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UNITED STATES DISTRICT COURT
ORTHERN DISTRICT OF CALIFORNIA

STATE OF CALIFORNIA, et al., Plaintiffs,

v.

HEALTH AND HUMAN SERVICES, et al., Defendants.

Case No.17-cv-05783-HSG

ORDER GRANTING PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

Re: Dkt. No. 28

T. 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

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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.

Α. 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).

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В. 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). 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

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.

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health issues. IOM Report² 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

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 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

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

See HEALTH RES. & SERVS. ADMIN., Women's Preventive 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/womensguidelines-2016/index.html.

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"

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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 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

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

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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 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

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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,

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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 coverage, including contraceptive coverage." FAQs at 4.

The 2017 IFRs at Issue I.

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.

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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/acapart-36.pdf.

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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. 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 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,

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

[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

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.

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 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

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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

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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

Plaintiffs thus have standing under Article III.

2. **Statutory Standing**

supporting Plaintiffs' motion. See Opp. at 9.

In addition to the requirements of Article III, "[a] plaintiff must also satisfy the non-

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

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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 "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,

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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).

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

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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 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).

> 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

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 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)).

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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 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-

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.

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

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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

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.

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

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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 wellsubstantiated 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

[&]quot;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.

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.

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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." 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-andcomment 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.

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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).

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For these reasons, Plaintiffs are, at a minimum, likely to succeed 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

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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).

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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. The balance of equities thus tips in Plaintiffs' favor.

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

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 (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).

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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

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 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

advanced by Plaintiffs.

¹⁸ Because the Court finds that entry of a preliminary injunction is warranted on the basis discussed above, it need not at this time consider the additional bases for injunctive relief

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

HAYWOOD S. GILLIAM, JR. United States District Judge