment through the group health insurance policy, or separate payment for contraceptive services. And as the government explained in its Supreme Court briefs, the regulatory requirement for eligible organizations to provide written notification of their objection is consistent with RFRA.

OTHER APPROACHES WITH RESPECT TO INSURED PLANS DESCRIBED IN THE SUPPLEMENTAL BRIEFING

The *Zubik* plaintiffs proposed that when an eligible employer with an insured plan requests insurance coverage that excludes contraceptive coverage to which it objects on religious grounds, the employer's issuer should be required to provide the required coverage through separate insurance policies that cover only contraceptives and in which women should

have to affirmatively enroll. Pet. Supp. Br. 3-12.[19] The Departments sought comments on whether this alternative procedure would resolve the RFRA claims of objecting organizations; whether it would be feasible for health insurance issuers and consistent with State insurance laws; what effect this approach would have on the ability of women enrolled in group health plans established by objecting employers to obtain seamless coverage for contraceptive services; and whether there might be alternatives other than contraceptive-only policies or affirmative enrollment requirements that would resolve the RFRA objections of objecting organizations.

In response to the RFI, objecting employers argued that to be truly independent, contraceptive coverage must be provided to women enrolled in health plans of objecting employers through separate insurance policies. The Departments identified no comments indicating that eliminating written notification by itself would be sufficient. In fact, several commenters stated that, even if the government were to eliminate the written notice requirement, the accommodation would have to be modified in other ways to satisfy their concerns. One commenter, quoting from the petitioners' brief in *Zubik*, stated that there must be an enrollment process that is distinct from (and not an automatic consequence of) enrolling in the employer's plan. Another commenter stated that the issuer or

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[19] As of the date of publication of this FAQ, petitioners' supplemental brief is available at http://www.scotusblog.com/wpcontent/uploads/2016/04/Non-profits-response-to-Zubik-order-4-12-16.pdf. Petitioners' supplemental reply brief is available at http://www.scotusblog.com/wp-content/uploads/2016/04/Zubik-order-non-profits-reply-brief-4-20-161.pdf.

third party administrator should be required to provide eligible participants and beneficiaries with a separate enrollment card for contraceptive coverage that would require activation by each participant or beneficiary. The commenter stated that this should replace the current requirement that participants automatically receive coverage for contraceptive services. (For further discussion of this issue, see section below titled "Separate Enrollment Cards and Activation.")

A number of commenters emphasized the significant problems posed by requiring separate contraceptive-only coverage. Commenters identified several obstacles under State contract and insurance law. Comments submitted on behalf of issuers asserted that some State insurance regulators do not have authority under State law to approve single-benefit policies (other than dental or vision). The commenters also explained that cost-free contraception policies would not satisfy laws conditioning policy approval on a "reasonable premium" or constitute valid contracts because the prospective policyholder would not provide consideration. In addition, they commented that under State licensure laws, issuers that sell group coverage could not offer contraceptive-only policies to individual women because they are not licensed to offer coverage in the individual market and that State laws would prevent issuers licensed to issue group coverage in one State from issuing individual policies to employees of an eligible organization residing in other States.

In addition, several commenters stated that separate contraceptive coverage policies may have a different provider network from that of the group

health plan that provides the women's other health benefits, which would mean that the separate contraceptive policies would not necessarily include women's regular doctors. One commenter stated that it would be costly and administratively burdensome for issuers to develop and implement new eligibility, enrollment, and claims-adjudication systems for contraception-only coverage, as they would differ from their existing systems. Several commenters also maintained that requiring women to seek out separate contraceptive coverage would create the same barriers in access that the Affordable Care Act's preventive services provision was designed to eliminate. The Departments agree these approaches would potentially undermine women's access to full and equal coverage, contrary to the statutory objective of reducing barriers to the use of important preventive services.

SELF-INSURED PLANS

The Supreme Court's supplemental briefing order in *Zubik* addressed only employers with "insured plans."[20] In its supplemental brief, the government described the operation of the accommodation for self-insured plans and explained that an alternative process like the one the Court posited for insured plans could not work for the many employers with self-insured plans:

> If an employer has a self-insured plan, the statutory obligation to provide contraceptive coverage falls only on the plan—there is no insurer with a preexisting duty to provide

[20] *Zubik*, 2016 WL 1203818, at *2.

coverage. Accordingly, to relieve self-insured employers of any obligation to provide contraceptive coverage while still ensuring that the affected women receive coverage without the employer's involvement, the accommodation establishes a mechanism for the government to designate the employer's TPA [third party administrator] as a 'plan administrator' responsible for separately providing the required coverage under [ERISA]. That designation is made by the government, not the employer, and the employer does not fund, control, or have any other involvement with the separate portion of the ERISA plan administered by the TPA.

The government's designation of the TPA must be reflected in a written plan instrument. To satisfy that requirement, the accommodation relies on either (1) a written designation sent by the government to the TPA, which requires the government to know the TPA's identity, or (2) the self-certification form, which the regulations treat as a plan instrument in which the government designates the TPA as a plan administrator. There is no mechanism for requiring TPAs to provide separate contraceptive coverage without a plan instrument; self-insured employers could not opt out of the contraceptive-coverage requirement by simply informing their TPAs that they do not want to provide coverage for contraceptives. Gov't Supp. Br. 16-17 (citations omitted).

The *Zubik* plaintiffs also stated that an

arrangement like the one posited in the Supreme Court's briefing order for insured plans could not work for self-insured plans. *See* Pet. Supp. Br. 16-17.

The RFI sought comment on any possible modifications to the current accommodation for self-insured plans, including self-insured church plans, which would resolve objecting organizations' RFRA objections while still providing women full and equal access to coverage. Specifically, the RFI asked whether there are any reasonable alternative means available under existing law by which the Departments could ensure that women enrolled in self-insured plans maintained by objecting employers receive separate contraceptive coverage that is not contracted, arranged, paid, or referred for by the objecting organization but that is provided through the same third party administrators that administer the rest of their health benefits.

The Departments did not identify any comments in response to the RFI that described a feasible pathway for oral notification to third party administrators with respect to self-insured plans to allow full and equal provision of contraceptive services to the women enrolled in those plans.

Some commenters noted that third party administrators often do not require separate notification, written or oral, that a self-insured plan will not be providing contraceptive coverage because other documentation, such as summary plan descriptions or provider contracts, will indicate that such coverage is not provided under the plan. However, without a written plan instrument, which is provided for in the current accommodation, there is no mechanism to designate a third party administrator

as the ERISA plan administrator for purposes of arranging or providing separate payments for contraceptive services.

Many commenters suggested that cost-free contraception should be provided by the federal government through mechanisms that differ substantially from the procedure for insured plans described in the Supreme Court's supplemental briefing order. For example, some commenters suggested that for those self-insured plans that have third party administrators that are not able to provide separate cost-free contraceptive coverage to covered employees, the objecting employer could simply inform such third party administrators of the employer's objection and the government would "exempt" such self-insured plans and third party administrators from the requirement to provide separate cost-free contraceptive coverage. In those cases, commenters proposed that the government could provide coverage by having the employer notify HHS that the employer will not provide coverage and HHS would then coordinate with IRS to determine the identity of that employer's employees through W-2 or other tax information otherwise supplied by the objecting employer. These commenters suggest that such a program could be paid for by using credits against Federally-facilitated Exchange (FFE) user fees (which are already being used for the existing accommodation).

One commenter asserted that the federal government could directly subsidize the cost of purchasing contraceptive items and services for those employees who participate in an eligible organization's group health plan. However, as the Departments have

previously indicated in rulemaking in response to comments suggesting that the government reimburse plan participants for the costs of contraceptive services,[21] and in its briefs to the Supreme Court, this approach raises legal and practical obstacles to access to seamless coverage. Consistent with the statutory objective of promoting access to preventive services, such as contraceptive coverage, without cost-sharing, plan participants and beneficiaries should not be required to incur additional costs or burdens to receive access. Therefore, they should not be required to enroll in new programs or to surmount other hurdles to receive access to coverage.

SEPARATE ENROLLMENT CARDS AND ACTIVATION

As stated above, several objecting organizations have suggested that some of their objections to the accommodation could be alleviated by providing a separate enrollment card for contraceptive coverage. Under this approach, women would not enroll in a separate insurance policy for contraceptive coverage, but would receive a separate enrollment card that would be automatically activated only when a woman who is enrolled in the group health plan attempts to obtain contraceptive benefits.

If objecting employers prefer the use of a separate enrollment card for contraceptive coverage, the Departments note that under the current accommodation regulations, issuers or third party administrators could provide a separate enrollment card for contraceptive coverage. The current

[21] 80 FR 41317, 41328 (July 14, 2015).

regulations do not specify the manner in which an issuer or third party administrator provides "enrollment cards" or other means of providing similar, relevant information to enrollees, as long as the manner in which the card or other information is provided does not unduly inhibit or hamper access to the benefit. *See* 29 CFR 2560.503-1, which is applicable to ERISA plans and incorporated in 26 CFR 54.9815-2719(b)(2)(i), 29 CFR 2590.715-2719(b)(2)(i), and 45 CFR 147.136(b)(2)(i), which are applicable to non-grandfathered health plans and coverage. As stated above, under current rules, the issuer or third party administrator could provide a separate enrollment card for contraceptive coverage.[22] The card could bear a different design to distinguish it from enrollment cards used to access services covered by the employer's group health plan, and could omit the name of the employer and/or the plan as well. The card could use the same identification number as is used on the enrollment card for services covered by the group health plan, or could have a different number provided there is a mechanism in place (such as by linking the two numbers in the issuer's or third party administrator's processing systems) that enables the issuer or third party administrator to easily identify enrollees. The foregoing arrangements are permissible if they are not used as an impediment to obtaining benefits and do not unduly inhibit or hamper a plan participant or beneficiary from accessing benefits provided pursuant to the accommodation (e.g., a plan procedure providing for the denial of benefits based on failure to present or "activate" the enrollment card or "opt in," even when

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[22] *Id.*

the provider has otherwise verified participant status).

APPENDIX B

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

STATE OF CALIFORNIA, et at., Plaintiffs, v. HEALTH AND HUMAN SERVICES, et al., Defendants.	Case No. 17-cv-05783 **ORDER GRANTING PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION** Re: Dkt. No. 28

I. INTRODUCTION

Pending before the Court is a motion for a preliminary injunction that would enjoin two interim final rules ("IFRs") exempting certain entities from the Affordable Care Act's mandate to employers to provide contraceptive coverage. Plaintiffs are the states of California, Delaware, Maryland, and New York, and the Commonwealth of Virginia. Defendants are the U.S. Department of Health & Human Services ("HHS"); Secretary of HHS Eric D. Hargan; the U.S. Department of Labor; Secretary of Labor R. Alexander Acosta; the U.S. Department of the Treasury; and Secretary of the Treasury Steven Mnuchin.

Defendants begin their brief in opposition to the motion for preliminary injunction with the contention that "[t]his case is about religious liberty and freedom of conscience." Dkt. No. 51 at 1. And without question, that is one of the important values at issue in this case. But Defendants' characterization leaves out an equally critical aspect of what this case is about. Since its enactment, the Affordable Care Act ("ACA") has required group health insurance plans to provide women access to preventive care, including contraceptives, without imposing any cost sharing requirement. Less than two years ago, in April 2016, Defendants (or, in the case of the individual defendants, their predecessors) represented to the Supreme Court that the United States Government has a compelling interest in ensuring access to such coverage for women. *See* Supplemental Br. for Resp'ts at 1, *Zubik* v. *Burwell*, 136 S. Ct. 1557 (2016) (per curiam) (No. 14-1418), 2016 WL 1445915, at *1 (explaining that rules in existence in April 2016 "further[ed] the compelling interest in ensuring that women covered by every type of health plan receive full and equal health coverage, including contraceptive coverage"). Moreover, Defendants have consistently recognized the need to balance this compelling interest with the important goal of "minimiz[ing] any burden on religious exercise." *Id.*

But the Defendants have now changed their position, dramatically. In the IFRs that became effective on October 6, 2017, Defendants asserted that there is no such compelling interest after all. They also markedly expanded the scope of the exemption available to religious entities under the ACA's contraceptive coverage mandate, and created an

entirely new exemption based on moral objections. In sum, the IFRs represent an abandonment of the Defendants' prior position with regard to the contraceptive coverage requirement, and a reversal of their approach to striking the proper balance between substantial governmental and societal interests.

These highly-consequential IFRs were implemented without any prior notice or opportunity to comment. The Court finds that, at a minimum, Plaintiffs are likely to succeed in showing that this process violated the Administrative Procedure Act, and that this violation will cause them imminent harm if enforcement of the IFRs is not enjoined. Accordingly, for the reasons set forth below, Plaintiffs' motion is **GRANTED**.

II. BACKGROUND

Before turning to Plaintiffs' challenge to the IFRs at issue in this case, the Court recounts the sequence of events which began with the enactment of the Affordable Care Act in 2010.

A. The Affordable Care Act

In March 2010, Congress enacted the Affordable Care Act. The ACA included a provision known as the Women's Health Amendment, which states:

> A group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for * * * with respect to women, such additional preventive care and screenings * * * as provided for in comprehensive guidelines supported by the

Health Resources and Services Administration for purposes of this paragraph.

42 U.S.C. § 300gg-13(a)(4).

B. The 2010 IFR and Subsequent Regulations

On July 19, 2010, under the authority of the Women's Health Amendment, several federal agencies (including HHS, the Department of Labor, and the Department of the Treasury) issued an interim final rule ("the 2010 IFR"). *See* 75 Fed. Reg. 41,726. It required, in part, that health plans provide "evidence-informed preventive care" to women, without cost sharing and in compliance with "comprehensive guidelines" to be provided by HHS' Health Resources and Services Administration ("HRSA"). *Id.* at 41,728.

The agencies found they had statutory authority "to promulgate any interim final rules that they determine[d were] appropriate to carry out the" relevant statutory provisions. *Id.* at 41,729-30. The agencies also determined they had good cause to forgo the general notice of proposed rulemaking required under the Administrative Procedure Act ("APA"), 5 U.S.C. § 553. *Id.* at 41,730. Specifically, the agencies determined that issuing such notice would be "impracticable and contrary to the public interest" because it would not allow sufficient time for health plans to be timely designed to incorporate the new requirements under the ACA, which were set to go into effect approximately two months later. *Id.* The agencies requested that comments be submitted by September 17, 2010, the date the IFR was scheduled to go into effect.

On September 17, 2010, the agencies first promulgated regulations pursuant to the 2010 IFR. *See* 45 C.F.R. § 147.310(a)(1)(iv) (HHS); 29 C.F.R. § 2590.715-2713 (Department of Labor); 26 C.F.R. § 54.9815-2713 (Department of the Treasury).[1] As relevant here, the regulations were substantively identical to the IFR, stating that HRSA was to provide "binding, comprehensive health plan coverage guidelines."

C. The 2011 HRSA Guidelines

From November 2010 to May 2011, a committee convened by the Institute of Medicine ("IOM") met in response to the charge of HHS' Office of the Assistant Secretary for Planning and Evaluation: to "convene a diverse committee of experts" related to, as relevant here, women's health issues. IOM Report[2] at 1, 23. In July 2011, the committee issued a report recommending that private health insurance plans be required to cover all contraceptive methods approved by the Food and Drug Administration ("FDA"), without cost sharing. *Id.* at 102-10.

On August 1, 2011, HRSA issued its preventive care guidelines ("2011 Guidelines"), defining preventive care coverage to include all FDA-approved contraceptive methods.[3]

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[1] The Department of Treasury's regulations were first promulgated in 2012, two years after those of the Health and Human Services and Labor departments.

[2] Institute of Medicine, Clinical Preventive Services for Women: Closing the Gaps (2011), *available at* https://www.nap.edu/read/13181/chapter/1.

[3] *See* HEALTH RES. & SERVS. ADMIN., Women's Preventive

D. The 2011 IFR and the Original Religious Exemption

On August 3, 2011, the agencies issued an IFR amending the 2010 IFR. *See* 76 Fed. Reg. 46,621 ("the 2011 IFR"). Based on the "considerable feedback" they received regarding contraceptive coverage for women, the agencies stated that it was "appropriate that HRSA, in issuing [its 2011] Guidelines, take[] into account the effect on the religious beliefs of certain religious employers if coverage of contraceptive services were required * * *." *Id.* at 46,623. As such, the agencies provided HRSA with the "additional discretion to exempt certain religious employers from the [2011] Guidelines where contraceptive services are concerned." *Id.* They defined a "religious employer" as one that:

> (1) [h]as the inculcation of religious values as its purpose; (2) primarily employs persons who share its religious tenets; (3) primarily serves persons who share its religious tenets; and (4) is a non-profit organization under [the relevant statutory provisions, which] refer to churches, their integrated auxiliaries, and conventions or associations of churches, as well as to the

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Services Guidelines, *available at* https://www.hrsa.gov/womens-guidelines/index.html. On December 20, 2016, HRSA updated the guidelines ("2016 Guidelines"), clarifying that "[c]ontraceptive care should include contraceptive counseling, initiation of contraceptive use, and follow-up care," as well as "enumerating the full range of contraceptive methods for women" as identified by the FDA. *See* HEALTH RES. & SERVS. ADMIN., Women's Preventive Services Guidelines, *available at* https://www.hrsa.gov/womens-guidelines-2016/index.html.

> exclusively religious activities of any religious order.

Id.

The 2011 IFR went into effect on August 1, 2011. The agencies again found that they had both statutory authority and good cause to forgo the APA's advance notice and comment requirement. *Id.* at 46,624. Specifically, they found that "providing for an additional opportunity for public comment [was] unnecessary, as the [2010 IFR] * * * provided the public with an opportunity to comment on the implementation of the preventive services requirement in this provision, and the amendments made in [the 2011 IFR were] in fact based on such public comments." *Id.* The agencies also found that notice and comment would be "impractical and contrary to the public interest," because that process would result in a delay of implementation of the 2011 Guidelines. *See id.* The agencies further stated that they were issuing the rule as an IFR in order to provide the public with some opportunity to comment. *Id.* They requested comments by September 30, 2011.

On February 15, 2012, after considering more than 200,000 responses, the agencies issued a final rule adopting the definition of "religious employer" set forth in the 2011 IFR. 77 Fed. Reg. 8,725. The final rule also established a temporary safe harbor, during which the agencies

> plan[ned] to develop and propose changes to these final regulations that would meet two goals—providing contraceptive coverage without cost-sharing to individuals who want it and accommodating non-exempted, non-profit

> organizations' religious objections to covering contraceptive services * * *.

Id. at 8,727.

E. The Religious Accommodation

On March 21, 2012, the agencies issued an advance notice of proposed rulemaking ("ANPR") requesting comments on "alternative ways of providing contraceptive coverage without cost sharing in order to accommodate non-exempt, non-profit religious organizations with religious objections to such coverage." 77 Fed. Reg. 16,503. They specifically sought to "require issuers to offer group health insurance coverage without contraceptive coverage to such an organization (or its plan sponsor)," while also "provid[ing] contraceptive coverage directly to the participants and beneficiaries covered under the organization's plan with no cost sharing." *Id.* The agencies requested comment by June 19, 2012.

On February 6, 2013, after reviewing more than 200,000 comments, the agencies issued proposed rules that (1) simplified the criteria for the religious employer exemption; and (2) established an accommodation for eligible organizations with religious objections to providing contraceptive coverage. 78 Fed. Reg. 8,458-59. The proposed rule defined an "eligible organization" as one that (1) "opposes providing coverage for some or all of the contraceptive services required to be covered"; (2) "is organized and operates as a nonprofit entity"; (3) "holds itself out as a religious organization"; and (4) self-certifies that it satisfies these criteria. *Id.* at 8,462. Comments on the proposed rule were due April 5, 2013.

On July 2, 2013, after reviewing more than 400,000 comments, the agencies issued final rules simplifying the religious employer exemption and establishing the religious accommodation. 78 Fed. Reg. 39,870.[4] With respect to the latter, the final rule retained the definition of "eligible organization" set forth in the proposed rule. *Id.* at 39,874. Under the accommodation, an eligible organization that met a "self-certification standard" was "not required to contract, arrange, pay, or refer for contraceptive coverage," but its "plan participants and beneficiaries * * * [would] still benefit from separate payments for contraceptive services without cost sharing or other charge," as required by law. *Id.* The final rules were effective August 1, 2013.

F. The *Hobby Lobby* and *Wheaton College* Decisions

On June 30, 2014, the Supreme Court issued its opinion in *Burwell* v. *Hobby Lobby Stores, Inc.*, in which three closely-held corporations challenged the requirement that they "provide health-insurance coverage for methods of contraception that violate[d] the sincerely held religious beliefs of the companies' owners." 134 S. Ct. 2751, 2759 (2014). The Court held that this requirement violated the Religious Freedom Restoration Act of 1993 ("RFRA"), 42 U.S.C. § 2000bb

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[4] As to the definition of a religious employer, the final rule "eliminate[ed] the first three prongs and clarif[ied] the fourth prong of the definition" adopted in 2012. 78 Fed. Reg. 39,874. Under this new definition, "an employer that [was] organized and operate[d] as a nonprofit entity and [was] referred to in section 6033(a)(3)(A)(i) or (iii) of the Code [was] considered a religious employer for purposes of the religious employer exemption." *Id.*

et seq., because it was not the "least restrictive means" of serving the compelling interest in guaranteeing cost-free access to certain methods of contraception. *See Hobby Lobby*, 134 S. Ct. at 2781-82.[5] The Court pointed to the religious accommodation as support for this point: "HHS itself has demonstrated that it has at its disposal an approach that is less restrictive than requiring employers to fund contraceptive methods that violate their religious beliefs. * * * HHS has already established an accommodation for nonprofit organizations with religious objections." *Id.* at 2782. The Court stated that the *Hobby Lobby* ruling "[did] not decide whether an approach of this type complies with RFRA for purposes of all religious claims," *id.*, and said its opinion "should not be understood to hold that an insurance-coverage mandate must necessarily fall if it conflicts with an employer's religious beliefs," *id.* at 2783.

Several days later, the Court issued its opinion in *Wheaton College* v. *Burwell*, 134 S. Ct. 2806 (2014). The plaintiff was a nonprofit college in Illinois that was eligible for the accommodation. *Id.* at 2808 (Sotomayor, J., dissenting). Wheaton College sought an injunction, however, "on the theory that its filing of a self-certification form [would] make it complicit in the provision of contraceptives by triggering the obligation for someone else to provide the services to which it objects." *Id.* The Court granted the application for an injunction, ordering that it was sufficient for the college to "inform[] the Secretary of Health and Human Services in writing that it is a

[5] The Court assumed without deciding that such an interest was compelling within the meaning of RFRA. *Hobby Lobby*, 134 S. Ct. at 2780.

nonprofit organization that holds itself out as religious and has religious objections to providing coverage for contraceptive services * * *." *Id.* at 2807. In other words, the college was not required to "use the form prescribed by the [g]overnment," nor did it need to "send copies to health insurance issuers or third-party administrators." *Id.* The Court stated the order "should not be construed as an expression of the Court's views on the merits." *Id.*

G. Post-*Hobby Lobby* and -*Wheaton* Regulatory Action

Shortly thereafter, on August 27, 2014, the agencies initiated two regulatory actions. First, in light of *Hobby Lobby*, they issued proposed rules "amend[ing] the definition of an eligible organization [for purposes of the religious accommodation] to include a closely held for-profit entity that has a religious objection to providing coverage for some or all of the contraceptive services otherwise required to be covered." 79 Fed. Reg. 51,121. Comments were due on October 21, 2014.

Second, in light of *Wheaton*, the agencies issued IFRs ("the 2014 IFRs") providing "an alternative process for the sponsor of a group health plan or an institution of higher education to provide notice of its religious objection to coverage of all or a subset of contraceptive services, as an alternative to the EBSA Form 700 [*i.e.*, the standard] method of self-certification." *Id.* at 51,095. The agencies asserted they had both statutory authority and good cause to forgo the notice and comment period, stating that such a process would be "impracticable and contrary to the public interest," particularly in light of *Wheaton*. *Id.* at

51,095-96. The IFRs were effective immediately, and comments were due October 27, 2014.

After considering more than 75,000 comments on the proposed rule, the agencies issued final rules "extend[ing] the accommodation to a for-profit entity that is not publicly traded, is majority-owned by a relatively small number of individuals, and objects to providing contraceptive coverage based on its owners' religious beliefs"—*i.e.*, to closely-held entities. 80 Fed. Reg. 41,324. The agencies also issued a final rule "continu[ing] to allow eligible organizations to choose between using EBSA Form 700 or the alternative process consistent with the Wheaton interim order." *Id.* at 41,323.

H. The *Zubik* Opinion and Subsequent Impasse

On May 16, 2016, the Supreme Court issued its opinion in *Zubik* v. *Burwell*, 136 S. Ct. 1557 (2016) (per curiam). The petitioners, primarily non-profit organizations, were eligible for the religious accommodation, but challenged the requirement that they submit notice to either their insurer or the federal government as a violation of RFRA. *Zubik*, 136 S. Ct. at 1558. "Following oral argument, the Court requested supplemental briefing from the parties addressing 'whether contraceptive coverage could be provided to petitioners' employees, through petitioners' insurance companies, without any such notice from petitioners.'" *Id.* at 1558-59. After the parties stated that "such an option [was] feasible," the Court remanded to afford them "an opportunity to arrive at an approach going forward that accommodates petitioners' religious exercise *while at the same time ensuring that women covered by*

petitioners' health plans 'receive full and equal health coverage, including contraceptive coverage.'" Id. at 1559 (emphasis added). As in *Wheaton*, "[t]he Court express[ed] no view on the merits of the cases," and did not decide "whether petitioners' religious exercise has been substantially burdened, whether the [g]overnment has a compelling interest, or whether the current regulations are the least restrictive means of serving that interest." *Id.* at 1560.

On July 22, 2016, the agencies issued a request for information ("RFI") on whether, in light of *Zubik*,

> there are alternative ways (other than those offered in current regulations) for eligible organizations that object to providing coverage for contraceptive services on religious grounds to obtain an accommodation, while still ensuring that women enrolled in the organizations' health plans have access to seamless coverage of the full range of [FDA]-approved contraceptives without cost sharing.

81 Fed. Reg. 47,741. Comments were due September 20, 2016. On January 9, 2017, the agencies issued a document titled "FAQs About Affordable Care Act Implementation Part 36" ("FAQs").[6] The FAQs stated that, based on the 54,000 comments received in response to the July 2016 RFI, there was "no feasible approach * * * at this time that would resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health

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[6] Dep't of Labor, FAQs About Affordable Care Act Implementation Part 36, *available at* https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf.

coverage, including contraceptive coverage." FAQs at 4.

I. The 2017 IFRs at Issue

On May 4, 2017, the President issued Executive Order No. 13,798, directing the secretaries of the departments of the Treasury, Labor, and HHS to "consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive care mandate * * *." 82 Fed. Reg. 21,675. Subsequently, on October 6, 2017, the agencies issued the Religious Exemption IFR and the Moral Exemption IFR at issue in this case (collectively, "the 2017 IFRs"). The 2017 IFRs departed from the prior regulations in several important ways.

1. The Religious Exemption IFR

First, with the Religious Exemption IFR, the agencies substantially broadened the scope of the religious exemption, extending it "to encompass entities, and individuals, with sincerely held religious beliefs objecting to contraceptive or sterilization coverage," and "making the accommodation process optional for eligible organizations." 82 Fed. Reg. 47,807-08. Such entities "will not be required to comply with a self-certification process." *Id.* at 47,808. Just as the IFR expanded eligibility for the exemption, it "likewise" expanded eligibility for the optional accommodation. *Id.* at 47,812-13.

In introducing these changes, the agencies stated they "recently exercised [their] discretion to reevaluate these exemptions and accommodations," and considered factors including: "the interests served by the existing Guidelines, regulations, and

accommodation process"; the "extensive litigation"; the President's executive order; the interest in protecting the free exercise of religion under the First Amendment and RFRA; the discretion afforded under the relevant statutory provisions; and "the regulatory process and comments submitted in various requests for public comments." *Id.* at 47,793. The agencies advanced several arguments they claimed justified the lack of an advance notice and comment process for the Religious Exemption IFR, which became effective immediately.

First, the agencies cited 26 U.S.C. § 9833, 29 U.S.C. § 1191c, and 42 U.S.C. § 300gg-92, asserting that those statutes authorized the agencies "to promulgate any interim final rules that they determine are appropriate to carry out" the relevant statutory provisions. 82 Fed. Reg. 47,813. Second, the agencies asserted that even if the APA did apply, they had good cause to forgo notice and comment because implementing that process "would be impracticable and contrary to the public interest." *Id.* Third, the agencies noted that "[i]n response to several of the previous rules on this issue—including three issued as [IFRs] under the statutory authority cited above—the Departments received more than 100,000 public comments on multiple occasions," which included "extensive discussion about whether and by what extent to expand the exemption." *Id.* at 47,814.[7] For all of these reasons, the agencies asserted, "it would be impracticable and contrary to the public interest to engage in full notice and comment rulemaking before

[7] The Court will discuss Defendants' proffered justifications in more detail below.

putting these interim final rules into effect * * *." *Id.* at 47,815. Comments were due on December 5, 2017.

2. The Moral Exemption IFR

Also on October 6, 2017, the agencies issued the Moral Exemption IFR, "expand[ing] the exemption[] to include additional entities and persons that object based on sincerely held moral convictions." *Id.* at 47,849. Additionally, "consistent with [their] expansion of the exemption, [the agencies] expand[ed] eligibility for the accommodation to include organizations with sincerely held moral convictions concerning contraceptive coverage," while also making the accommodation process optional for those entities. *Id.* The agencies included in the IFR a section called "Congress' History of Providing Exemptions for Moral Convictions," referencing statutes and legislative history, case law, executive orders, and state analogues. *See id.* at 47,844-48. The agencies justified the immediate issuance of the Moral Exemption IFR without an advance notice and comment process on grounds similar to those offered regarding the Religious Exemption IFR, stating that "[o]therwise, our regulations would simultaneously provide and deny relief to entities and individuals that are, in the [agencies'] view, similarly deserving of exemptions and accommodations consistent[] with similar protections in other federal laws." *Id.* at 47,855. Comments were due on December 5, 2017.

J. This District Court Action

On November 1, 2017, Plaintiffs filed the First Amended Complaint. Dkt. No. 24 ("FAC"). They filed this motion for a preliminary injunction on November 9, 2017. Dkt. No. 28 ("Mot."). On November 29, 2017,

Defendants filed an opposition, Dkt. No. 51 ("Opp."), to which Plaintiffs replied on December 6, 2017, Dkt. No. 78 ("Reply"). The Court held a hearing on the motion on December 12, 2017. Dkt. No. 100.[8]

III. LEGAL STANDARD

A preliminary injunction is a matter of equitable discretion and is "an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter* v. *Natural Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). "A plaintiff seeking preliminary injunctive relief must establish that [it] is likely to succeed on the merits, that [it] is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in [its] favor, and that an injunction is in the public interest." *Id.* at 20. Alternatively, an injunction may issue where "the likelihood of success is such that serious questions going to the merits were raised and the balance of hardships tips sharply in [the plaintiff's] favor," provided that the plaintiff can also demonstrate the other two *Winter* factors. *Alliance for the Wild Rockies* v. *Cottrell*, 632 F.3d 1127, 1131-32 (9th Cir. 2011) (citation and internal quotation marks omitted). Under either standard, Plaintiffs bear the burden of making a clear showing that it is entitled to this extraordinary remedy. *Earth*

[8] The Court also granted several motions filed by groups seeking leave to file amicus curiae briefs. *See* Dkt. Nos. 72 (American Association of University Women, Service Employees International Union, and 14 additional professional, labor, and student associations); 74 (14 states and the District of Columbia); 76 (American Center for Law & Justice). The Court has considered those briefs along with the parties' moving papers.

Island Inst. v. *Carlton*, 626 F.3d 462, 469 (9th Cir. 2010).

IV.ANALYSIS

The Court first addresses the threshold issues of standing and venue, then turns to the preliminary injunction analysis.

A. Plaintiffs Have Standing to Sue.

1. Plaintiffs have Article III standing.

The standing doctrine is "rooted in the traditional understanding of a case or controversy," and "limits the category of litigants empowered to maintain a lawsuit in federal court to seek redress for a legal wrong." *Spokeo, Inc.* v. *Robins*, 136 S. Ct. 1540, 1547 (2016). In this way, the doctrine, "which is built on separation-of-powers principles, serves to prevent the judicial process from being used to usurp the powers of the political branches." *Clapper* v. *Amnesty Int'l USA*, 568 U.S. 398, 408 (2013). For this reason, the "standing inquiry has been especially rigorous when reaching the merits of a dispute would force [a court] to decide whether an action taken by one of the other two branches of the [f]ederal [g]overnment was unconstitutional." *Raines* v. *Byrd*, 521 U.S. 811, 819-20 (1997).

"States are not normal litigants for the purposes of invoking federal jurisdiction," *Mass.* v. *Envtl. Prot. Agency*, 549 U.S. 497, 518 (2007), and are "entitled to special solicitude in [the] standing analysis," *id.* at 520. States have standing to protect their sovereign interests, such as the interest in their physical territory. *See Or.* v. *Legal Servs. Corp.*, 552 F.3d 965, 970 (9th Cir. 2009) (quoting *Mass.*, 549 U.S. at 518-

19). They may also sue to assert their quasi-sovereign interests, like "the health and well-being—both physical and economic—of [their] residents in general." *Alfred L. Snapp & Son, Inc.* v. *P.R. ex rel. Barez,* 458 U.S. 592, 607 (1982). In the latter situation, however, "the State must be more than a nominal party." *Id.* at 608. "A quasi-sovereign interest must be sufficiently concrete to create an actual controversy between the State and the defendant." *Id.* at 602.

State or not, a plaintiff invoking federal jurisdiction bears the burden of establishing "the irreducible constitutional minimum" of standing. *Spokeo*, 136 S. Ct. at 1547 (quoting *Lujan* v. *Defenders of Wildlife*, 504 U.S. 555, 560 (1992)). That is, "the plaintiff must have suffered an injury in fact—an invasion of a legally protected interest" that is concrete, particularized, and actual or imminent, rather than conjectural or hypothetical. *Lujan*, 504 U.S. at 560 (internal quotation marks omitted). The plaintiff's injury must also be "fairly traceable to the challenged conduct of the defendant," as well as "likely to be redressed by a favorable judicial decision." *Spokeo*, 136 S. Ct. at 1547 (citing *Lujan*, 504 U.S. at 560-61).

Agency action that causes a state to "incur significant costs" is sufficient to constitute injury in fact. *See Tex.* v. *U.S.*, 809 F.3d 134, 155 (5th Cir. 2015) (finding that Texas had standing to sue federal government because Deferred Action for Parents of Americans and Lawful Permanent Residents program required the state to issue driver's licenses to program beneficiaries "at a financial loss"). Federal courts may also "recognize a 'procedural injury' when a procedural requirement has not been met, so long as the plaintiff

also asserts a 'concrete interest' that is threatened by the failure to comply with that requirement." *City of Sausalito* v. *O'Neill*, 386 F.3d 1186, 1197 (9th Cir. 2004). Such a plaintiff "must show that the procedures in question are designed to protect some threatened concrete interest of his that is the ultimate basis of his standing." *Citizens for a Better Forestry* v. *U.S. Dep't of Agric.*, 341 F.3d 961, 969 (9th Cir. 2003). The plaintiff must also "establish the reasonable probability of the challenged action's threat to [his or her] concrete interest." *Id.* (citation and internal quotation marks omitted) (original brackets). In such cases, once a plaintiff has established a procedural injury in fact, "the causation and redressability requirements are relaxed." *Id.* (citation and internal quotation marks omitted).

Plaintiffs have stated a procedural injury that is sufficient for the purposes of Article III standing. They assert that Defendants failed to comply with the APA's notice and comment requirement, resulting in Plaintiffs' being "denied the opportunity to comment and be heard, prior to the effective date of the [2017] IFRs, concerning the impact of the rules on the States and their residents." FAC ¶ 16. Plaintiffs must also show that these procedures "are designed to protect some concrete threatened interest" that "is the ultimate basis of [their] standing." *See Citizens for a Better Forestry*, 341 F.3d at 969. Plaintiffs do so by explaining that they have an "interest in ensuring that women have access to no-cost contraceptive coverage" under the ACA, in large part because without that access, Plaintiffs will incur economic obligations, either to cover contraceptive services necessary to fill in the gaps left by the 2017 IFRs or for "expenses

associated with unintended pregnancies." Reply at 3; *see also* Dkt. No. 28-8 (Decl. of Lawrence Finer) ¶ 61 ("Unintended pregnancies cost the state approximately $689 million * * * in 2010."); Dkt. No. 28-14 (Decl. of Jenna Tosh) ¶ 27 (stating that California pays for 64 percent of unplanned births, with the average cost estimated at more than $15,000 per birth). Accordingly, Plaintiffs are more than merely a "nominal party" in this suit asserting a quasi-sovereign interest in the physical health and well-being of their citizens. *See Alfred L. Snapp & Son*, 458 U.S. at 607-08. Rather, they have shown that the 2017 IFRs will impact their fiscs in a manner that corresponds with the IFRs' impact on their citizens' access to contraceptive care. And, while the causation and redressability requirements are relaxed in cases of procedural injury, Plaintiffs also satisfy those prongs of the standing inquiry. The injury asserted is directly traceable to Defendants' decision to issue the IFRs without advance notice and comment, and granting a preliminary injunction would enjoin enforcement of those IFRs until the Court can assess the merits.[9]

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[9] While Defendants' primary argument is that Plaintiffs lack standing, they fail to address, or even acknowledge, Plaintiffs' asserted procedural injury under the APA in this context, focusing instead on opposing Plaintiffs' standing to bring any substantive claims. *See* Opp. at 8-11. Defendants thus fail to contend with the "relaxed" causation and redressability requirements. *See Citizens for a Better Forestry,* 341 F.3d at 969. They also inaccurately cast Plaintiffs' allegations regarding their fiscal injury as "conclusory," failing to address the substantial declarations supporting Plaintiffs' motion. *See* Opp. at 9.

Plaintiffs thus have standing under Article III.

2. Statutory Standing

In addition to the requirements of Article III, "[a] plaintiff must also satisfy the non-constitutional standing requirements of the statute under which [it] seeks to bring suit." *City of Sausalito*, 386 F.3d at 1199. The APA provides that "[a] person * * * adversely affected or aggrieved by agency action within the meaning of a relevant statute is entitled to judicial review thereof." 5 U.S.C. § 702.[10] Courts have interpreted this provision to require a petitioner bringing suit under the APA to "establish (1) that there has been final agency action adversely affecting the plaintiff, and (2) that, as a result, it suffers legal wrong or that its injury falls within the zone of interests of the statutory provision the plaintiff claims was violated." *Citizens for a Better Forestry*, 341 F.3d at 976 (citation and internal quotation marks omitted).

To qualify as "final agency action," (1) "the action must mark the consummation of the agency's decisionmaking process" and (2) "the action must be one by which rights or obligations have been determined, or from which legal consequences will flow * * *." *Bennett* v. *Spear*, 520 U.S. 154, 177-78 (2014) (citations and internal quotations marks omitted). And the "zone of interests" inquiry is

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[10] The Court is satisfied that Plaintiffs are persons under the APA. *See, e.g.*, *Texas*, 809 F.3d at 162-63 (finding that Texas, the plaintiff, met the APA's statutory standing requirements); *Ariz.* v. *Inter Tribal Council of Ariz., Inc.*, 133 S. Ct. 2247, 2259 (2013) (noting, in dicta, that a state may challenge the decision of a federal commission under the APA).

"construed generously" and is "not meant to be especially demanding": a court should only deny standing on this ground where "the plaintiff's interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit." *City of Sausalito*, 386 F.3d at 1200 (quoting *Clarke* v. *Secs. Indus. Ass'n*, 479 U.S. 388, 399 (1987)) (internal quotation marks omitted).

The IFRs are final agency action. Despite the presence of the word "interim" in "interim final rule," "the key word * * * is not interim, but final," because interim "refers only to the Rule's intended duration—not its tentative nature." *See Beverly Enters.* v. *Herman*, 50 F. Supp. 2d. 7, 17 (D.D.C. 1999) (citing *Career Coll. Ass'n* v. *Riley*, 74 F.3d 1265, 1268 (D.C. Cir. 1996)). The IFRs are thus properly understood as the consummation of the relevant agencies' decisionmaking process. And it is plain that "rights or obligations have been determined" by the IFRs. For example, the Religious Exemption IFR extends the exemption to any entity with a "sincerely held religious belief[] objecting to contraceptive or sterilization coverage," 82 Fed. Reg. 47,807-08, while the Moral Exemption IFR broadens eligibility even more dramatically by making the exemption available to those "with sincerely held moral convictions by which they object to contraceptive or sterilization coverage," *id.* at 47,849 (emphasis added).

Plaintiffs' asserted injury is also squarely within the APA's "zone of interests." Here, Plaintiffs allege a procedural injury because Defendants failed to comply with the APA's notice and comment requirement, arguing they "have been denied the opportunity to

comment and be heard, prior to the effective date of the IFRs, concerning the impact of the rules on the States and their residents." FAC ¶ 16. The purpose of the APA's notice and comment provision is

> (1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review.

Envtl. Integrity Project v. *Envtl. Prot. Agency*, 425 F.3d 992, 996 (D.C. Cir. 2005) (citation omitted). Plaintiffs' right to be heard regarding the 2017 IFRs' prospective impact on them and their citizens is plainly within the ambit of the APA.

Plaintiffs accordingly have statutory standing under the APA.

B. Venue Is Proper in the Northern District of California.

Defendants next assert that venue is improper here, reasoning that the venue statute requires Plaintiffs to bring suit in their principal place of business, and claiming that "there is no plausible 'principal place of business' for the State of California other than Sacramento," its capital, which is in the Eastern District of California. Opp. at 12-13. While there is scant authority on this issue, the Court finds venue in this district proper.

In a suit against the United States, its officers, or its agencies, a civil action "may, except as otherwise provided by law, be brought in any judicial district in

which * * * the plaintiff resides if no real property is involved in the action." 28 U.S.C. § 1391(e)(1). There is no real property at stake in this action, so the venue inquiry turns on the question of Plaintiffs' residence. While this appears to be an issue of first impression in this district, common sense dictates that for venue purposes, a state plaintiff with multiple federal judicial districts resides in any of those districts. The only other federal court that appears to have examined the question in any detail reached the same conclusion, finding that a state may bring suit under 28 U.S.C. § 1391(e)(1) "in any district within the state":

> Given the complete absence of authority presented directly on this point, this court is not willing to create the new rule proposed by the Federal Defendants that would, for no just or logical reason, limit a state containing more than one federal judicial district to suing the Federal Government only in the district containing the state capital, regardless of any other consideration relevant to the case or the parties' convenience. Indeed, the absence of authority may be precisely because common sense dictates that a state resides throughout its sovereign borders and the idea has not previously been challenged.

Ala. v. *U.S. Army Corp of Eng'rs*, 382 F. Supp. 2d 1301, 1329 (N.D. Ala. 2005).[11] The Court finds this

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[11] Defendants, in contrast, cite a 27-year-old unpublished case from the Eastern District of Pennsylvania which involved a different section of the venue statute and addressed the residence

reasoning persuasive, and declines to adopt Defendants' rule that would limit the State of California to bringing suit in the Eastern District of California. Venue is therefore proper in this district.

C. Plaintiffs Have Shown They Are Entitled to a Preliminary Injunction.

Plaintiffs are entitled to a preliminary injunction because (1) they have shown that, at a minimum, they are likely to succeed on their claim that Defendants violated the APA by issuing the 2017 IFRs without advance notice and comment; (2) they have shown that they are likely to suffer irreparable harm as a result of this procedural violation; and (3) the balance of equities tips in Plaintiffs' favor, and the public interest favors granting the injunction.

1. Plaintiffs are likely to succeed in showing that Defendants violated the APA in issuing the 2017 IFRs without advance notice and comment.

The most important *Winter* factor is likelihood of success on the merits. *See Disney Enters., Inc.* v. *VidAngel, Inc.*, 869 F.3d 848, 856 (9th Cir. 2017).

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of state agencies and state officials, not the states themselves. *See* Opp. at 13 (citing *Bentley* v. *Ellam*, No. 89-5418, 1990 WL 63734, at *1 (E.D. Pa. May 8, 1990)).

a. With few exceptions, the APA requires agencies to publish notice of proposed rules and consider public comment before final promulgation.

Plaintiffs contend that "Defendants evaded their obligations under the APA by promulgating rules without proper notice and comment." Mot. at 15. The Court agrees. Under the APA, an agency promulgating a rule normally must first publish a "[g]eneral notice of proposed rule making" in the Federal Register, including: "(1) a statement of the time, place, and nature of public rule making proceedings; (2) reference to the legal authority under which the rule is proposed; and (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b). After such notice has issued, "the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation." *Id.* § 553(c). The agency must then consider any "relevant matter presented * * *." *Id.* As relevant here, these notice and comment requirements do not apply "when the agency for good cause finds * * * that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." *Id.* § 553(b)(3)(B).[12]

The APA's notice and comment requirement reflects Congress' "judgment that notions of fairness

[12] Defendants do not argue that notice and comment was "unnecessary" for either the Religious Exemption IFR, *see* 82 Fed. Reg. 47,813, or the Moral Exemption IFR, *see id.* at 47,855.

and informed administrative decisionmaking require that agency decisions be made only after affording interested persons notice and an opportunity to comment." *Paulsen* v. *Daniels*, 413 F.3d 999, 1004-05 (9th Cir. 2005) (quoting *Chrysler Corp.* v. *Brown*, 441 U.S. 281, 316 (1979)). "It is antithetical to the structure and purpose of the APA for an agency to implement a rule first, and then seek comment later." *Id.* at 1005. Accordingly, an agency "must overcome a high bar if it seeks to invoke the good cause exception to bypass the notice and comment requirement," given that the exception "is essentially an emergency procedure." *U.S.* v. *Valverde*, 628 F.3d 1159, 1164-65 (9th Cir. 2010) (citations, internal quotations marks, and brackets omitted). In other words, "a failure to comply with the APA's notice and comment procedures may be excused only in those narrow circumstances in which delay would do real harm." *Id.* (citation and internal quotation marks omitted); *see also Indep. Guard Ass'n of Nev., Local No. 1.* v. *O'Leary ex rel. U.S. Dep't of Energy*, 57 F.3d 766, 769 (9th Cir. 1995) (emphasizing that good-cause exceptions to section 553 are to be "narrowly construed and only reluctantly countenanced") (citation omitted). The inquiry as to whether an agency has demonstrated good cause "proceeds case-by-case, sensitive to the totality of the factors at play." *Valverde*, 628 F.3d at 1164 (citations and internal quotation marks omitted).

On October 6, 2017, Defendants promulgated the Religious Exemption IFR and Moral Exemption IFR, effective immediately. Although both IFRs solicited public comment until December 5, 2017, their immediate promulgation violated the APA's notice and comment requirement because Defendants failed to

publish the required advance notice of proposed rulemaking. Nor did they provide the public with an advance opportunity to comment, making it impossible for the agency to consider the input of any interested parties before enactment. Thus, the issuance of the 2017 IFRs was unlawful unless either (a) the APA does not apply or (b) the Defendants can show that an exception to its requirements applies.

b. Defendants had no statutory authority to forgo the APA's notice and comment requirement as to the 2017 IFRs.

Defendants first argue that they had "express statutory authorization" to promulgate the IFRs, thus exempting them from the APA's advance notice and comment requirement. *See* Opp. at 15. Specifically, Defendants cite the authority conferred upon them by 26 U.S.C. § 9833, 29 U.S.C. § 1191c, and 42 U.S.C. § 300gg-92. *See id*. Each of those provisions, in turn, contains this nearly identical phrase: "[t]he Secretary may promulgate any interim final rules as the Secretary determines are appropriate to" carry out its statutory duties in this realm. Defendants interpret this as a signal that Congress intended to free them from the APA's requirements. But "[t]he APA provides that no subsequent statute shall be deemed to modify it 'except to the extent that it does so expressly.'" *Castillo-Villagra* v. *Immigration & Naturalization Serv.*, 972 F.2d 1017, 1025 (9th Cir. 1992) (quoting 5 U.S.C. § 559); *see also Lake Carriers Ass'n* v. *Envtl. Prot. Agency*, 652 F.3d 1, 6 (D.C. Cir. 2011) (per curiam) (citing section 559 for the same principle). The D.C. Circuit has framed the question as "whether Congress has established procedures so clearly

different from those required by the APA that it must have intended to displace the norm." *Asiana Airlines* v. *Fed. Aviation Admin.*, 134 F.3d 393, 397 (D.C. Cir. 1998).

Here, the statutory authority cited by Defendants does not support their argument that Congress intended to displace the APA's notice and comment requirements. *Castilla-Villagra* involved the question of whether the APA or the Immigration and Naturalization Act ("INA") governed the court's analysis of an administrative notice. 972 F.2d at 1025. In deciding that the INA governed, the court cited the INA's exclusivity provision, as well as the Supreme Court's interpretation of that provision. *Id.* at 1026. In contrast, the authority cited by Defendants contains no such exclusivity provision. And in *Lake Carriers*, the court considered whether the Environmental Protection Agency ("EPA") violated the APA when it issued a permit without providing an opportunity for notice and comment regarding certain state certification conditions. 652 F.3d at 5-6. In support of its position, the EPA cited a provision of the Clean Water Act ("CWA") that required certifying states to "establish procedures for public notice * * * and, to the extent it deems appropriate, procedures for public hearings * * *." *Id.* at 6 (quoting 33 U.S.C. § 1341(a)). While the court ultimately found on another ground that the EPA was not required to engage in notice and comment, *id*. at 10, the court "doubt[ed] that [the CWA provision's] requirement that states provide for notice and comment regarding proposed conditions constitute[d] the requisite 'plain express[ion]' of congressional intent to supersede the APA's requirements," *id*. at 6. This Court likewise finds that

the statutory authority cited by Defendants—which is much more broadly worded than the CWA provision in Lake Carriers—is not so clearly different from the APA's procedures so as to reflect an intent to displace them. Finally, in *Asiana Airlines*, the court found that a statute directing the Federal Aviation Administration to "publish in the Federal Register an initial fee schedule and associated collection process as interim final rule, pursuant to which public comment will be sought and a final rule issued" supplanted the APA's requirements. 134 F.3d at 396-98. In this case, the authority cited by Defendants makes no mention of any analogous procedure (or any procedure at all).

Defendants' arguments to the contrary are unavailing. No case cited by the parties or identified by the Court has held that the statutory provisions cited by the Defendants supplant the APA's procedural requirements. Defendants quote *Real Alternatives, Inc.* v. *Burwell*, 150 F. Supp. 3d 419, 427 n.6 (M.D. Pa. 2015), for the proposition that the "APA * * * did not apply to the 2011 IFR under this specific statutory authority." *See* Opp. at 15. But that reading is not supported by the case, which simply quoted the agencies' argument in the 2011 IFR that they had statutory authority to forgo notice and comment for that IFR. *See Real Alternatives*, 150 F. Supp. 3d at 427 n.6 (quoting 76 Fed. Reg. 46,624). Defendants also cite *Coalition for Parity, Inc.* v. *Sebelius*, 709 F. Supp. 2d 10 (D.D.C. 2010), in support of their argument that the asserted statutory authority contemplates procedures that are "clearly different" from the APA's requirements. *See* Opp. at 15. But that case only undermines their argument, because there, the court considered the same statutory

grants of IFR-promulgating authority cited by Defendants in this case (i.e., 26 U.S.C. § 9833, 29 U.S.C. § 1191c, and 42 U.S.C. § 300gg-92), and found that they were not sufficiently different from the APA to displace the latter's requirements. *See Coalition for Parity*, 709 F. Supp. 2d at 17-19.

Defendants accordingly had no statutory authority to forgo notice and comment before issuing the 2017 IFRs.

c. The "totality of factors" establishes that Defendants had no good cause to forgo advance notice and comment for the 2017 IFRs.

The Court also finds that the "totality of factors" compels the conclusion that Defendants had no good cause to forgo notice and comment. Defendants argue that engaging in notice and comment before issuing the 2017 IFRs would have been "impracticable and contrary to the public interest." *See* 82 Fed. Reg. 47,813; *id*. at 47,855. "Notice and comment is 'impracticable' when the agency cannot 'both follow section 553 and execute its statutory duties.'" *Riverbend Farms, Inc.* v. *Madigan*, 958 F.2d 1479, 1484 n.2 (9th Cir. 1992) (quoting *Levesque* v. *Block*, 723 F.2d 175, 184 (1st Cir. 1983)). And it is "contrary to the public interest" when "public rule-making procedures * * * prevent an agency from operating." *Id.* (citation and internal quotation marks omitted); *see also Levesque*, 723 F.2d at 185 ("Congress's view seems to have been that any time one can expect real interest from the public in the content of the proposed regulation, notice-and-comment rulemaking will not be contrary to the public interest.").

Defendants fail to show that their decision to forgo advance notice and comment was justified by good cause under section 553. In the Religious Exemption IFR, they set forth several purported justifications: (1) the "[d]ozens" of pending lawsuits challenging the contraceptive mandate; (2) the desire to cure violations of RFRA, based on the contention that "requiring certain objecting entities or individuals to choose between the Mandate, accommodation, or penalties for [noncompliance]" constitutes such a violation; (3) the desire to bring HRSA guidelines into "accord with the legal realities" of the temporary injunctions issued in various cases; (4) the desire "to provide immediate resolution" to parties with religious objections to the mandate; (5) the desire to avoid increases in the costs of health insurance caused by entities remaining on more expensive grandfathered plans—which are exempt from the mandate—to avoid becoming subject to the mandate; and (6) the desire to avoid delay in making the accommodation available to a broader category of entities. 82 Fed. Reg. 47,813-15. In the Moral Exemption IFR, Defendants set forth similar justifications. *Id.* at 47,855-56.

None of these proffered reasons justified the use of the "emergency procedure" that is the good-cause exception. *See Valverde*, 628 F.3d at 1164-65. Defendants make no argument that the above considerations made it impossible for them to both satisfy the notice and comment requirement and execute their statutory duties under the ACA. Defendants also fail to establish (or even claim) that notice and comment would have effectively prevented them from operating. Instead, they argue that "any additional delay in issuing the Rules would be

contrary to the public interest," because "[p]rompt effectiveness would provide entities and individuals facing burdens on their sincerely held religious beliefs and moral convictions with important and urgent relief." Opp. at 16.[13] But "[i]f 'good cause' could be satisfied by an Agency's assertion that 'normal procedures were not followed because of the need to provide immediate guidance and information * * * then an exception to the notice requirement would be created that would swallow the rule." *See Valverde*, 628 F.3d at 1166 (quoting *Zhang* v. *Slattery*, 55 F.3d 732, 746 (2d Cir. 1995)).[14]

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[13] Indeed, as to the public interest justification, Defendants estimated at oral argument that they have received hundreds of thousands of comments regarding the 2017 IFRs. This weakens the suggestion that engaging in advance notice and comment would have been contrary to the public interest, given the public's evident "real interest" in this matter. *See Levesque*, 723 F.2d at 185.

[14] Defendants cite *Priests for Life* v. *U.S. Department of Health & Human Services*, 772 F.3d 229 (D.C. Cir. 2014), *vacated*, *Zubik*, 136 S. Ct. at 1561, as a decision finding good cause to forgo advance notice and comment in circumstances similar to these. *See* Opp. at 16-17. But *Priests for Life* is distinguishable. There, the court rejected the religious objector plaintiffs' argument that the government lacked the requisite good cause to promulgate the 2014 IFRs without advance notice and comment, noting that the 2014 IFRs modified regulations that "were recently enacted pursuant to notice and comment rulemaking, and *presented virtually identical issues* * * * ." *Priests for Life*, 772 F.3d at 276 (emphasis added); *see also id.* (describing the modifications in the 2014 IFRs as "minor" and "meant only to augment current regulations in light of" the Supreme Court's decision in *Wheaton*) (citation and internal quotation marks omitted). The 2017 IFRs, in contrast, represent a dramatic about-face in federal policy, and adopt sweeping changes with regard to the exemption and accommodation.

Defendants also argue that they "demonstrated a willingness to consider public comment, both prior and following issuance of the rules." Opp. at 16. But Defendants' willingness to consider comments "on the exemption and accommodation issues" generally, see *id*. at 17, does not excuse their failure to do so before enacting the 2017 IFRs. This is particularly true because the 2017 IFRs represent a direct repudiation of Defendants' prior well-documented and well-substantiated public positions. Moreover, these IFRs are much broader in scope, and introduce an entirely new moral conviction basis for objecting to the contraceptive mandate. Until October 6, 2017, the public had no notice of Defendants' intent to dramatically broaden eligibility for the exemption and to make the accommodation optional. The fact that the public may have previously commented on these broad topics in the context of past iterations of the rules does not change that.

In addition, whether or not Defendants are willing to consider post-promulgation comments, it remains "antithetical to the structure and purpose of the APA for an agency to implement a rule first, and then seek comment later." *Paulsen*, 413 F.3d at 1005; *see also Valverde*, 628 F.3d at 1166 (noting that "[t]he Attorney General's request for post-promulgation comments in issuing the interim rule casts further doubt upon the authenticity and efficacy of the" asserted basis for good cause under section 553). The same reasoning defeats Defendants' argument that "the Rules are effective only until final rules are issued." *See* Opp. at 17. And that argument is further undercut by the fact that on November 30, 2017 the Centers for Medicare & Medicaid Services, which are part of HHS, issued

guidance for the implementation of the 2017 IFRs.[15] The Court agrees with Plaintiffs that the issuance of this guidance, before the end of the post-promulgation comment period, suggests that "it does not appear that the Defendants expect public comment to inform implementation." Reply at 10.

In short, Defendants had no good cause to forgo the APA's notice and comment requirements, because their asserted justifications do not "overcome the high bar" they must clear to do so. *See Valverde*, 628 F.3d at 1164-65.

d. Defendants' failure to provide an advance notice and comment process for the 2017 IFRs was not harmless error.

Defendants argue that, in any event, "any error in forgoing notice and comment was harmless," citing the APA's instruction to take "due account" of "the rule of prejudicial error." Opp. at 18 (quoting 5 U.S.C. § 706). The Court, however, exercises "great caution in applying the harmless error rule in the administrative rulemaking context," lest it "gut[] the APA's procedural requirements." *Paulsen*, 413 F.3d at 1006 (quoting *Riverbend Farms*, 958 F.2d at 1487). "[T]he failure to provide notice and comment is harmless only where the agency's mistake 'clearly had no bearing on the procedure used or the substance of decision reached.'"

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[15] *See* Ctrs. for Medicare & Medicaid Servs., Notice by Issuer or Third Party Administrator for Employer/Plan Sponsor of Revocation of the Accommodation for Certain Preventive Services, *available at* https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Notice-Issuer-Third-Party-Employer-Preventive.pdf.

Id. (*quoting Riverbend Farms*, 958 F.2d at 1487). In Paulsen, the court found that the Bureau of Prisons' "violation of the APA was not merely technical," because "the Bureau failed to provide the required notice-and-comment period before effectuating [an] interim regulation, thereby precluding public participation in the rulemaking." *Id.* Defendants' actions here are analogous: they precluded public participation in the promulgation of the 2017 IFRs before those rules became effective. As such, there is no way to conclude that Defendants' violation "clearly had no bearing on the procedure used or the substance of decision reached," meaning that the error was not harmless.

Defendant argues that "the Rules were issued after the Agencies received 'more than 100,000 public comments' throughout six years of publishing and modifying these regulations." Opp. at 18. But as discussed above, that does not render harmless this procedural error, regarding these IFRs. Nor does it take into account the substantial differences between the previous iterations of these rules and the IFRs at issue.[16] Far from being harmless, Defendants' error prevented Plaintiffs from vindicating the purpose of the APA's notice and comment requirement. For these reasons, Plaintiffs are, at a minimum, likely to succeed

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[16] *See* 75 Fed. Reg. 41,730 (2010 IFR was necessary to allow health plans sufficient time to comply with the requirements of the newly-enacted ACA within an approximately two-month timeframe); 76 Fed. Reg. 46,624 (2011 IFR was based on public comments received in response to the 2010 IFR, before HRSA's 2011 Guidelines were in effect); 79 Fed. Reg. 51,095-96 (2014 IFR was issued in direct response to the *Wheaton College* decision).

in showing that Defendants violated the APA's procedural requirements.

2. Plaintiffs are likely to suffer irreparable harm unless the Court enjoins the 2017 IFRs.

A procedural injury may serve as a basis for a finding of irreparable harm when a preliminary injunction is sought. *See N. Mariana Islands* v. *U.S.*, 686 F. Supp. 2d 7, 17 (D.D.C. 2009) (finding, in preliminary injunction analysis, that "[a] party experiences actionable harm when 'depriv[ed] of a procedural protection to which he is entitled' under the APA") (*quoting Sugar Cane Growers Coop. of Fla.* v. *Veneman*, 289 F.3d 89, 94-95 (D.C. Cir. 2002)); *Save Strawberry Canyon* v. *Dep't of Energy*, 613 F. Supp. 2d 1177, 1189-90 (N.D. Cal. 2009) (finding irreparable harm requirement satisfied where plaintiff claimed procedural violation of National Environmental Policy Act). "[A] plaintiff must demonstrate immediate threatened injury as a prerequisite to preliminary injunctive relief." *Boardman* v. *Pac. Seafood Group*, 822 F.3d 1011, 1022 (9th Cir. 2016) (citation and emphasis omitted). A threat is sufficiently immediate "if the plaintiff is likely to suffer irreparable harm before a decision on the merits can be rendered." *Id.* at 1023 (citation and internal quotation marks omitted). A court's analysis focuses on whether harm is irreparable, "irrespective of the magnitude of the injury." *Simula, Inc.* v. *Autoliv, Inc.*, 175 F.3d 716, 725 (9th Cir. 1999).

Plaintiffs are not only likely to suffer irreparable procedural harm in the absence of a preliminary injunction, they already have done so. Because the 2017 IFRs were effective immediately, Plaintiffs' harm

is ongoing. Every day the IFRs stand is another day Defendants may enforce regulations likely promulgated in violation of the APA's notice and comment provision, without Plaintiffs' advance input. And Plaintiffs' right to provide such input does not exist in a vacuum. Rather, it is in large part defined by what is at stake: the health of Plaintiffs' citizens and Plaintiffs' fiscal interests. Under the 2017 IFRs, more employers than ever before are eligible for the exemption and the accommodation, the latter of which is now entirely optional for organizations asserting a religious or moral objection. Put another way, for a substantial number of women, the 2017 IFRs transform contraceptive coverage from a legal entitlement to an essentially gratuitous benefit wholly subject to their employer's discretion. *See* generally Dkt. No. 72 at 6-14 (amicus brief for American Association of University Women et al., describing "wide and potentially boundless range" of employers who "will be able to claim religious or moral exemptions" under the 2017 IFRs). The impact on the rules governing the health insurance coverage of Plaintiffs' citizens—and the stability of that coverage—was immediate, which also implicates Plaintiffs' fiscal interests as described above. If the Court ultimately finds in favor of Plaintiffs on the merits, any harm caused in the interim by rescinded contraceptive coverage would not be susceptible to remedy. Thus, Plaintiffs have satisfied the irreparable harm prong of the inquiry.

3. The balance of the equities tips in Plaintiffs' favor, and a public interest

favors granting preliminary injunctive relief.

Plaintiffs also prevail on the balance of equities and public interest analyses. When the government is a party to a case in which a preliminary injunction is sought, the balance of the equities and public interest factors merge. *Drakes Bay Oyster Co.* v. *Jewell*, 747 F.3d 1073, 1092 (9th Cir. 2014). Broadly speaking, there are two interests at stake in that balance: "the interest in ensuring coverage for contraceptive and sterilization services" as provided for under the ACA, and the interest in "provid[ing] conscience protections for individuals and entities with sincerely held religious beliefs [or moral convictions] in certain health care contexts." 82 Fed. Reg. 47,793; *see also id*. at 47,839. Here, but for the APA violation the Court has found likely to be shown, Plaintiffs could have participated in Defendants' rulemaking process, "explain[ed] the practical effects of [the] rule before [it was] implemented," and helped "ensure[] that the agency proceed in a fully informed manner, exploring alternative, less harmful approaches" to expanding eligibility for the exemption and making the accommodation optional. *See* Mot. at 18-19. That does not mean the outcome necessarily would have been different, but section 553 is concerned with the important value served by proper process. *See Citizens for a Better Forestry*, 341 F.3d at 976 (stating that petitioners alleging procedural injury under an environmental statute were required to show only that adherence to statutory procedures could influence an agency's decision, and not that such adherence "would result in a different conclusion") (citation omitted).

With those interests in mind, the Court concludes that the balance of equities tips in Plaintiffs' favor. Plaintiffs face potentially dire public health and fiscal consequences as a result of a process as to which they had no input. On the other hand, returning to the state of affairs before the enactment of the 2017 IFRs—in which eligible entities still would be permitted to avail themselves of the exemption or the accommodation—does not constitute an equivalent harm to the Defendants pending resolution of the merits. While Defendants' interest in "protecting religious liberty and conscience" is unquestionably legitimate, *see* Opp. at 35, the Court believes it likely that the prior framing of the religious exemption and accommodation permissibly ensured such protection. That is to say, the Court views as likely correct the reasoning of the eight Circuit Courts of Appeals (of the nine to have considered the issue) which found that the procedure in place prior to the 2017 IFRs did not impose a substantial burden on religious exercise under RFRA.[17] The balance of equities thus tips in Plaintiffs' favor.

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[17] *See Priests for Life* v. *U.S. Dep't of Health & Human Servs.*, 772 F.3d 229 (D.C. Cir. 2014), *vacated*, *Zubik*, 136 S. Ct. at 1561; *Geneva Coll.* v. *Sec'y U.S. Dep't of Health & Human Servs.*, 778 F.3d 422 (3d Cir. 2015), *vacated*, *Zubik*, 136 S. Ct. at 1561; *E. Tex. Baptist Univ.* v. *Burwell*, 793 F.3d 449 (5th Cir. 2015), *vacated*, *Zubik*, 136 S. Ct. at 1561; *Little Sisters of the Poor Home for the Aged, Denver, Colo.* v. *Burwell*, 794 F.3d 1151 (10th Cir. 2015), *vacated*, *Zubik*, 136 S. Ct. at 1561; *Univ. of Notre Dame* v. *Burwell*, 786 F.3d 606 (7th Cir. 2015), *vacated*, 136 S. Ct. 2007 (2016); *Catholic Health Care Sys.* v. *Burwell*, 796 F.3d 207 (2d Cir. 2015), *vacated*, 136 S. Ct. 2450 (2016); *Mich. Catholic Conference & Catholic Family Servs.* v. *Burwell*, 807 F.3d 738

For similar reasons, the public interest favors the granting of a preliminary injunction. The Court notes that "[t]he public interest is served when administrative agencies comply with their obligations under the APA." *N. Mariana Islands*, 686 F. Supp. 2d. at 21 (citation omitted); *see also Alcaraz* v. *Block*, 746 F.2d 593, 610 (9th Cir. 1984) ("The APA creates a statutory scheme for informal or notice-and-comment rulemaking reflecting 'a judgment by Congress that the public interest is served by a careful and open review of proposed administrative rules and regulations.'") (citation omitted).

Plaintiffs have therefore shown that the balance of equities tips in their favor, and that the public interest favors granting a preliminary injunction. Because the standard set forth in *Winter* is met, the Court grants Plaintiffs' motion.[18]

(6th Cir. 2015), *vacated*, 136 S. Ct. 2450 (2016); *Grace Schs.* v. *Burwell*, 801 F.3d 788 (7th Cir. 2015), *vacated*, 136 S. Ct. 2011 (2016); *Eternal Word Television Network* v. *Sec'y of U.S. Dep't Health & Human Servs.*, 818 F.3d 1122 (11th Cir. 2016). Only the Eighth Circuit has found that the religious accommodation, as it existed before the promulgation of the 2017 IFRs, imposed a substantial burden on religious exercise under RFRA. *See Sharpe Holdings, Inc.* v. *U.S. Dep't of Health & Human Servs.*, 801 F.3d 927, 945 (8th Cir. 2015) (affirming grant of preliminary injunction to religious objectors because "they [were] likely to succeed on the merits of their RFRA challenge to the contraceptive mandate and the accommodation regulations"), *vacated*, *Dep't of Health & Human Servs.* v. *CNS Int'l Ministries*, --- S. Ct. ---, 2016 WL 2842448 (2016); *Dordt Coll.* v. *Burwell*, 801 F.3d 946 (8th Cir. 2015) (applying reasoning of *Sharpe Holdings* to similar facts), *vacated*, *Burwell* v. *Dordt Coll.*, 136 S. Ct. 2006 (2016).

[18] Because the Court finds that entry of a preliminary injunction

D. This Preliminary Injunction Effectively Reinstates the Regime in Place Before the Issuance of the 2017 IFRs.

The Court next turns to the contours of Plaintiffs' remedy. "The scope of an injunction is within the broad discretion of the district court * * * ." *TrafficSchool.com, Inc.* v. *Edriver Inc.*, 653 F.3d 820, 829 (9th Cir. 2011). "Ordinarily when a regulation is not promulgated in compliance with the APA, the regulation is invalid." *Paulsen*, 413 F.3d at 1008. "The effect of invalidating an agency rule is to reinstate the rule previously in force." *Id.*

Under the circumstances, the Court finds it appropriate to issue a nationwide preliminary injunction. Defendants did not violate the APA just as to Plaintiffs: no member of the public was permitted to participate in the rulemaking process via advance notice and comment. Accordingly, Defendants are (1) preliminarily enjoined from enforcing the 2017 IFRs, and (2) required to continue under the regime in place before October 6, 2017, pending a determination on the merits. This is consistent with the general practice of invalidating rules not promulgated in compliance with the APA and reinstating the "rule previously in force," and maintains the status quo that existed before the implementation of the likely invalid 2017 IFRs.

The Court notes that simply enjoining Defendants from enforcing the 2017 IFRs, without requiring them to proceed under the prior regime pending resolution of the merits, would result in a problematic regulatory

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is warranted on the basis discussed above, it need not at this time consider the additional bases for injunctive relief advanced by Plaintiffs.

vacuum, in which the rights of both women seeking cost-free contraceptive coverage and employers seeking religious exemption or accommodation would be uncertain. *See* Opp. at 35 n.25. At oral argument, counsel for Defendants confirmed that they do not advocate for such a vacuum in the event the Court grants a preliminary injunction. This nationwide injunction does not conflict with the plaintiff-specific injunctions issued by the courts in the *Zubik* cases or any other case. Returning to the state of affairs before October 6, 2017 means just that: the exemption and accommodation as they existed following the *Zubik* remand remain in effect, as do any court orders enjoining Defendants from enforcing those rules against specific plaintiffs.

V. CONCLUSION

For the reasons set forth above, Plaintiffs' motion for a preliminary injunction is **GRANTED**, effective as of the date of this order. The case management conference currently set for January 9, 2018 at 2:00 p.m. is **ADVANCED** to January 9, 2018 at 10:00 a.m. The parties shall submit a joint case management statement by January 5, 2018 at 5:00 p.m.

IT IS SO ORDERED.

Dated: 12/21/2017

s/ HAYWOOD S. GILLIAM, JR.
United States District Judge

APPENDIX C

42 U.S.C. § 2000bb-1 provides:

§ 2000bb-1. Free exercise of religion protected

(a) In general

Government shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability, except as provided in subsection (b) of this section.

(b) Exception

Government may substantially burden a person's exercise of religion only if it demonstrates that application of the burden to the person—

(1) is in furtherance of a compelling governmental interest; and

(2) is the least restrictive means of furthering that compelling governmental interest.

(c) Judicial relief

A person whose religious exercise has been burdened in violation of this section may assert that violation as a claim or defense in a judicial proceeding and obtain appropriate relief against a government. Standing to assert a claim or defense under this section shall be governed by the general rules of standing under article III of the Constitution.

42 U.S.C. § 300gg-13(a)(4) provides:

§ 300gg-13. Coverage of preventive health services

(a) In general

A group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for—

* * *

(4) with respect to women, such additional preventive care and screenings not described in paragraph (1) as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph.

29 U.S.C. § 1185d provides:

§ 1185d. Additional market reforms

(a) General rule

Except as provided in subsection (b)—

(1) the provisions of part A of title XXVII of the Public Health Service Act (as amended by the Patient Protection and Affordable Care Act) shall apply to group health plans, and health insurance issuers providing health insurance coverage in connection with group health plans, as if included in this subpart; and

(2) to the extent that any provision of this part conflicts with a provision of such part A with respect to group health plans, or health insurance issuers providing health insurance coverage in connection

with group health plans, the provisions of such part A shall apply.

(b) Exception

Notwithstanding subsection (a), the provisions of sections 2716 and 2718 of title XXVII of the Public Health Service Act (as amended by the Patient Protection and Affordable Care Act) shall not apply with respect to self-insured group health plans, and the provisions of this part shall continue to apply to such plans as if such sections of the Public Health Service Act (as so amended) had not been enacted.

26 U.S.C. § 4980D provides:

§ 4980D. Failure to meet certain group health plan requirements

(a) General rule.—There is hereby imposed a tax on any failure of a group health plan to meet the requirements of chapter 100 (relating to group health plan requirements).

(b) Amount of tax.—

(1) In general.—The amount of the tax imposed by subsection (a) on any failure shall be $100 for each day in the noncompliance period with respect to each individual to whom such failure relates.

(2) Noncompliance period.—For purposes of this section, the term "noncompliance period" means, with respect to any failure, the period—

(A) beginning on the date such failure first occurs, and

(B) ending on the date such failure is corrected.

(3) Minimum tax for noncompliance period where

failure discovered after notice of examination.—Notwithstanding paragraphs (1) and (2) of subsection (c)—

(A) In general.—In the case of 1 or more failures with respect to an individual—

(i) which are not corrected before the date a notice of examination of income tax liability is sent to the employer, and

(ii) which occurred or continued during the period under examination, the amount of tax imposed by subsection (a) by reason of such failures with respect to such individual shall not be less than the lesser of $2,500 or the amount of tax which would be imposed by subsection (a) without regard to such paragraphs.

(B) Higher minimum tax where violations are more than de minimis.—To the extent violations for which any person is liable under subsection (e) for any year are more than de minimis, subparagraph (A) shall be applied by substituting "$15,000" for "$2,500" with respect to such person.

(C) Exception for church plans.—This paragraph shall not apply to any failure under a church plan (as defined in section 414(e)).

(c) Limitations on amount of tax.—

(1) Tax not to apply where failure not discovered exercising reasonable diligence.—No tax shall be imposed by subsection (a) on any failure during any period for which it is established to the satisfaction of the Secretary that the person otherwise liable for such tax did not know, and exercising reasonable diligence would not have known, that such failure existed.

(2) Tax not to apply to failures corrected within certain periods.—No tax shall be imposed by subsection (a) on any failure if—

(A) such failure was due to reasonable cause and not to willful neglect, and

(B)(i) in the case of a plan other than a church plan (as defined in section 414(e)), such failure is corrected during the 30-day period beginning on the first date the person otherwise liable for such tax knew, or exercising reasonable diligence would have known, that such failure existed, and

(ii) in the case of a church plan (as so defined), such failure is corrected before the close of the correction period (determined under the rules of section 414(e)(4)(C)).

(3) Overall limitation for unintentional failures.— In the case of failures which are due to reasonable cause and not to willful neglect—

(A) Single employer plans.—

(i) In general.—In the case of failures with respect to plans other than specified multiple employer health plans, the tax imposed by subsection (a) for failures during the taxable year of the employer shall not exceed the amount equal to the lesser of—

(I) 10 percent of the aggregate amount paid or incurred by the employer (or predecessor employer) during the preceding taxable year for group health plans, or

(II) $500,000.

(ii) Taxable years in the case of certain controlled groups.—For purposes of this subparagraph, if not all persons who are treated as a single employer for

purposes of this section have the same taxable year, the taxable years taken into account shall be determined under principles similar to the principles of section 1561.

(B) Specified multiple employer health plans.—

(i) In general.—In the case of failures with respect to a specified multiple employer health plan, the tax imposed by subsection (a) for failures during the taxable year of the trust forming part of such plan shall not exceed the amount equal to the lesser of—

(I) 10 percent of the amount paid or incurred by such trust during such taxable year to provide medical care (as defined in section 9832(d)(3)) directly or through insurance, reimbursement, or otherwise, or

(II) $500,000.

For purposes of the preceding sentence, all plans of which the same trust forms a part shall be treated as one plan.

(ii) Special rule for employers required to pay tax.—If an employer is assessed a tax imposed by subsection (a) by reason of a failure with respect to a specified multiple employer health plan, the limit shall be determined under subparagraph (A) (and not

under this subparagraph) and as if such plan were not a specified multiple employer health plan.

(4) Waiver by Secretary.—In the case of a failure which is due to reasonable cause and not to willful neglect, the Secretary may waive part or all of the tax imposed by subsection (a) to the extent that the payment of such tax would be excessive relative to the failure involved.

(d) Tax not to apply to certain insured small employer plans.—

(1) In general.— In the case of a group health plan of a small employer which provides health insurance coverage solely through a contract with a health insurance issuer, no tax shall be imposed by this section on the employer on any failure (other than a failure attributable to section 9811) which is solely because of the health insurance coverage offered by such issuer.

(2) Small employer.—

(A) In general.—For purposes of paragraph (1), the term "small employer" means, with respect to a calendar year and a plan year, an employer who employed an average of at least 2 but not more than 50 employees on business days during the preceding calendar year and who employs at least 2 employees on the first day of the plan year. For purposes of the preceding sentence, all persons treated as a single employer under subsection (b), (c), (m), or (o) of section 414 shall be treated as one employer.

(B) Employers not in existence in preceding year.—In the case of an employer which was not in existence throughout the preceding calendar year, the determination of whether such employer is a small employer shall be based on the average number of employees that it is reasonably expected such employer will employ on business days in the current calendar year.

(C) Predecessors.—Any reference in this paragraph to an employer shall include a reference to any predecessor of such employer.

(3) Health insurance coverage; health insurance issuer.—For purposes of paragraph (1), the terms "health insurance coverage" and "health insurance issuer" have the respective meanings given such terms by section 9832.

(e) Liability for tax.—The following shall be liable for the tax imposed by subsection (a) on a failure:

(1) Except as otherwise provided in this subsection, the employer.

(2) In the case of a multiemployer plan, the plan.

(3) In the case of a failure under section 9803 (relating to guaranteed renewability) with respect to a plan described in subsection (f)(2)(B), the plan.

(f) Definitions.—For purposes of this section—

(1) Group health plan.—The term "group health plan" has the meaning given such term by section 9832(a).

(2) Specified multiple employer health plan.—The term "specified multiple employer health plan" means a group health plan which is—

(A) any multiemployer plan, or

(B) any multiple employer welfare arrangement (as defined in section 3(40) of the Employee Retirement Income Security Act of 1974, as in effect on the date of the enactment of this section).

(3) Correction.—A failure of a group health plan shall be treated as corrected if—

(A) such failure is retroactively undone to the extent possible, and

(B) the person to whom the failure relates is placed in a financial position which is as good as such person

would have been in had such failure not occurred.

26 U.S.C. § 4980H provides:

§ 4980H. Shared responsibility for employers regarding health coverage.

(a) Large employers not offering health coverage.—If—

(1) any applicable large employer fails to offer to its full-time employees (and their dependents) the opportunity to enroll in minimum essential coverage under an eligible employer-sponsored plan (as defined in section 5000A(f)(2)) for any month, and

(2) at least one full-time employee of the applicable large employer has been certified to the employer under section 1411 of the Patient Protection and Affordable Care Act as having enrolled for such month in a qualified health plan with respect to which an applicable premium tax credit or cost-sharing reduction is allowed or paid with respect to the employee,

then there is hereby imposed on the employer an assessable payment equal to the product of the applicable payment amount and the number of individuals employed by the employer as full-time employees during such month.

(b) Large employers offering coverage with employees who qualify for premium tax credits or cost-sharing reductions.—

(1) In general. —If—

(A) an applicable large employer offers to its full-time employees (and their dependents) the opportunity to

enroll in minimum essential coverage under an eligible employer-sponsored plan (as defined in section 5000A(f)(2)) for any month, and

(B) 1 or more full-time employees of the applicable large employer has been certified to the employer under section 1411 of the Patient Protection and Affordable Care Act as having enrolled for such month in a qualified health plan with respect to which an applicable premium tax credit or cost-sharing reduction is allowed or paid with respect to the employee, then there is hereby imposed on the employer an assessable payment equal to the product of the number of full-time employees of the applicable large employer described in subparagraph (B) for such month and an amount equal to 1/12 of $3,000.

(2) Overall limitation.—The aggregate amount of tax determined under paragraph (1) with respect to all employees of an applicable large employer for any month shall not exceed the product of the applicable payment amount and the number of individuals employed by the employer as full-time employees during such month.

[(3) Repealed. Pub. L. 112-10, Div. B, Title VIII,

§ 1858(b)(4), Apr. 15, 2011, 125 Stat. 169]

(c) Definitions and special rules.—For purposes of this section—

(1) Applicable payment amount.—The term "applicable payment amount" means, with respect to any month, 1/12 of $2,000.

(2) Applicable large employer.—

(A) In general.— The term "applicable large employer"

means, with respect to a calendar year, an employer who employed an average of at least 50 full-time employees on business days during the preceding calendar year.

(B) Exemption for certain employers.—

(i) In general.—An employer shall not be considered to employ more than 50 full-time employees if—

(I) the employer's workforce exceeds 50 full-time employees for 120 days or fewer during the calendar year, and

(II) the employees in excess of 50 employed during such 120-day period were seasonal workers.

(ii) Definition of seasonal workers.— The term "seasonal worker" means a worker who performs labor or services on a seasonal basis as defined by the Secretary of Labor, including workers covered by section 500.20(s)(1) of title 29, Code of Federal Regulations and retail workers employed exclusively during holiday seasons.

(C) Rules for determining employer size.—For purposes of this paragraph—

(i) Application of aggregation rule for employers.— All persons treated as a single employer under subsection (b), (c), (m), or (o) of section 414 of the Internal Revenue Code of 1986 shall be treated as 1 employer.

(ii) Employers not in existence in preceding year.— In the case of an employer which was not in existence throughout the preceding calendar year, the determination of whether such employer is an applicable large employer shall be based on the average number of employees that it is reasonably

expected such employer will employ on business days in the current calendar year.

(iii) Predecessors.—Any reference in this subsection to an employer shall include a reference to any predecessor of such employer.

(D)Application of employer size to assessable penalties—

(i) In general.—The number of individuals employed by an applicable large employer as full-time employees during any month shall be reduced by 30 solely for purposes of calculating—

(I) the assessable payment under subsection (a), or

(II) the overall limitation under subsection (b)(2).

(ii) Aggregation—In the case of persons treated as 1 employer under subparagraph (C)(i), only 1 reduction under subclause (I) or (II) shall be allowed with respect to such persons and such reduction shall be allocated among such persons ratably on the basis of the number of full-time employees employed by each such person.

(E) Full-time equivalents treated as full-time employees.—Solely for purposes of determining whether an employer is an applicable large employer under this paragraph, an employer shall, in addition to the number of full-time employees for any month otherwise determined, include for such month a number of full-time employees determined by dividing the aggregate number of hours of service of employees who are not full-time employees for the month by 120.

(F) Exemption for health coverage under TRICARE or the Department of Veterans Affairs.—Solely for

purposes of determining whether an employer is an applicable large employer under this paragraph for any month, an individual shall not be taken into account as an employee for such month if such individual has medical coverage for such month under—

(i) chapter 55 of title 10, United States Code, including coverage under the TRICARE program, or

(ii) under a health care program under chapter 17 or 18 of title 38, United States Code, as determined by the Secretary of Veterans Affairs, in coordination with the Secretary of Health and Human Services and the Secretary.

(3) Applicable premium tax credit and cost-sharing reduction.—The term "applicable premium tax credit and cost-sharing reduction" means—

(A) any premium tax credit allowed under section 36B,

(B) any cost-sharing reduction under section 1402 of the Patient Protection and Affordable Care Act, and

(C) any advance payment of such credit or reduction under section 1412 of such Act.

(4) Full-time employee—

(A) In general.—The term "full-time employee" means, with respect to any month, an employee who is employed on average at least 30 hours of service per week.

(B) Hours of service.—The Secretary, in consultation with the Secretary of Labor, shall prescribe such regulations, rules, and guidance as may be necessary to determine the hours of service of an employee, including rules for the application of this paragraph to

employees who are not compensated on an hourly basis.

(5) Inflation adjustment.—

(A) In general.—In the case of any calendar year after 2014, each of the dollar amounts in subsection (b) and paragraph (1) shall be increased by an amount equal to the product of—

(i) such dollar amount, and

(ii) the premium adjustment percentage (as defined in section 1302(c)(4) of the Patient Protection and Affordable Care Act) for the calendar year.

(B) Rounding.—If the amount of any increase under subparagraph (A) is not a multiple of $10, such increase shall be rounded to the next lowest multiple of $10.

(6) Other definitions.—Any term used in this section which is also used in the Patient Protection and Affordable Care Act shall have the same meaning as when used in such Act.

(7) Tax nondeductible.—For denial of deduction for the tax imposed by this section, see section 275(a)(6).

(d) Administration and procedure.—

(1) In general.—Any assessable payment provided by this section shall be paid upon notice and demand by the Secretary, and shall be assessed and collected in the same manner as an assessable penalty under subchapter B of chapter 68.

(2) Time for payment.—The Secretary may provide for the payment of any assessable payment provided by this section on an annual, monthly, or other periodic basis as the Secretary may prescribe.

(3) Coordination with credits, etc.— The Secretary shall prescribe rules, regulations, or guidance for the repayment of any assessable payment (including interest) if such payment is based on the allowance or payment of an applicable premium tax credit or cost-sharing reduction with respect to an employee, such allowance or payment is subsequently disallowed, and the assessable payment would not have been required to be made but for such allowance or payment.

26 U.S.C. § 5000A provides:

§ 5000A. Requirement to maintain minimum essential coverage

(a) Requirement to maintain minimum essential coverage.—An applicable individual shall for each month beginning after 2013 ensure that the individual, and any dependent of the individual who is an applicable individual, is covered under minimum essential coverage for such month.

(b) Shared responsibility payment.—

(1) In general.—If a taxpayer who is an applicable individual, or an applicable individual for whom the taxpayer is liable under paragraph (3), fails to meet the requirement of subsection (a) for 1 or more months, then, except as provided in subsection (e), there is hereby imposed on the taxpayer a penalty with respect to such failures in the amount determined under subsection (c).

(2) Inclusion with return.—Any penalty imposed by this section with respect to any month shall be included with a taxpayer's return under chapter 1 for the taxable year which includes such month.

(3) Payment of penalty.—If an individual with respect to whom a penalty is imposed by this section for any month—

(A) is a dependent (as defined in section 152) of another taxpayer for the other taxpayer's taxable year including such month, such other taxpayer shall be liable for such penalty, or

(B) files a joint return for the taxable year including such month, such individual and the spouse of such individual shall be jointly liable for such penalty.

(c) Amount of penalty.—

(1) In general.—The amount of the penalty imposed by this section on any taxpayer for any taxable year with respect to failures described in subsection (b)(1) shall be equal to the lesser of—

(A) the sum of the monthly penalty amounts determined under paragraph (2) for months in the taxable year during which 1 or more such failures occurred, or

(B) an amount equal to the national average premium for qualified health plans which have a bronze level of coverage, provide coverage for the applicable family size involved, and are offered through Exchanges for plan years beginning in the calendar year with or within which the taxable year ends.

(2) Monthly penalty amounts.—For purposes of paragraph (1)(A), the monthly penalty amount with respect to any taxpayer for any month during which any failure described in subsection (b)(1) occurred is an amount equal to 1/12 of the greater of the following amounts:

(A) Flat dollar amount.—An amount equal to the lesser of—

(i) the sum of the applicable dollar amounts for all individuals with respect to whom such failure occurred during such month, or

(ii) 300 percent of the applicable dollar amount (determined without regard to paragraph (3)(C)) for the calendar year with or within which the taxable year ends.

(B) Percentage of income.—An amount equal to the following percentage of the excess of the taxpayer's household income for the taxable year over the amount of gross income specified in section 6012(a)(1) with respect to the taxpayer for the taxable year:

(i) 1.0 percent for taxable years beginning in 2014.

(ii) 2.0 percent for taxable years beginning in 2015.

(iii) Zero percent for taxable years beginning after 2015.

(3) Applicable dollar amount.—For purposes of paragraph (1)—

(A) In general.—Except as provided in subparagraphs (B) and (C), the applicable dollar amount is $0.

(B) Phase in.—The applicable dollar amount is $95 for 2014 and $325 for 2015.

(C) Special rule for individuals under age 18.—If an applicable individual has not attained the age of 18 as of the beginning of a month, the applicable dollar amount with respect to such individual for the month shall be equal to one-half of the applicable dollar amount for the calendar year in which the month occurs.

[(D) Repealed. Pub. L. 115-97, Title I, § 11081(a)(2)(B), Dec. 22, 2017, 131 Stat. 2092]

(4) Terms relating to income and families.—For purposes of this section—

(A) Family size.—The family size involved with respect to any taxpayer shall be equal to the number of individuals for whom the taxpayer is allowed a deduction under section 151 (relating to allowance of deduction for personal exemptions) for the taxable year.

(B) Household income.—The term "household income" means, with respect to any taxpayer for any taxable year, an amount equal to the sum of—

(i) the modified adjusted gross income of the taxpayer, plus

(ii) the aggregate modified adjusted gross incomes of all other individuals who—

(I) were taken into account in determining the taxpayer's family size under paragraph (1), and

(II) were required to file a return of tax imposed by section 1 for the taxable year.

(C) Modified adjusted gross income.—The term "modified adjusted gross income" means adjusted gross income increased by—

(i) any amount excluded from gross income under section 911, and

(ii) any amount of interest received or accrued by the taxpayer during the taxable year which is exempt from tax.

[(D) Repealed. Pub.L. 111-152, Title I, § 1002(b)(1),

Mar. 30, 2010, 124 Stat. 1032]

(d) Applicable individual.—For purposes of this section—

(1) In general.—The term "applicable individual" means, with respect to any month, an individual other than an individual described in paragraph (2), (3), or (4).

(2) Religious exemptions.—

(A) Religious conscience exemptions.—

(i) In general.—Such term shall not include any individual for any month if such individual has in effect an exemption under section 1311(d)(4)(H) of the Patient Protection and Affordable Care Act which certifies that—

(I) such individual is a member of a recognized religious sect or division thereof which is described in section 1402(g)(1), and is adherent of established tenets or teachings of such sect or division as described in such section; or

(II) such individual is a member of a religious sect or division thereof which is not described in section 1402(g)(1), who relies solely on a religious method of healing, and for whom the acceptance of medical health services would be inconsistent with the religious beliefs of the individual.

(ii) Special rules.—

(I) Medical health services defined.—For purposes of this subparagraph, the term "medical health services" does not include routine dental, vision and hearing services, midwifery services, vaccinations, necessary medical services provided to children, services

required by law or by a third party, and such other services as the Secretary of Health and Human Services may provide in implementing section 1311(d)(4)(H) of the Patient Protection and Affordable Care Act.

(II) Attestation required.—Clause (i)(II) shall apply to an individual for months in a taxable year only if the information provided by the individual under section 1411(b)(5)(A) of such Act includes an attestation that the individual has not received medical health services during the preceding taxable year.

(B) Health care sharing ministry.—

(i) In general.—Such term shall not include any individual for any month if such individual is a member of a health care sharing ministry for the month.

(ii) Health care sharing ministry.—The term "health care sharing ministry" means an organization—

(I) which is described in section 501(c)(3) and is exempt from taxation under section 501(a),

(II) members of which share a common set of ethical or religious beliefs and share medical expenses among members in accordance with those beliefs and without regard to the State in which a member resides or is employed,

(III) members of which retain membership even after they develop a medical condition,

(IV) which (or a predecessor of which) has been in existence at all times since December 31, 1999, and medical expenses of its members have been shared continuously and without interruption since at least

December 31, 1999, and

(V) which conducts an annual audit which is performed by an independent certified public accounting firm in accordance with generally accepted accounting principles and which is made available to the public upon request.

(3) Individuals not lawfully present.—Such term shall not include an individual for any month if for the month the individual is not a citizen or national of the United States or an alien lawfully present in the United States.

(4) Incarcerated individuals.—Such term shall not include an individual for any month if for the month the individual is incarcerated, other than incarceration pending the disposition of charges.

(e) Exemptions.—No penalty shall be imposed under subsection (a) with respect to—

(1) Individuals who cannot afford coverage.—

(A) In general.—Any applicable individual for any month if the applicable individual's required contribution (determined on an annual basis) for coverage for the month exceeds 8 percent of such individual's household income for the taxable year described in section 1412(b)(1)(B) of the Patient Protection and Affordable Care Act. For purposes of applying this subparagraph, the taxpayer's household income shall be increased by any exclusion from gross income for any portion of the required contribution made through a salary reduction arrangement.

(B) Required contribution.—For purposes of this paragraph, the term "required contribution" means—

(i) in the case of an individual eligible to purchase minimum essential coverage consisting of coverage through an eligible-employer-sponsored plan, the portion of the annual premium which would be paid by the individual (without regard to whether paid through salary reduction or otherwise) for self-only coverage, or

(ii) in the case of an individual eligible only to purchase minimum essential coverage described in subsection (f)(1)(C), the annual premium for the lowest cost bronze plan available in the individual market through the Exchange in the State in the rating area in which the individual resides (without regard to whether the individual purchased a qualified health plan through the Exchange), reduced by the amount of the credit allowable under section 36B for the taxable year (determined as if the individual was covered by a qualified health plan offered through the Exchange for the entire taxable year).

(C) Special rules for individuals related to employees.—For purposes of subparagraph (B)(i), if an applicable individual is eligible for minimum essential coverage through an employer by reason of a relationship to an employee, the determination under subparagraph (A) shall be made by reference to required contribution of the employee.

(D) Indexing.—In the case of plan years beginning in any calendar year after 2014, subparagraph (A) shall be applied by substituting for "8 percent" the percentage the Secretary of Health and Human Services determines reflects the excess of the rate of premium growth between the preceding calendar year and 2013 over the rate of income growth for such period.

(2) Taxpayers with income below filing threshold.—Any applicable individual for any month during a calendar year if the individual's household income for the taxable year described in section 1412(b)(1)(B) of the Patient Protection and Affordable Care Act is less than the amount of gross income specified in section 6012(a)(1) with respect to the taxpayer.

(3) Members of Indian tribes.—Any applicable individual for any month during which the individual is a member of an Indian tribe (as defined in section 45A(c)(6)).

(4) Months during short coverage gaps.—

(A) In general.—Any month the last day of which occurred during a period in which the applicable individual was not covered by minimum essential coverage for a continuous period of less than 3 months.

(B) Special rules.—For purposes of applying this paragraph—

(i) the length of a continuous period shall be determined without regard to the calendar years in which months in such period occur,

(ii) if a continuous period is greater than the period allowed under subparagraph (A), no exception shall be provided under this paragraph for any month in the period, and

(iii) if there is more than 1 continuous period described in subparagraph (A) covering months in a calendar year, the exception provided by this paragraph shall only apply to months in the first of such periods.

The Secretary shall prescribe rules for the collection of the penalty imposed by this section in cases where

continuous periods include months in more than 1 taxable year.

(5) Hardships.—Any applicable individual who for any month is determined by the Secretary of Health and Human Services under section 1311(d)(4)(H) to have suffered a hardship with respect to the capability to obtain coverage under a qualified health plan.

(f) Minimum essential coverage.—For purposes of this section—

(1) In general.—The term "minimum essential coverage" means any of the following:

(A) Government sponsored programs.—Coverage under—

(i) the Medicare program under part A of title XVIII of the Social Security Act,

(ii) the Medicaid program under title XIX of the Social Security Act,

(iii) the CHIP program under title XXI of the Social Security Act or under a qualified CHIP look-alike program (as defined in section 2107(g) of the Social Security Act),

(iv) medical coverage under chapter 55 of title 10, United States Code, including coverage under the TRICARE program;

(v) a health care program under chapter 17 or 18 of title 38, United States Code, as determined by the Secretary of Veterans Affairs, in coordination with the Secretary of Health and Human Services and the Secretary,

(vi) a health plan under section 2504(e) of title 22, United States Code (relating to Peace Corps

volunteers); or

(vii) the Nonappropriated Fund Health Benefits Program of the Department of Defense, established under section 349 of the National Defense Authorization Act for Fiscal Year 1995 (Public Law 103-337; 10 U.S.C. 1587 note).

(B) Employer-sponsored plan.—Coverage under an eligible employer-sponsored plan.

(C) Plans in the individual market.—Coverage under a health plan offered in the individual market within a State.

(D) Grandfathered health plan.—Coverage under a grandfathered health plan.

(E) Other coverage.—Such other health benefits coverage, such as a State health benefits risk pool, as the Secretary of Health and Human Services, in coordination with the Secretary, recognizes for purposes of this subsection.

(2) Eligible employer-sponsored plan.—The term "eligible employer-sponsored plan" means, with respect to any employee, a group health plan or group health insurance coverage offered by an employer to the employee which is—

(A) a governmental plan (within the meaning of section 2791(d)(8) of the Public Health Service Act), or

(B) any other plan or coverage offered in the small or large group market within a State.

Such term shall include a grandfathered health plan described in paragraph (1)(D) offered in a group market.

(3) Excepted benefits not treated as minimum essential coverage.—The term "minimum essential coverage" shall not include health insurance coverage which consists of coverage of excepted benefits—

(A) described in paragraph (1) of subsection (c) of section 2791 of the Public Health Service Act; or

(B) described in paragraph (2), (3), or (4) of such subsection if the benefits are provided under a separate policy, certificate, or contract of insurance.

(4) Individuals residing outside United States or residents of territories.—Any applicable individual shall be treated as having minimum essential coverage for any month—

(A) if such month occurs during any period described in subparagraph (A) or (B) of section 911(d)(1) which is applicable to the individual, or

(B) if such individual is a bona fide resident of any possession of the United States (as determined under section 937(a)) for such month.

(5) Insurance-related terms.—Any term used in this section which is also used in title I of the Patient Protection and Affordable Care Act shall have the same meaning as when used in such title.

(g) Administration and procedure.—

(1) In general.—The penalty provided by this section shall be paid upon notice and demand by the Secretary, and except as provided in paragraph (2), shall be assessed and collected in the same manner as an assessable penalty under subchapter B of chapter 68.

(2) Special rules.—Notwithstanding any other

provision of law—

(A) Waiver of criminal penalties.—In the case of any failure by a taxpayer to timely pay any penalty imposed by this section, such taxpayer shall not be subject to any criminal prosecution or penalty with respect to such failure.

(B) Limitations on liens and levies.—The Secretary shall not—

(i) file notice of lien with respect to any property of a taxpayer by reason of any failure to pay the penalty imposed by this section, or

(ii) levy on any such property with respect to such failure.

45 C.F.R. § 147.132 (Oct. 1, 2018) provides:

§ 147.132 Religious exemptions in connection with coverage of certain preventive health services.

(a) *Objecting entities.*

(1) Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to a group health plan established or maintained by an objecting organization, or health insurance coverage offered or arranged by an objecting organization, and thus the Health Resources and Service Administration will exempt from any guidelines' requirements that relate to the provision of contraceptive services:

(i) A group health plan and health insurance coverage provided in connection with a group health plan to the

extent the non-governmental plan sponsor objects as specified in paragraph (a)(2) of this section. Such non-governmental plan sponsors include, but are not limited to, the following entities—

(A) A church, an integrated auxiliary of a church, a convention or association of churches, or a religious order.

(B) A nonprofit organization.

(C) A closely held for-profit entity.

(D) A for-profit entity that is not closely held.

(E) Any other non-governmental employer.

(ii) An institution of higher education as defined in 20 U.S.C. 1002 in its arrangement of student health insurance coverage, to the extent that institution objects as specified in paragraph (a)(2) of this section. In the case of student health insurance coverage, this section is applicable in a manner comparable to its applicability to group health insurance coverage provided in connection with a group health plan established or maintained by a plan sponsor that is an employer, and references to "plan participants and beneficiaries" will be interpreted as references to student enrollees and their covered dependents; and

(iii) A health insurance issuer offering group or individual insurance coverage to the extent the issuer objects as specified in paragraph (a)(2) of this section. Where a health insurance issuer providing group health insurance coverage is exempt under this paragraph (a)(1)(iii), the plan remains subject to any requirement to provide coverage for contraceptive services under Guidelines issued under

§ 147.130(a)(1)(iv) unless it is also exempt from that requirement.

(2) The exemption of this paragraph (a) will apply to the extent that an entity described in paragraph (a)(1) of this section objects to its establishing, maintaining, providing, offering, or arranging (as applicable) coverage, payments, or a plan that provides coverage or payments for some or all contraceptive services, based on its sincerely held religious beliefs.

(b) *Objecting individuals.* Guidelines issued under § 147.130(a)(1)(iv) by the Health Resources and Services Administration must not provide for or support the requirement of coverage or payments for contraceptive services with respect to individuals who object as specified in this paragraph (b), and nothing in § 147.130(a)(1)(iv), 26 CFR 54.9815–2713(a)(1)(iv), or 29 CFR 2590.715–2713(a)(1)(iv) may be construed to prevent a willing health insurance issuer offering group or individual health insurance coverage, and as applicable, a willing plan sponsor of a group health plan, from offering a separate benefit package option, or a separate policy, certificate or contract of insurance, to any individual who objects to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs.

(c) *Definition.* For the purposes of this section, reference to "contraceptive" services, benefits, or coverage includes contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).

(d) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied

to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.