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10 IN THE UNITED STATES DISTRICT COURT
 11 FOR THE NORTHERN DISTRICT OF CALIFORNIA

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 13
 14 **THE STATE OF CALIFORNIA; THE**
 15 **STATE OF DELAWARE; THE STATE OF**
 16 **MARYLAND; THE STATE OF NEW**
 17 **YORK; THE COMMONWEALTH OF**
 18 **VIRGINIA,**

19 Plaintiffs,

20 v.

21 **ERIC D. HARGAN, in His Official Capacity**
 22 **as Acting Secretary of the U.S. Department**
 23 **of Health & Human Services; U.S.**
 24 **DEPARTMENT OF HEALTH HUMAN**
 25 **SERVICES; R. ALEXANDER ACOSTA, In**
 26 **His Official Capacity as Secretary of the**
 27 **U.S. DEPARTMENT OF LABOR;**
 28 **STEVEN MNUCHIN, In His Official**
Capacity as Secretary of the U.S.
DEPARTMENT OF THE TREASURY;
U.S. DEPARTMENT OF THE
TREASURY; DOES 1-100,

Defendants.

4:17-cv-05783-HSG

STATES' REPLY IN SUPPORT OF
MOTION FOR PRELIMINARY
INJUNCTION

Date: Dec. 12, 2017
 Time: 2:00 p.m.
 Dept: 2, 4th Floor
 Judge: Hon. Haywood S. Gilliam, Jr.
 Trial Date: Not set
 Action Filed: October 6, 2017

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INTRODUCTION

1
2 Women across the nation must continue to have access to the no-cost contraceptive
3 guaranteed under the Patient Protection and Affordable Care Act (ACA). Defendants’ interim
4 final rules (IFRs) make this important benefit optional. Defendants’ characterization of this case
5 as about “religious liberty and freedom of conscience,” ECF No. 51 at 1, mirrors the IFRs
6 themselves, which disregard the very law they should implement.

7 Congress made women’s access to affordable preventive care a priority when it enacted the
8 Women’s Health Amendment to ensure that health plans cover women’s “preventive care and
9 screenings” without “impos[ing] any cost sharing.” 42 U.S.C. § 300gg-13(a)(4). Contraception
10 and family planning were to be central to the preventive services covered in improving public
11 health and lowering health costs for women.¹ Later, Congress considered but declined to include
12 a “conscience amendment” to permit employers and insurers to deny coverage based on
13 “religious beliefs or moral convictions.” 158 Cong. Rec. S539 (Feb. 9, 2012) (S. Amdt. 1520,
14 Section (b)(1), 112th Congress (2011-2012)). But employers with sincere religious objections
15 were expressly acknowledged through a carefully tailored exemption and accommodation to
16 relieve such employers from the obligation to provide contraceptive coverage. The States seek to
17 maintain this religious protection.

18 In contrast, rather than continuing to allow for *both* contraceptive access—a public health
19 imperative—and sincere religious objections, Defendants rushed into effect, without notice or
20 public comment, two IFRs—one with an exceedingly broad religious exemption and another,
21 novel exemption for *moral* objections. This about-face in policy effectively nullifies the ACA
22 guarantee that, since 2012, has afforded women equal access to preventive medical care,
23 including access to contraceptives, sterilization, and related patient education, counseling, and
24 doctor’s office visits. ECF No. 24-1 at 8. Defendants purport to “bring to a close” litigation
25 brought by religious objectors, *id.* at 33, yet the IFRs run afoul of the Supreme Court’s directive
26 in *Zubik v. Burwell*, 136 S. Ct. 1557 (2016), not only to “accommodate[] petitioners’ religious

27
28 ¹ See, e.g., 155 Cong. Rec. S12,033, S12,052 (Sen. Franken) (“health reform includes . . .
access to affordable family planning services . . . Access to contraception is fundamental”).

1 exercise,” but also to “ensur[e] that women covered by petitioners’ health plans receive full and
2 equal health coverage, including contraceptive coverage.” *Id.* at 1560 (quotations omitted).

3 Defendants’ urgency in implementing the IFRs circumvents the Administrative Procedure
4 Act’s (APA) normal rule-making process without adequate legal justification.² And in
5 undermining the ACA, rather than faithfully implementing it, the IFRs further violate the APA
6 because they exceed statutory authority and are arbitrary and capricious. The IFRs are also
7 unconstitutional; in discriminating against women, they violate the Establishment Clause and
8 Equal Protection Clause. The public interest would be served by a nationwide injunction
9 maintaining the status quo that existed before the IFRs were issued.

10 ARGUMENT

11 I. THE STATES ARE LIKELY TO SUCCEED ON THE MERITS

12 A. The Northern District of California Is the Proper Venue for This Lawsuit

13 A civil action against an officer of a United States agency in his official capacity may be
14 brought in any judicial district in which “the *plaintiff resides* if no real property is involved in the
15 action.” 28 U.S.C. § 1391(e)(1)(C) (emphasis added). Here, the plaintiff is the state, which “is
16 held to reside in any district within it.” 14D Wright & Miller, *Fed. Prac. & Proc.* § 3815 (4th ed.
17 2017) (citing *Ala. v. Army Corps of Eng’rs*, 382 F. Supp. 2d 1301, 1327-29 (N.D. Ala. 2005) (in
18 action by state against federal government, the state “resided,” and venue was proper, in any
19 district within the state). As no real property is involved here, venue is proper in this Court.

20 B. The States’ APA Claims Are Likely to Succeed

21 1. The States Have Standing to Bring APA Claims

22 The States have “a sufficiently personal stake in the outcome of the controversy to ensure
23 that the parties will be truly adverse and their legal presentations sharpened.” *Washington v.*
24 *Trump*, 847 F.3d 1151, 1159 (9th Cir. 2017) (quotations omitted) (citing *Massachusetts v. EPA*,
25 549 U.S. 497, 517 (2007)). To establish standing, the States, like any other party, must
26 demonstrate that (1) they have suffered an “injury in fact,” (2) there exists a “causal connection”

27 ² This urgency—and Little Sisters of the Poor’s eagerness to contest this lawsuit—also
28 suggest that religious objectors are likely to avail themselves of the new exemptions, causing
women to lose contraceptive coverage and strengthening the States’ standing as affected parties.

1 between the injury and the challenged conduct, and (3) a favorable judicial ruling will “likely”
2 redress the injury. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992).

3 In bringing APA claims, the States are asserting a “procedural injury,” which requires a
4 showing that (1) the federal agency violated certain procedural rules, (2) these rules protect the
5 States’ concrete interests, and (3) it is reasonably probable that the challenged action will threaten
6 the States’ concrete interests. *Citizens for Better Forestry v. U.S. Dep’t of Agric.*, 341 F.3d 961,
7 969-70 (9th Cir. 2003). Importantly, the States can establish standing for a procedural injury
8 under the APA “without meeting all the normal standards for redressability and immediacy.”
9 *Hall v. Norton*, 266 F.3d 969, 975 (9th Cir. 2001) (quoting *Lujan*, 504 U.S. at 572 & n.7).

10 The States satisfy these three criteria for standing. First, Defendants violated the APA by
11 issuing, without notice and prior opportunity for comment, IFRs that are not in accordance with
12 law, exceed statutory authority, and are arbitrary and capricious. Second, these procedural rules
13 requiring notice and comment protect the States’ concrete interest in ensuring that women have
14 access to no-cost contraceptive coverage. This interest of the States is “congruent” with that of
15 their women residents, *City of Sausalito v. O’Neill*, 386 F.3d 1186, 1197 (9th Cir. 2004); the IFRs
16 create a barrier to contraceptive access that burdens the States with increased costs of providing
17 contraceptive services to eligible residents and of funding medical procedures and other expenses
18 associated with unintended pregnancies. *See, e.g.*, Decl. of Lawrence Finer [Finer Decl.] ¶¶ 54,
19 61, 69, 77, 85, 93; Decl. of Massey Whorley [Whorley Decl.] ¶¶ 8, 10, 11; Decl. of Mari
20 Cantwell [Cantwell Decl.] ¶ 17; Decl. of Jenna Tosh [Tosh Decl.] ¶¶ 26-28, 34; Decl. of Karen
21 Nelson [Nelson Decl.] ¶ 15; Decl. of Karyl Rattay [Rattay Decl.] ¶¶ 5, 7, 8.³ Third, given that
22 both IFRs apply immediately, ECF Nos. 24-1 at 1, 24-2 at 1, and as Defendants concede, allow
23 employers not bound by state contraceptive equity laws to claim an exemption or
24 accommodation, ECF No. 51 at 9-10, the IFRs will threaten this concrete interest.⁴ Indeed, even

25 _____
26 ³ Defendants argue that the Court should not consider declarations and should rely only on
27 the administrative record. ECF No. 51 at 27. Yet the record is clearly inadequate—it ends in
28 2016, before any public comment on these IFRs— and the States also raise constitutional claims.

⁴ Defendants suggest that the contraceptive equity laws in California, Delaware,
Maryland, and New York, which required insurance plans that cover prescription drugs to also

1 under the IFRs' conservative estimates, tens of thousands of women will lose contraceptive
 2 coverage under the new regime. ECF Nos. 24-1 at 24-33, 24-2 at 19-21. Because enjoining the
 3 IFRs would redress the States' procedural injuries, the States have standing.⁵

4 **2. The IFRs Are Invalid Under the APA Because They Are Not in**
 5 **Accordance with the Law and Exceed Statutory Authority**

6 **a. The IFRs Are Contrary to Law Because They Violate the ACA**

7 Defendants contend that Congress delegated to them complete authority to determine the
 8 scope of required women's health coverage under the ACA, and even whether to provide
 9 contraceptive coverage at all. ECF No. 51 at 3, 20-21. But the plain language of the ACA insists
 10 that "preventive care" with respect to women "shall" be provided. 42 U.S.C. § 300gg-13(a)(4).

11 Defendants claim that because the guidelines implementing the Women's Health
 12 Amendment were not yet drafted at the time the ACA was passed, Congress irrevocably
 13 delegated unfettered authority to Defendants. ECF No. 51 at 20. Defendants acknowledge that
 14 the other three categories of services that must receive coverage without cost-sharing (42 U.S.C.
 15 § 300gg-13(a)(1)-(3)) are limited by the scope of the applicable guidelines. Defendants further
 16 recognize that subdivision (a)(3), which provides for children's services, and subdivision (a)(4),
 17 which provides for women's services, have nearly the same language. Children must receive the
 18 services "provided by" HRSA, whereas women must receive the services "as provided by"
 19 HRSA. Those two phrases have no difference in meaning and the scope of the covered services
 20 in both subdivisions should be equally bound by the content of the respective guidelines. In an
 21 argument not asserted in the IFRs themselves, Defendants contend that "the use of the word 'as'

22 cover contraceptives, are alone enough to ensure that women will not lose contraceptive coverage
 23 under the IFRs. ECF No. 51 at 9-10. Yet Defendants acknowledge that Virginia does not have a
 24 contraceptive equity law. *Id.* Additionally, Delaware does not require cost-fee coverage. ECF
 25 No. 24 at 16. And Defendants neglect to mention that these laws do not apply to self-insured
 26 plans, which are governed by the Employee Retirement Income Security Act (ERISA). *See* 29
 U.S.C. §§ 1144(a), (b)(2)(A). Self-insured plans cover 3 in 5 U.S. workers with employer-
 sponsored insurance and are governed exclusively by the federal government. Kaiser Family
 Foundation, *Employer Health Benefits 2017 Annual Survey*, at 164, available at
<http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017>.

27 ⁵ The States also have nonconstitutional standing to bring APA claims: under section
 28 10(a) of the APA, "any 'person . . . adversely affected or aggrieved by agency action within the
 meaning of a relevant statute, is entitled to judicial relief thereof.'" *City of Sausalito*, 386 F.3d at
 1200 (quoting 5 U.S.C. § 702). A "person" includes the States. 5 U.S.C. § 551(2).

1 reinforces Congress’s delegation to HRSA to determine . . . the manner and reach of that
2 coverage,” ECF No. 51 at 20, but Defendants provide no reasoning for the weight they attach to
3 that single word. The fact that the guidelines were not drafted when the ACA was enacted does
4 not allow Defendants to avoid or ignore the scope of coverage those guidelines now require.

5 To the contrary, the ACA expressly forbids a regulation that “creates any unreasonable
6 barriers” to medical care, “impedes timely access to health care services,” or discriminates based
7 on sex. 42 U.S.C. §§ 18114, 18116. The IFRs constitute such unreasonable barriers for women.
8 Broadly, the ACA sought to ensure universal access to quality, affordable health coverage. More
9 specifically, the ACA sought to reduce gender disparities in health for women by requiring
10 coverage of reproductive health care, maternity care, and other services that only women require,
11 while also reforming the way insurance companies charge women for health care. Congress
12 determined that preventive services are critical to improving public health outcomes and,
13 relatedly, social and economic status for women. Thus, Congress included a specific provision
14 for women’s health services to remedy the problem that women were paying significantly more
15 out-of-pocket for preventive care and thus often failed to seek critical preventive services. *Priests*
16 *for Life v. HHS*, 772 F.3d 229, 235 (D.C. Cir. 2014); *Burwell v. Hobby Lobby*, 134 S. Ct. 2751,
17 2785-2786 (2014) (Kennedy, J., concurring).

18 “Extensive empirical evidence demonstrates what common sense would predict:
19 eliminating costs leads to more effective and continuous use of contraception,” and using
20 contraception is a necessary part of women’s health care. *Finer Decl.* ¶ 25. The inclusion of
21 women’s preventive services as a core part of the ACA’s essential health benefits requirement,
22 42 U.S.C. § 18022, was critical to fulfilling Congress’s goals of ensuring complete coverage of
23 preventive care, better health outcomes for women, and an end to discrimination against women
24 in health care. The IFRs increase the impediment to contraceptive access, and that, “in turn, will
25 increase those women’s risk of unintended pregnancy and interfere with their ability to plan and
26 space wanted pregnancies. These barriers could therefore have considerable negative health,
27 social and economic impacts for those women and their families.” *Finer Decl.* ¶ 38. In short,
28

1 enacting IFRs that eliminate cost-free contraceptive coverage do precisely what the ACA forbids:
2 create barriers between women and access to no-cost preventive care.

3 Defendants point to the exception for grandfathered plans as evidence that Congress did not
4 universally require preventive services, as if the grandfathering suggests that those services were
5 less important. ECF No. 51 at 21. But this exception allowed for gradual implementation of the
6 ACA mandates, not complete avoidance. Defendants cite no authority showing Congressional
7 intent to weaken the mandated coverage for preventive care. To the contrary, the specificity of
8 this narrow exception shows that Congress intended a broad reach of the ACA mandated benefits.

9 **b. The Religious Freedom and Restoration Act Does Not Require**
10 **Defendants to Promulgate a Rule that Prevents Women from**
11 **Accessing Their Statutorily-Entitled Benefits**

12 Defendants claim that the Religious Freedom and Restoration Act of 1993 (RFRA) requires
13 the Religious IFR, but they concede it cannot support the Moral IFR. ECF No. 51 at 25. Under
14 RFRA, if the government substantially burdens the exercise of religion, then the burden must be
15 in furtherance of a compelling interest and the least restrictive means of furthering that interest.
16 42 U.S.C. § 2000bb-1(b). Thus, RFRA requires the agency to find narrowly tailored solutions to
17 provide for compelling governmental interests without trampling on religious freedom.

18 No court has ever required, or even considered, a religious exemption of the IFRs' breadth.
19 *Hobby Lobby* was limited to closely-held for-profit corporations and *Zubik* was limited to non-
20 profits. But the IFRs extend the exemptions to publicly-traded, for-profit corporations. Further,
21 as Defendants concede, *Zubik* left open the question of whether the self-certification process was
22 a "substantial burden on the exercise of religion." ECF No. 51 at 6-7. Before *Zubik*, nine courts
23 had considered this question, and eight of them had concluded that there was no RFRA violation.
24 *Zubik* simply allowed Defendants to consider a compromise, but in no way did it require that the
25 accommodation become optional and the exemption be extended to for-profit corporations,
26 insurers, and individuals—entities that were not even party to the *Zubik* litigation.⁶

27 _____
28 ⁶ The States do not concede that the contraceptive coverage requirement as modified with
accommodations would substantially burden the exercise of religion. *Contra* ECF No. 51 at 26.

1 The agency Defendants here once asserted that the “accommodation furthers the
2 compelling interest in ensuring that women covered by every type of health plan receive full and
3 equal health coverage, including contraceptive coverage. At the same time, it goes to great
4 lengths to separate objecting employers from the provision of contraceptive coverage and to
5 minimize any burden on religious exercise.” *Zubik*, Case No. 14-1418, 2016 WL 1445915 (U.S.
6 April 12, 2016) (Supp. Brief). As of April 2016, “[r]eligious organizations providing coverage to
7 hundreds of thousands of people have now invoked the accommodation to opt out of the
8 contraceptive-coverage requirement.” *Id.* Only a year later, these same agencies now abandon
9 the compelling interest in ensuring that those hundreds of thousands of people receive equal
10 access to health care. ECF No. 51 at 26.

11 Defendants attempt to justify their decision under RFRA, in part, by minimizing the interest
12 of providing contraceptive coverage. Birth control, they have decided, is just not that important
13 after all. ECF No. 51 at 26-27. They assert that this is a “technical judgment” within their
14 expertise, and so the Court should not second-guess it. ECF No. 51 at 27. But this ignores that
15 Defendants deferred such technical judgment first to the Institute of Medicine (IOM) to determine
16 what services to cover, and the IOM found—after exhaustive review of scientific evidence—that
17 contraception *is* essential preventive medicine for women. *See* ECF No. 24 at 7-8. Later, in
18 December 2016, as the federal government sought to update the women’s preventive guidelines,
19 it deferred this technical judgment to the American Congress of Obstetricians and Gynecologists
20 (ACOG). ACOG likewise determined that contraception is essential preventive care for women.
21 *See* ECF No. 24 at 10. Defendants fail to adequately justify a complete about-face in abandoning
22 their former compelling interest in public health and women’s preventive care and screenings,
23 including contraceptive coverage as an essential women’s health benefit.

24 Defendants attempt to justify their new position by relying on the exclusion of
25 grandfathered plans and the previously available exemption and accommodation. ECF No. 51 at
26 26-27. These excuses minimize the importance not just of birth control, but of resolving
27 compelling interests. The IFRs fail to reconcile, as RFRA itself requires, the federal law’s
28 guarantee of women’s access to contraceptive services and religious interests.

1 **3. The IFRs Were Improperly Issued Without Notice and Comment**

2 **a. Defendants Have Not Shown that Good Cause Excused Their**
 3 **Compliance with Notice and Comment Procedures**

4 Defendants wrongly contend that providing notice and comment would be “contrary to the
 5 public interest,” and thus that they have established “good cause” for their failure to comply with
 6 the full procedural requirements of the ACA.⁷ ECF No. 51 at 16; 5 U.S.C. § 553(b)(B).

7 Defendants’ stated purposes—the need to effectuate their desired policies more quickly and to
 8 end litigation and general uncertainty surrounding the contraceptive mandate—fail to satisfy the
 9 high bar for an agency’s burden to show that providing notice and comment would be contrary to
 10 the public interest.⁸ See *San Diego Air Sports Ctr., Inc. v. FAA*, 887 F.2d 966, 969 (9th Cir.
 11 1989) (good cause exception “must be narrowly construed and only reluctantly countenanced”).

12 To determine whether Defendants have shown “good cause,” the court must ascertain “not
 13 whether *dispensing* with notice and comment would be contrary to the public interest, but
 14 whether *providing* notice and comment would be contrary to the public interest.” *Mack Trucks,*
 15 *Inc. v. EPA*, 682 F.3d 87, 95 (D.C. Cir. 2012) (italics original). Providing notice may be contrary
 16 to the public interest where, for example, “announcement of a proposed rule would enable the sort
 17 of financial manipulation the rule sought to prevent.” *Util. Solid Waste Activities Grp. v. EPA*,
 18 236 F.3d 749, 755 (D.C. Cir. 2001); see also *United States v. Valverde*, 628 F.3d 1159, 1165-
 19 1168 (9th Cir. 2010) (rejecting “contrary to public interest” justification).

20 Defendants’ desire for expediency and their interest in reducing uncertainty and litigation
 21 are factors that are present in nearly every agency rulemaking.⁹ Were these factors sufficient to

22 ⁷ The IFRs stated that “good cause” was supported both by the “impracticability” and
 23 “public interest” exceptions, although Defendants argue only the latter exception in their
 24 opposition brief. See ECF No. 51 at 16-18. Defendants have never argued that providing notice
 25 and comment was “unnecessary.”

26 ⁸ Defendants also argue that failing to comply with notice and comment is justified
 27 because of the interim nature of the rule, the availability of post-promulgation public comment,
 28 and the fact that it received comments on related issues in the past. ECF No. 51 at 16-18. But
 these arguments do not speak to whether providing notice and comment would be contrary to the
 public interest, and are more properly addressed in the harmless error analysis. See *infra* at 9-10.

⁹ Given that the prior regulations generated over 400,000 comments, ECF No. 51 at 5,
 indicating a strong public interest in contraception coverage, it was particularly important to
 allow notice and comment here.

1 support good cause, the requirement of notice and comment would be obsolete. *See Valverde*,
 2 628 F.3d at 1166 (if interest in eliminating uncertainty constituted “good cause,” the exception
 3 “would swallow the rule”); *United States v. Cain*, 583 F.3d 408, 421 (6th Cir. 2009). And these
 4 justifications do not show that this is the “rare circumstance when ordinary procedures—
 5 generally presumed to serve the public interest—would in fact harm that interest.” *Mack Trucks*,
 6 682 F.3d at 95. Thus, the IFRs are procedurally defective and legally invalid. *See Linoz v.*
 7 *Heckler*, 800 F.2d 871, 878 (9th Cir. 1986).

8 **b. The Error Was Not Harmless Because It Directly Affected the**
 9 **Procedure**

10 It is “antithetical to the structure and purpose of the APA for an agency to implement a rule
 11 first, and then seek comment later.” *Paulsen v. Daniels*, 413 F.3d 999, 1005 (9th Cir. 2005).
 12 Courts must “exercise great caution” in applying the harmless error rule in the APA context. *Id.*
 13 at 1006. Failure to provide notice and comment is harmless only where the “agency’s mistake
 14 clearly had no bearing on the *procedure used* or the substance of decision reached.”¹⁰ *Id.*
 15 (emphasis added); *see also Buschmann v. Schweiker*, 676 F.2d 352, 358 (9th Cir. 1982) (error not
 16 harmless even where agency subsequently promulgated valid rule with identical language).

17 Much like their arguments in support of “good cause,” Defendants’ proffered reasons for
 18 why failure to provide notice and comment was harmless error—post-promulgation public
 19 comment, the interim nature of the rule, and prior opportunities to comment on rules relating to
 20 the same general subject matter—are present in nearly every issuance of an IFR. ECF No. 51 at
 21 18. Notice and comment procedures may not be so easily evaded. Indeed, the Ninth Circuit held
 22 that failure to provide notice and comment was not harmless under very similar circumstances.
 23 *See Paulsen*, 413 F.3d at 1006-08 (error not harmless despite interim nature of rule, post-

24 ¹⁰ Defendants cite *Shinseki v. Sanders*, 556 U.S. 396, 409 (2009) for the proposition that a
 25 plaintiff bears the burden of demonstrating that the error was harmless. ECF No. 51 at 18. But
 26 *Sanders* held no such thing. *Sanders* interpreted a harmless error statute specific to agency
 27 adjudication of veteran disability claims. *Sanders*, 556 U.S. at 406. Its analysis did not extend to
 28 harmless error analysis in the agency rulemaking context. Moreover, the Court held that harmless
 error should generally be determined based on a “case-specific application of judgment” and
 “examination of the record,” not “through the use of mandatory presumptions and rigid rules.”
Id. at 407. *Sanders* is accordingly inapposite.

1 promulgation comment, and public comment on prior rule relating to same issue).¹¹ Defendants’
 2 failure to observe notice and comment procedures denied the States meaningful opportunity to
 3 offer comments before the IFRs were enacted, and the States’ comments submitted to these IFRs,
 4 already in effect, do not suffice.¹² This error cannot be harmless because it is not “clear” that the
 5 error “had no bearing on the procedure used.” *Id.* at 1006.

6 **c. Congress Has Not Expressed a “Clear Intent” that Notice and**
 7 **Comment Procedures “Need Not Be Followed”**

8 Defendants argue that they are statutorily empowered to issue regulations relating to health
 9 plans without observing notice and comment procedures. Congress may exempt certain
 10 rulemakings from compliance with notice and comment procedures, but only when it “sets forth
 11 specific procedures that ‘express[] its clear intent that APA notice and comment procedures need
 12 not be followed.’” *Asiana Airlines v. F.A.A.*, 134 F.3d 393, 398 (D.C. Cir. 1998); 5 U.S.C. § 559.
 13 Congress indicates an intent to supplant notice and comment procedures when a statute directs
 14 that the agency “shall” issue an IFR, specifically identifies the subject matter of the exempt
 15 regulation, and establishes deadlines that could generally not be met were notice and comment
 16 procedures followed. *See Asiana Airlines*, 134 F.3d at 395; *Methodist Hosp. of Sacramento v.*
 17 *Shalala*, 38 F.3d 1225, 1236 n.18 (D.C. Cir. 1994). The statutes at issue here do none of these
 18 things. Their language merely confirms the agencies’ existing powers under the APA. 26 U.S.C.
 19 § 9833; 29 U.S.C. § 1191c; 42 U.S.C. § 300gg-92 (agency “may promulgate” IFRs as agency
 20 determines “appropriate”). Under Defendants’ reading, these statutes would confer broad power
 21 to jettison notice and comment procedures whenever they so desire. But if Congress intended
 22 such an extraordinary result, it surely would have said so clearly. The only court to consider the
 23 issue reached precisely this conclusion when it rejected the notion that 42 U.S.C. § 300gg-92

24 ¹¹ The cases cited by Defendants holding that the error was harmless are distinguishable.
 25 ECF No. 51 at 18. Unlike those cases, here the public received no notice that “enabled [it] to
 participate in the rulemaking process before” the rule was adopted. *Paulsen*, 413 F.3d at 1007
 (distinguishing *Idaho Farm Bureau*, *Riverbend*, and *Sagebrush Rebellion*).

26 ¹² Given that the HHS has already issued guidance on how to implement the IFRs, it does
 27 not appear that the Defendants expect public comment to inform implementation. Memorandum
 28 from Randy Pate, Director, Center for Consumer Information and Insurance Oversight,
 November 30, 2017 (<https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Notice-Issuer-Third-Party-Employer-Preventive.pdf>) (CMS Memo).

1 conferred such broad discretionary authority. *Coalition for Parity, Inc. v. Sebelius*, 709 F. Supp.
2 2d 10, 17-19 (D.D.C. 2010). There is no reason for this Court to arrive at a different result.

3 **4. The IFRs Are Arbitrary and Capricious Because Defendants Failed**
4 **to Provide an Adequate Justification for Changing Its Position**

5 When the government enacts a change in policy through regulation, it must acknowledge
6 and explain its changing position. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515
7 (2009); *Jicarilla Apache Nation v. U.S. Dep't of Interior*, 613 F.3d at 1112, 1119 (D.C. Cir.
8 2010). The IFRs allowed a new broad class of employers, insurers, and individuals to evade the
9 ACA's contraception coverage requirement. Whereas previously, contraception was among the
10 suite of required preventive services, subject to narrowly-tailored exemptions and
11 accommodations, under the IFRs contraception is the sole preventive health benefit that an
12 insurer or employer may simply decide to exclude—thereby transmuted contraceptive coverage
13 from a requirement into an option. The federal government fails to provide adequate justification
14 and cannot gloss over the 62 million women who have relied on access to no-cost birth control for
15 preventive health care since the ACA was enacted. ECF No. 24 at 13; *see FCC*, 556 U.S. at 515
16 (“detailed justification” is necessary where there are “serious reliance issues” at stake). The IFRs
17 constitute arbitrary and capricious rulemaking where medical science—which indicates that
18 women and children have better health outcomes because of the ability to plan pregnancies—has
19 not changed since the original accommodation process. *Finer Decl.* ¶ 43.

20 Defendants rely on the President's Executive Order directing them to “consider issuing
21 amended regulations, consistent with applicable law, to address conscience-based objections to
22 the preventive-care mandate promulgated under section 300gg-13(a)(4).” ECF No. 51 at 23; *see*
23 ECF No. 24-1 at 2. But the President cannot order Defendants to ignore the Congressional
24 mandate that Defendants “shall provide” women's preventive care. 42 U.S.C. § 300gg-13(a)(4).

25 Defendants claim that these regulations are simply the last step in its attempts to
26 accommodate religious objections. ECF No. 51 at 1, 7. While this narrative might be a facile
27 way to downplay the impact of Defendants' regulatory action, it leaves them ill-equipped to meet
28 the requirement of acknowledging and explaining their change in position. Defendants side-step

1 their responsibility to acknowledge or explain the significant change in policy by accusing the
 2 States of attempting to subject them to a “more searching standard of review.” ECF No. 51 at 22.
 3 But the requirement to recognize the nature of their action—and its impact on millions of
 4 women—is not a standard of review. Rather, the APA requires that analysis which is entirely
 5 lacking in the IFRs. Defendants embrace that omission by minimizing the impact of the IFRs,
 6 stating that the accommodations are still available and that the exemptions are “cabined to those
 7 with sincere religious and moral beliefs.” ECF No. 51 at 24. But there is no “cabining” such
 8 exemptions in practice. Rather, the IFRs make the accommodations process “optional” and
 9 “voluntary.” ECF No. 24-1 at 1; ECR No. 24-2 at 1.¹³

10 C. The States’ Constitutional Claims Are Likely to Succeed

11 1. The States Have Standing to Bring Constitutional Claims

12 Defendants argue that the States lack standing because they have purportedly failed to show
 13 any injury. To demonstrate an “injury in fact,” the States must show (1) an invasion of a legally
 14 protected interest (2) that is concrete and particularized, and (3) harm that is actual or imminent,
 15 not conjectural or hypothetical. *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1548 (2016). Here, the
 16 States have standing based primarily on the fiscal harm the IFRs cause.¹⁴ *Clinton v. New York*,
 17 524 U.S. 417, 432-33 (1998) (New York had standing to contest veto of legislation to permit the
 18 state to keep disputed Medicaid funds); *Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel. Barez*,
 19 458 U.S. 592, 601-602 (1982) (state can assert standing based on its fiscal interests). Standing
 20 requires a litigant show only a minimal amount of financial harm, or predicted financial harm.
 21 *Council of Ins. Agents & Brokers v. Molasky-Arman*, 522 F.3d 925, 932 (9th Cir. 2008)

22
 23 ¹³ The Centers for Medicare & Medicaid Services’ guidance on implementing the IFRs
 24 provide that an employer or insurer could notify an insured who will no longer receive
 25 contraceptive coverage the same way it would notify the policyholder of any other change in
 26 benefits, through the Summary of Benefits of Coverage. CMS Memo, *supra* n. 11 at 3.

27 ¹⁴ Defendants erroneously suggest that the States have attempted to establish standing
 28 through their *parens patriae* interest. ECF No. 51 at 10-11. Not so. The States allege that they
 will suffer direct harm, and that they are suing to protect their sovereign, quasi-sovereign, and
 proprietary interests. ECF No. 24 at ¶ 14. And contrary to Defendants’ claim that Virginia has
 not adequately pled that it is has proprietary interest through its state-funded hospitals, ECF No.
 51 at 11, n.12, the amended complaint explicitly states that these hospitals are “state providers.”
 ECF No. 24 at ¶ 93.

1 (monetary loss need only be an “identifiable trifle”) (quoting *United States v. Students*
2 *Challenging Regulatory Agency Procedures*, 412 U.S. 669, 690 (1973)); *Mass. v. EPA*, 549 U.S.
3 497, 521-26 (2007) (Massachusetts had standing to petition EPA to regulate greenhouse gas
4 emissions based on predicted financial losses caused by failure to reduce global warming).

5 As detailed in the States’ opening brief, *see* ECF No. 28 at 29-32, the States will be injured
6 by the IFRs in at least two ways. First, the States will bear increased costs of providing
7 contraceptive services to eligible residents who lose coverage. *Finer Decl.* ¶¶ 58-59 (California),
8 66-67 (Delaware), 74-75 (Maryland), 82-83 (New York), 90-91 (Virginia); *Whorley Decl.* ¶ 10,
9 11; *Cantwell Decl.* ¶ 17; *Tosh Decl.* ¶ 34; *Nelson Decl.* ¶ 15; *Rattay Decl.* ¶ 7. This is especially
10 true in Virginia, where there is no contraceptive equity law requiring insurance plans cover
11 contraception. *Whorley Decl.* ¶ 8. There is no question that this harm is real; Defendants admit
12 in the IFRs that as many as 120,000 women who need contraceptive coverage will lose it. ECF
13 Nos. 24-1 at 24-33, 24-2 at 19-21. Of this number, more than one in five are residents of the
14 States. *See* 2010 Census Briefs, *Age and Sex Composition: 2010*, at 4, 7 (issued May 2011),
15 *available at* <https://www.census.gov/prod/cen2010/briefs/c2010br-03.pdf>. Given that the
16 numerous employers involved in the *Zubik* litigation are likely to avail themselves of the new
17 exemption, rather than the accommodation, Defendants appear to have significantly
18 underestimated the impact of the IFRs on women and the States. *See also Decl. of Sharita*
19 *Gruberg, Ex. A* (partial records obtained from federal government show that at least four large
20 employers with employees in the States requested an accommodation between January 2014 and
21 March 2016).

22 Defendants allege that this harm is self-inflicted, ECF No. 51 at 10, yet later acknowledge
23 that in the absence of the IFRs “numerous other governmental programs” will “assist low-income
24 women to access free or subsidized contraception.” ECF No. 51 at 23. Indeed, the IFRs
25 explicitly rely on the “multiple Federal, State, and local programs that provide free or subsidized
26 contraceptives for low-income women” to fill the coverage gap created by the undoing of the no-
27 cost guarantee by the IFRs. ECF No. 1-1 at 42. Defendants also stated in their brief in *Zubik* that
28 if a small employer elects not to provide coverage, “employees will ordinarily obtain coverage

1 through . . . [options including] Medicaid or another government program.” *Zubik*, No. 14-1418,
2 Brief of Respondents, 2016 WL 537623 (U.S. Feb. 10, 2016) at 65. In any event, leaving women
3 without any public assistance to obtain contraception would rob Peter to pay Paul; the States
4 would not reap any financial benefit because they would bear responsibility for covering the costs
5 associated with the even greater rise in unintended pregnancies that would result.

6 Second, women who lose no-cost contraceptive coverage are more likely to become
7 pregnant, and the States will suffer financial harm as a result of these unintended and often high-
8 risk pregnancies. *Finer Decl.* ¶¶ 28, 38-43; *Decl. of Hal Lawrence [Lawrence Decl.]* ¶ 9; *Decl. of*
9 *Dan Grossman* ¶¶ 8-9, *Decl. of Lisa Ikemoto* ¶ 5; *Decl. of Dave Jones [Jones Decl.]* ¶ 15; *Tosh*
10 *Decl.* ¶ 35; *Nelson Decl.* ¶ 30; *Rattay Decl.* ¶¶ 6, 8; *Decl. of Ruth Lytle-Barnaby* ¶ 28. Whether
11 these pregnancies end in miscarriage or abortion, or result in live birth, the States will share the
12 cost of funding these medical procedures, both during and after pregnancy, as well as the long-
13 term costs of social services. *Finer* ¶¶ 54, 61 (California), 69 (Delaware), 77 (Maryland), 85
14 (New York), 93 (Virginia); *Tosh Decl.* ¶¶ 26-28; *Rattay Decl.* ¶¶ 5, 8. This is particularly true
15 because self-insured plans are not required to cover essential health benefits, including maternity
16 care. *See* 29 U.S.C. § 1144(a), (b)(2)(A).

17 Defendants suggest that these “alleged harms rely on an attenuated chain of causation.”
18 ECF No. 51 at 10. But a causal chain “does not fail simply because it has several links.” *Maya v.*
19 *Centex Corp.*, 658 F.3d 1060, 1070 (9th Cir. 2011) (internal quotations omitted). Instead, “what
20 matters is not the ‘length of the chain of causation,’ but rather the ‘plausibility of the links that
21 comprise the chain.’” *Nat’l Audobon Soc’y v. Davis*, 307 F.3d 835, 849 (9th Cir. 2002) (quoting
22 *Autolog Corp. v. Regan*, 731 F.2d 25, 31 (D.C.Cir.1984)). None of the links in the chain here is
23 “hypothetical” or “tenuous”; the declarations that accompany this motion—from respected
24 researchers and public servants—show that the IFRs will block women from receiving
25 contraceptive services, that unintended pregnancies will result from the lack of contraceptive
26 access, and that these pregnancies will impose a financial burden on the States. In short, the
27 financial harm borne by the States is an “injury in fact” sufficient to bring constitutional claims.
28

2. The IFRs Violate the Establishment Clause

The IFRs violate the Establishment Clause because they impose religious beliefs on third parties. Defendants point out that the government must sometimes accommodate the exercise of religion, and “there is room for play in the joints” between the Free Exercise Clause and the Establishment Clause. ECF No. 51 at 30 (quoting *Cutter v. Wilkinson*, 544 U.S. 709, 713 (2005)). While there may be “play in the joints” between the competing interests of allowing the free exercise of religion and avoiding government favoritism toward religion, “[a]t some point, accommodation may devolve into ‘an unlawful fostering of religion.’” *Corp. of Presiding Bishop of Church of Jesus Christ of Latter-Day Saints v. Amos*, 483 U.S. 327, 334–35 (1987) (quoting *Hobbie v. Unemployment Appeals Comm’n of Fla.*, 480 U.S. 136 (1987)). This is that case. While the prior regulations’ accommodation and exemption were narrowly-tailored to allow for exercise of religious freedoms and still provide essential women’s preventive care, the IFRs go needlessly far toward endorsing religion.

The IFRs cannot pass the three-pronged test under *Lemon v. Kurtzman*, 403 U.S. 602 (1971). A failure of any one of these parts is sufficient to invalidate the IFRs under the Establishment Clause. First, the IFRs do not have a secular purpose. Defendants contend that the IFRs alleviate governmental interference with religion. ECF No. 51 at 30-31. But this is not the case; the ACA is, on its face, entirely religion-neutral. The previous structure of accommodations and exemptions was narrowly tailored to allow for the practice of religion and still provide contraceptive coverage. Here, Defendants have jettisoned this dual purpose and fashioned a regulation solely to favor religion. Defendants concede they crafted the IFRs in response to Executive Order 13,798, which was directed at religion. ECF No. 51 at 7. And Defendants cannot salvage the Religious IFR by including the Moral IFR; laws that privilege religious institutions are invalid, even if they extend that privilege to non-religious institutions. *See Larkin v. Grendel’s Den*, 459 U.S. 116 (1982) (zoning law violates Establishment Clause when it allows either churches or schools to veto liquor licenses to nearby businesses).

Second, the primary effect of the IFRs is to advance religion because it forces women employees to bear the burden of their employers’ belief. Defendants contend that the IFRs

1 remove a burden on religious employers, but the exemption and accommodation already removed
2 that burden. Rather, Defendants placed the burden on employees. Defendants blithely maintain
3 that employees are not burdened by their employer’s religious beliefs because “[n]othing in the
4 rule obligates women working for objecting employers to change their beliefs about
5 contraceptives.” ECF No. 51 at 28. Of course, this avoids the issue. The female employees bear
6 the burden of their objecting employers’ religious beliefs because they lose their contraceptive
7 coverage, thereby forcing them to seek other employment; obtain birth control at their own
8 expense or the States’ expense; or forgo birth control altogether.

9 This third-party burden is exactly what the Establishment Clause prohibits under *Estate of*
10 *Thornton v. Caldor*, 472 U.S. 703 (1985). There, the Court held that a statute requiring
11 employers to allow employees time off to observe religious holidays violated the Establishment
12 Clause because it forced employers and fellow employees to shoulder the burden of the religious
13 employee’s faith: “The State has thus decreed that those who observe a Sabbath any day of the
14 week as a matter of religious conviction must be relieved of the duty to work on that day, no
15 matter what burden or inconvenience this imposes on the employer or fellow workers.” *Id.* at
16 708-09. Notably, the court stated that the statute could have been narrowed and tailored to
17 mitigate that burden, by allowing exceptions or reasonable accommodations, and thus resolved
18 the constitutional violation. *Id.* at 709-10. But because the statute made no attempt to relieve the
19 burden of the religious observance from the third parties, the Court found that it “goes beyond
20 having an incidental or remote effect of advancing religion. The statute has a primary effect that
21 impermissibly advances a particular religious practice.” *Id.* at 710 (citations omitted). The same
22 is true here, and Defendants make little argument to the contrary.

23 Third, the IFRs excessively entangle the government with the religious interests that object
24 to contraceptive coverage. Among other things, Congress enacted the ACA to ensure access to
25 essential preventive health care and to improve equality in health care for women. The IFRs
26 undermine the reforms enacted by the ACA to empower patients to make decisions about their
27 own healthcare, and instead put employers’ religious interests in the position of determining
28 whether an employee may receive birth control coverage without cost-sharing.

3. The IFRs Violate the Equal Protection Clause

The IFRs violate the Equal Protection Clause because Defendants fail to demonstrate an “exceedingly persuasive justification” for the IFRs, which draw a gender classification. *United States v. Virginia*, 518 U.S. 515, 531 (1996). Defendants claim that the IFRs do not discriminate based on sex by pointing to the fact that male contraceptives are not required at all under the ACA. ECF No. 51 at 33. In fact, this simply proves the point, because contraceptives are required under the ACA as preventive health care for *women*. Only women get pregnant. So the gender classification is whether contraceptives, as an essential element of women’s preventive care, are treated similarly to men’s preventive care—and they are not.

No exceedingly persuasive justification supports this gender classification, which is directly contrary to the ACA’s intent to eliminate gender disparities in health care. Defendants summarily restate their conclusion that the Religious IFR is required to accommodate religious interests, ECF No. 51. at 34, but such a broad exemption is unwarranted. *See supra* 6-7. Defendants’ sole support for the Moral IFR is that it is consistent with other conscience provisions that did not involve constitutional claims. In fact, although Defendants reject any intent to discriminate, ECF No. 51 at 34, they are openly dismissive of the need for contraceptive coverage; they plainly state that—despite the IOM and ACOG reports finding contraceptive care to be basic preventive care for women—“the effect of contraceptives and broad coverage mandates on women’s health . . . [were] not adequate to establish a compelling interest.” ECF No. 51 at 27.

II. THE IFRS INFLICT IRREPARABLE HARM UPON THE STATES

The States will suffer irreparable harm in at least three ways. First, as Defendants admit, irreparable harm exists if one or both of the States’ constitutional claims are likely to succeed on the merits. ECF No. 51 at 13. Second, the APA violations here, particularly the deprivation of a meaningful public comment period before the IFRs became effective, will cause harm that cannot be undone, given the “far-reaching changes that will likely have significant effects” on the States. *See Northern Mariana Islands v. United States*, 686 F. Supp. 2d 7, 17, 18 (D.D.C. 2009). And third, the States will be burdened not only with providing contraceptive coverage to those who lose it, but with the irreversible consequences of an upswing in unintended pregnancies—short-

1 term medical costs associated with the pregnancies and their aftermath and long-term costs from
 2 the inability of affected women to contribute to the States as students, researchers, workers, and
 3 taxpayers. *Finer Decl.* ¶¶ 45, 54, 61, 69, 77, 85, 93; *Tosh Decl.* ¶¶ 26-28, *Rattay Decl.* ¶¶ 5, 8;
 4 *Lawrence Decl.* ¶ 5; *Arensmeyer Decl.* ¶ 4; *Nelson Decl.* ¶ 31, *Decl. of Keisha Bates* ¶¶ 3, 6.

5 Defendants suggest that the States have not shown that these harms are imminent and
 6 concrete.¹⁵ *ECF No. 51* at 14. Yet the IFRs took effect immediately on October 6, 2017,
 7 allowing employers not covered by contraceptive equity laws to exempt themselves from the no-
 8 cost contraceptive coverage requirement at any time after providing sufficient notice to affected
 9 employees. *ECF Nos. 24-1* at 2, *24-2* at 1. Given that the IFRs eliminate the requirement for
 10 employers to disclose their exempt status to the government, the scope of the harm to women and
 11 the States is, by design, not easily quantified. But no matter the “magnitude of the injury,” *see*
 12 *Simula, Inc. v. Autoliv, Inc.*, 175 F.3d 716, 724 (9th Cir. 1999), some number of women have
 13 already lost coverage or will soon lose coverage, and the States will suffer irreparable harm as a
 14 result. *ECF Nos. 24-1* at 24-33, *24-2* at 19-21; *see also Jones Decl.* ¶¶ 23-24.

15 **III. ISSUING AN INJUNCTION TO PRESERVE THE STATUS QUO WOULD PROPERLY** 16 **BALANCE THE EQUITIES AND SERVE THE PUBLIC INTEREST**

17 While prior ACA regulations struck a delicate balance that both accommodated sincere
 18 religious beliefs and ensured full and equal health coverage for women—and the Supreme Court
 19 endorsed this aim, *Zubik*, 136 S. Ct. at 1560—the IFRs attempt no such compromise, but instead
 20 favor the former values to the exclusion of the latter. Returning the parties to the status quo that
 21 existed before the IFRs would properly balance the equities and serve the public interest by
 22 ensuring that the significant public health benefits of contraception are more widely available to
 23 women. *Chalk v. U.S. Dist. Court Cent. Dist. Cal.*, 840 F.2d 701, 704 (9th Cir. 1988) (purpose of
 24 injunction is to preserve the status quo).

25 **CONCLUSION**

26 The States request that the Court grant this motion for preliminary injunction.

27 _____
 28 ¹⁵ While Defendants rushed the IFRs into effect without notice and comment to provide immediate relief to religious and moral objectors, they now assert a lack of imminent harm.

1 Dated: December 6, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

Case Name: St. of Ca. et. al v. Health & Human Services, et al. No: 4:17-cv-05783-HSG

I hereby certify that on December 6, 2017, I electronically filed the following documents with the Clerk of the Court by using the CM/ECF system:

States' Reply in Support of Motion for Preliminary Injunction

I certify that **all** participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

I declare under penalty of perjury under the laws of the State of California the foregoing is true and correct and that this declaration was executed on December 6, 2017, at Sacramento, California.

Francina M. Stevenson
Declarant

/s/ Francina M. Stevenson
Signature