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11	IN THE UNITED STATES DISTRICT COURT	
12	FOR THE NORTHERN DI	STRICT OF CALIFORNIA
13		
14	της στατε σε σαι ιεσανία. Της	4:17-cv-05783-HSG
15	THE STATE OF CALIFORNIA; THE STATE OF DELAWARE; THE STATE OF MARYLAND; THE STATE OF NEW	FIRST AMENDED COMPLAINT FOR
16	YORK; THE COMMONWEALTH OF VIRGINIA,	DECLARATORY AND INJUNCTIVE RELIEF
17	Plaintiffs,	
18	v.	
19 20	EDICD HADCAN IN HIS OFFICIAL	
20 21	ERIC D. HARGAN, IN HIS OFFICIAL Capacity as Acting Secretary of the U.S. Department of Health & Human	
21	Services; U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; R.	
23	ALEXANDER ACOSTA, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE U.S.	
24	DEPARTMENT OF LABOR; U.S. DEPARTMENT OF LABOR; STEVEN	
25	MNUCHIN, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE U.S. DEPARTMENT OF	
26	THE TREASURY; U.S. DEPARTMENT OF THE TREASURY; DOES 1-100,	
27	Defendants.	
28		
		l or Declaratory and Injunctive Relief (4:17-cv-05783-HSG)
	i nat Amenaca Comptanti i	(4.17-0.05703-1100)

	Case 4:17-cv-05783-HSG Document 24 Filed 11/01/17 Page 2 of 33
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26	
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28	
	First Amended Complaint for Declaratory and Injunctive Relief (4:17-cv-05783-HSG)

INTRODUCTION

1. Ensuring women access to preventive health care, including contraception, is a key element in safeguarding women's overall health and well-being, and is therefore a critical component of the States' public health interests. Contraceptives are among the most widely used medical services in the United States and are much less costly than maternal deliveries for women, insurers, employers and states, and consequently the use of contraceptives has been shown to result in net savings to women and to states. Starting in 2012, as part of the Patient Protection and Affordable Care Act (ACA), most group health insurance plans were required to cover all Food and Drug Administration (FDA)-approved contraceptive methods without cost-sharing (e.g. out of pocket health expenses on copays, deductibles, or coinsurance) for beneficiaries. 45 C.F.R. § 147.130(a)(1)(iv); 29 C.F.R. § 2590.715-2713(a)(1)(iv); 26 C.F.R. § 54.9815-2713(a)(1)(iv). Since this contraceptive-coverage requirement took effect, women across the country have saved \$1.4 billion.

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2. On October 6, 2017, the U.S. Health and Human Services (HHS), in conjunction with 15 the U.S. Department of Labor and U.S. Department of the Treasury, issued two illegal interim 16 final rules (IFRs), 2017-21851 and 2017-21852. The IFRs drastically change access to 17 contraceptive coverage by expanding the scope of the religious exemption to, among other things, 18 allow any employer or health insurer with religious objections to opt out of the contraceptive-19 coverage requirement with no assurances that the federal government will provide critical 20 oversight to ensure coverage. Additionally, the IFRs expand the exemption to include employers 21 with "moral" objections to providing contraceptive coverage. Unlike the prior regulations, the 22 IFRs eliminate the automatic seamless mechanism for women to continue to receive 23 contraceptive coverage if their employer opts out. Further, under this new regime, there is not 24 even a requirement that the employer notify the federal government of a decision to stop 25 providing contraceptive coverage. Therefore, millions of women across the nation may be left 26 without access to contraceptives and contraceptive counseling, leaving the States to shoulder the 27 additional fiscal and administrative burdens as women seek access for this coverage through

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state-funded programs, and the public health consequences if women are unable to gain that
 access.

The State of California, the State of Delaware, the State of Maryland, the State of
 New York, and the Commonwealth of Virginia (collectively, "the States"), challenge the illegal
 IFRs and seek an injunction to prevent the IFRs from taking effect because the regulations violate
 the Administrative Procedure Act (APA), the Establishment Clause of the First Amendment, and
 the Equal Protection Clause of the Fifth Amendment. Furthermore, the issuance of the IFRs will
 cause immediate and irreparable harm to the States.

9

JURISDICTION AND VENUE

4. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 (action arising under the
laws of the United States), 28 U.S.C. § 1361 (action to compel officer or agency to perform duty
owed to Plaintiff), and 5 U.S.C. §§ 701-706 (Administrative Procedure Act). An actual
controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a), and this Court
may grant declaratory relief, injunctive relief, and other relief pursuant to 28 U.S.C. §§ 22012202 and 5 U.S.C. §§ 705-706.

16 5. Defendants' issuance of the IFRs on October 6, 2017, constitutes a final agency
17 action and is therefore judicially reviewable within the meaning of the Administrative Procedure
18 Act. 5 U.S.C. §§ 704, 706.

Venue is proper in this Court pursuant to 28 U.S.C. § 1391(e) because this is a
 judicial district in which the State of California resides and this action seeks relief against federal
 agencies and officials acting in their official capacities.

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INTRADISTRICT ASSIGNMENT

Pursuant to Civil Local Rules 3-5(b) and 3-2(c), there is no basis for assignment of
this action to any particular location or division of this Court.

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PARTIES

8. Plaintiff, the State of California, by and through its Attorney General Xavier Becerra,
brings this action. The Attorney General is the chief law enforcement officer of the State and has
the authority to file civil actions in order to protect public rights and interests. Cal. Const., art. V,

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§ 13. This challenge is brought pursuant to the Attorney General's independent constitutional,
 statutory, and common law authority to represent the public interest.

9. Plaintiff, the State of Delaware, by and through its Attorney General Matthew P.
 Denn, brings this action. The Attorney General is the chief law enforcement officer of the State
 of Delaware and has the authority to file civil actions in order to protect public rights and interests.
 29 *Del. C.* § 2504.

7 Plaintiff, the State of Maryland, by and through its Attorney General Brian E. Frosh, 10. 8 brings this action. The Attorney General is Maryland's chief legal officer with general charge, 9 supervision, and direction of the State's legal business. The Attorney General's powers and 10 duties include acting on behalf of the State and the people of Maryland in the federal courts on 11 matters of public concern. Under the Constitution of Maryland, and as directed by the Maryland 12 General Assembly, the Attorney General has the authority to file suit to challenge action by the 13 federal government that threatens the public interest and welfare of Maryland residents. Md. 14 Const. art. V, § 3(a)(2); 2017 Md. Laws, Joint Resolution 1.

15 11. Plaintiff, the State of New York, by and through its Attorney General, Eric T.
16 Schneiderman, brings this action. New York is a sovereign state in the United States of America.
17 The Attorney General is New York State's chief law enforcement officer and is authorized to
18 advance the State's interest in protecting women's access to critical health care services.

Plaintiff, the Commonwealth of Virginia, by and through its Attorney General Mark
 R. Herring, brings this action. Virginia law provides that the Attorney General, as chief executive
 officer of the Department of Law, performs all legal services in civil matters for the
 Commonwealth. Va. Const. art. V, § 15; Va. Code Ann. §§ 2.2-500, 2.2-507 (2017).

13. The States have an interest in ensuring women's health care is both available and
accessible. Health care is one of the police powers of the States. The States rely on Defendants'
compliance with the procedural and substantive requirements of the APA in order to obtain
timely and accurate information about activities that may have significant adverse impacts on
access to health care, including contraceptive coverage, and to meaningfully participate in an

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impartial and public decision-making process that is consistent with the Affordable Care Act's
 requirements of free contraceptive coverage.

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14. Each State is aggrieved by the actions of Defendants and has standing to bring this
action because of the injury to its state sovereignty caused by Defendants' issuance of the illegal
IFRs, including immediate and irreparable injuries to its sovereign, quasi-sovereign, and
proprietary interests. In particular, the States will suffer concrete and substantial harm because
the IFRs frustrate the States' public health interests by curtailing women's access to contraceptive
care through employer-sponsored health insurance.¹

9 15. Further, the States are aggrieved by the actions of Defendants and have standing to
bring this action because of the injuries that will be caused to the States by the enforcement of
Defendants' IFRs limiting women's ability to obtain contraception. The States will suffer
concrete and substantial harm because it will incur increased costs of providing contraceptive
coverage to many of the women who lost coverage through the IFRs, as well as increased costs
associated with resulting unintended pregnancies and the related attendant harms.

15 16. The States are also aggrieved by Defendants' failure to comply with the notice and
16 comment procedures required by the APA, because the States have been denied the opportunity to
17 comment and be heard, prior to the effective date of the IFRs, concerning the impact of the rules
18 on the States and their residents.

19 17. Defendant Eric D. Hargan is Acting Secretary of HHS and is sued in his official
20 capacity. Acting Secretary Hargan has responsibility for implementing and fulfilling HHS's
21 duties under the Constitution, the ACA, and the APA.

18. Defendant HHS is an agency of the United States government and bears
responsibility, in whole or in part, for the acts complained of in this Complaint. The Centers for
Medicare and Medicaid Services is an entity within the HHS.

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¹ Though this complaint focuses on how the IFRs target women, the IFRs also may affect people who do not identify as women, including some gender non-confirming people and some transgender men.

1	19. Defendant R. Alexander Acosta is Secretary of the U.S. Department of Labor and is				
2	sued in his official capacity. Secretary Acosta has responsibility for implementing and fulfilling				
3	the U.S. Department of Labor's duties under the Constitution, the ACA, and the APA.				
4	20. Defendant U.S. Department of Labor is an agency of the United States government				
5	and bears responsibility, in whole or in part, for the acts complained of in this Complaint. The				
6	Employee Benefits Security Administration is an entity within the U.S. Department of Labor.				
7	21. Defendant Steven Mnuchin is Secretary of the U.S. Department of the Treasury and is				
8	sued in his official capacity. Secretary Mnuchin has responsibility for implementing and				
9	fulfilling the U.S. Department of the Treasury's duties under the Constitution, the ACA, and the				
10	APA.				
11	22. Defendant U.S. Department of the Treasury is an agency of the United States				
12	government and bears responsibility, in whole or in part, for the acts complained of in this				
13	Complaint. The Internal Revenue Service (IRS) is an entity within the U.S. Department of the				
14	Treasury.				
15	STATUTORY BACKGROUND				
16	I. THE PATIENT PROTECTION AND AFFORDABLE CARE ACT				
	 I. THE PATIENT PROTECTION AND AFFORDABLE CARE ACT 23. The ACA requires that certain group health insurance plans cover preventive care and 				
17					
17 18	23. The ACA requires that certain group health insurance plans cover preventive care and				
17 18 19	23. The ACA requires that certain group health insurance plans cover preventive care and screenings without imposing costs on the employee and his/her covered dependents. 42 U.S.C.				
17 18 19 20	 23. The ACA requires that certain group health insurance plans cover preventive care and screenings without imposing costs on the employee and his/her covered dependents. 42 U.S.C. § 300gg-13(a). Importantly, this includes women's "preventive care and screenings as 				
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 16 17 18 19 20 21 22 23 24 25 26 27 28 	23. The ACA requires that certain group health insurance plans cover preventive care and screenings without imposing costs on the employee and his/her covered dependents. 42 U.S.C. § 300gg-13(a). Importantly, this includes women's "preventive care and screenings as provided for in comprehensive guidelines supported by the Health Resources and Services Administration." 42 U.S.C. § 300gg-13(a)(4). During the 2009 debates leading up to the ACA's passage, the United States Congress specifically proposed an amendment to require health plans to cover comprehensive women's preventive care and screenings. This amendment, which came to be called the Women's Health Amendment, relied on guidelines developed by the independent, nonpartisan Institute of Medicine (IOM) and adopted by HHS. It required coverage for "preventive care and screenings" for women to ensure essential protections for women's access to				

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- 1 24. The IOM assembled a diverse, expert committee to draft a report to determine what 2 should be included in cost-free "preventive care" coverage for women. The report underwent 3 rigorous, independent external review prior to its release.

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4 On or about July 19, 2011, the IOM issued its expert report which included a 25. 5 comprehensive set of eight evidence-based recommendations for strengthening preventive health 6 care services. Specifically, the IOM recommended that private health insurance plans be required 7 to cover all contraceptive benefits and services approved by the FDA without cost-sharing (also known as out-of-pocket costs such as deductibles and copays).

9 These IOM recommendations, developed after an exhaustive review of the medical 26. 10 and scientific evidence, were intended to fill important gaps in coverage. The recommendations 11 include coverage for an annual well-woman preventive care visit, specific services for pregnant 12 women and nursing mothers, counseling and screening for HIV and domestic violence, as well as 13 services for the early detection of reproductive cancers and sexually transmitted infections. 14 Significantly, the recommendations include coverage of the full range of all FDA-approved 15 contraceptive methods, sterilization procedures, and patient education and counseling for all 16 women with reproductive capacity. The IOM acknowledged the reality that cost can be a 17 daunting barrier for women when it comes to choosing and using the most effective contraceptive 18 method. For instance, certain highly-effective contraceptive methods, such as the intrauterine 19 device (IUD) and the implant, have high up-front costs, which act as a barrier to access despite 20 the fact that these contraceptives are long-acting and 99 percent effective. The IOM considers 21 these services essential so that "women can better avoid unwanted pregnancies and space their 22 pregnancies to promote optimal birth outcomes."

23

27. The IOM also recommended that "preventive care" include not only contraceptive 24 coverage such as access to all FDA-approved contraceptives but also counseling and education to 25 ensure that women received information on the best method for their individual set of 26 circumstances.

27 28. Following the IOM's recommendations relating to contraceptive coverage, HHS, the 28 U.S. Department of Labor, and the U.S. Department of the Treasury promulgated regulations

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requiring that group health insurance plans cover all FDA-approved contraceptive methods without cost to women and their covered dependents. 45 C.F.R. § 147.130(a)(1)(iv); 29 C.F.R. § 2590.715-2713(a)(1)(iv); 26 C.F.R. § 54.9815-2713(a)(1)(iv).

3

4 29. In implementing this statutory scheme, HHS made clear that these coverage
5 requirements were not applicable to group health plans sponsored by religious employers.
6 Further, HHS made available a religious accommodation to certain employers who seek to not
7 provide this coverage. Through this religious accommodation, the federal government ensured
8 that women had access to seamless contraceptive coverage as entitled under the ACA, while also
9 providing employers with a mechanism to opt-out of providing or paying for this coverage.

30. In order to effectuate this policy, the Health Resources and Services Administration
(HRSA) issued guidelines implementing the IOM's expert report's recommendations. These
guidelines guaranteed that women received a comprehensive set of preventive services without
having to pay a co-payment, co-insurance, or a deductible.

14 HRSA's comprehensive guidelines included a list of each type of preventive service, 31. 15 and the frequency with which that service should be offered. Under the guidelines, HHS 16 recognized that well-woman visits should be conducted annually for adult women to obtain the 17 recommended preventive services that are age- and development-appropriate, including pre-18 conception care and many services necessary for prenatal care. Although HSRA recognized that 19 the well-woman health screening should occur at least on an annual basis, HSRA also noted that 20 several visits may be needed to obtain all necessary recommended preventive services, depending 21 on a woman's health status, health needs, and other risk factors. HRSA's guidelines also 22 included annual counseling on sexually transmitted infections for all sexually active women, 23 annual counseling and screening for human immunodeficiency virus infection for all sexually 24 active women, all FDA-approved contraceptive methods, sterilization procedures, and patient 25 education and counseling for all women with reproductive capacity. These guidelines ensured 26 that women could access a comprehensive set of preventive services without having to pay a co-27 payment, co-insurance, or a deductible to ensure there was no cost barrier.

1 32. In March 2016, HRSA awarded a five-year cooperative agreement to the American 2 Congress of Obstetricians and Gynecologists (ACOG) to update the women's preventive services 3 guidelines originally recommended by the IOM and work to develop additional recommendations 4 to enhance women's overall health. In that same month, ACOG launched the "Women's Preventive Services Initiative" (WPSI), which was a multidisciplinary steering committee headed 5 6 by ACOG to update the eight IOM recommendations from 2011. Through this initiative, ACOG 7 partnered with the American Academy of Family Physicians, the American College of 8 Physicians, and the National Association of Nurse Practitioners in Women's Health to achieve 9 this goal. The WPSI issued draft recommendations for public comments in September of 2016 10 and the updated "Women's Preventive Service Guidelines" were finalized and implemented by 11 HRSA on December 20, 2016 to take effect December 20, 2017. Importantly, these expert, 12 evidence-based medical recommendations continued to include coverage of all FDA-approved 13 contraceptive methods and counseling for women with reproductive capacity, thereby 14 underscoring their importance to women.

15 33. The ACA forbids the Secretary of HHS from promulgating regulations that block
16 access to health care, and prohibits discrimination on the basis of sex. 42 U.S.C. §§ 18114, §
17 18116.

18

II. ADMINISTRATIVE PROCEDURE ACT

19 Pursuant to the APA, 5 U.S.C. § 551 et seq., a reviewing court shall "(1) compel 34. 20 agency action unlawfully withheld or unreasonably delayed; and (2) hold unlawful and set aside 21 agency action, findings, and conclusions found to be ... arbitrary, capricious, an abuse of 22 discretion, otherwise not in accordance with law; [or] without observance of procedure required 23 by law." 5 U.S.C. § 706. The APA defines "agency action" to include "the whole or a part of an 24 agency rule, *order*, license, sanction, relief, or the equivalent or denial thereof, or failure to act." 25 Id. § 551(13) (emphasis added); see id. § 551(6) (defining "order" to mean "the whole or a part of 26 a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency 27 in a matter other than rule making but including licensing").

1 2

FACTUAL AND PROCEDURAL BACKGROUND

I. CONTRACEPTIVE COVERAGE

Contraceptives are among the most widely used medical products in the United 35. 3 States, with 99 percent of sexually active women having used at least one type of contraception in 4 her lifetime. By the age of 40, American women have used an average of three or four different 5 methods (some of which are available only by prescription), after considering their relative 6 effectiveness, side effects, drug interactions and hormones, the frequency of sexual conduct, 7 perceived risk of sexually transmitted infections, the desire for control, cost, and a host of other 8 9 factors. Of course, women face the possibility of having children for many years of their life and therefore if a woman only wants two children, for instance, she would need to spend roughly 10 three decades on birth control to avoid unintended pregnancies. Due to the positive impact of 11 contraception for women and society, the Centers for Disease Control and Prevention concluded 12 that family planning, including access to modern contraception, was one of the ten greatest 13 achievements of the 20th Century. Further, one-third of the wage gains women have made since 14 the 1960s are the result of access to oral contraceptives. Access to birth control has helped 15 narrow the wage gap between women and men. The decrease in the wage gap among 25 to 49-16 year-olds between men's and women's annual incomes would have been 10 percent smaller in the 17 1980s and 30 percent smaller in the 1990s in the absence of widespread legal birth control access 18 19 for women.

36. Unintended pregnancy has negative health, fiscal, and societal impacts across the 20 United States. In 2001, an estimated 49 percent of all pregnancies in the United States were 21 unintended, and 42 percent of those unintended pregnancies ended in abortion. More recent 22 studies estimate that the national rate of unintended pregnancies is 45 per 1,000 women aged 15 23 to 44. Unintended pregnancies are associated with increases in maternal and child morbidity, 24 including increased odds of preterm birth term, low birth weight, and the potentially life-long 25 negative health effects of premature birth. Significantly, the risk of unintended pregnancy is 26 greatest for the most vulnerable women: young, low-income, minority women, without high 27 school or college education. 28

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37. There is considerable evidence that the use of contraception has resulted in lower
unintended pregnancy and abortion rates in the United States. The Guttmacher Institute has
found that the two-thirds of women who are at risk for unintended pregnancy and use
contraception consistently account for only 5 percent of unintended pregnancies. Another study
showed that, from the early 1990s to early 2000s, increased rates of contraceptive use by
adolescents were associated with a marked decline in teen pregnancies, with contraception use
accounting for 86 percent of the decline.

8 38. With the decrease in unintended pregnancies and abortions, there is a corresponding 9 decrease in the risk of maternal mortality, adverse child outcomes, behavior problems in children, 10 and negative psychological outcomes associated with unintended pregnancies for both mothers 11 and children. Significantly, access to contraceptive coverage helps women to delay childbearing 12 and pursue additional education, spend additional time in their careers, and have increased 13 earning power over the long-term. Contraceptive use also allows for spacing between 14 pregnancies, which is important because there is an increased risk of adverse health outcomes for 15 pregnancies that are too closely spaced, and is especially critical for the health of women with 16 certain medical conditions. There are additional benefits of contraceptive use for treating medical 17 conditions, including menstrual disorders and pelvic pain, and long-term use of oral 18 contraceptives has been shown to reduce women's risk of endometrial cancer, pelvic 19 inflammatory disease, and some breast diseases.

39. Contraceptive use achieves significant cost savings as well. In 2002, the direct
medical cost of unintended pregnancy in the United States was nearly \$5 billion, with the cost
savings due to contraceptive use estimated to be \$19.3 billion. Nationwide, in 2010, the
government expended an estimated \$21 billion to cover the medical costs for unplanned births,
miscarriages and abortions.

40. Contraceptives are much less costly than maternal deliveries for states, insurers,
employers, and patients, and consequently, they have been shown to result in net savings to
women. The ACA's requirement to cover contraception benefits and services has saved
American women \$1.4 billion since the law took effect in 2012. For instance, the share of

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1 women of reproductive age who had out-of-pocket spending on oral contraceptive pills fell 2 sharply after the ACA; spending on oral contraceptive pills plummeted from 20.9 percent in 2012 3 to 3.6 percent in 2014, corresponding to the timing of the ACA provision. To date, over 62.4 4 million women have benefited from this coverage, including 7.4 million in California, over 5 175,000 in Delaware, nearly 1.3 million in Maryland, 3.8 million in New York, and more than 1.6 6 million in Virginia. Although both men and women benefit from access to safe and reliable 7 contraceptive care, women disproportionately bear the cost of obtaining contraceptives. This is in 8 part because, of the FDA-approved methods of contraceptives, only two-male sterilization 9 surgery and male condoms—are available for use by men. The methods of contraception at issue 10 in this matter are only available for women. 11 41. The U.S. Office of the Assistant Secretary for Planning and Evaluation (ASPE) 12 estimated that, in 2011-13, approximately 6,324,503 women in California, 171,575 women in 13 Delaware, 1,225,095 women in Maryland, 3,582,133 women in New York, and 1,587,663 women 14 in Virginia, ages 15-64, had preventative services coverage with zero cost sharing. 15 42. These cost savings to women have a corresponding fiscal impact on public health, 16 and thus on the States, as well. The ACA's contraceptive-coverage requirement decreases the 17 number of unintended pregnancies, and thereby reduces the costs associated with those 18 pregnancies or termination of those pregnancies. Furthermore, unintended pregnancy is 19 associated with poor birth outcomes and maternal health issues, and thus, the contraceptive-20 coverage requirement also reduces the number of high-cost births and infants born in poor health. 21 CALIFORNIA 22 43. In California, 48 percent of all pregnancies were unintended in 2010. Of those 23 unplanned pregnancies that resulted in births, 64.3 percent were publicly funded, costing 24 California \$689.3 million on unintended pregnancies. 25 44. In 2014, the California Legislature passed the Contraceptive Equity Act of 2014 (SB 26 1053), which requires certain health plans to cover certain prescribed FDA-approved 27 contraceptives for women without cost-sharing. Twenty-seven other states have similar 28 contraceptive equity laws, aimed at making contraception cheaper and more accessible. 13 First Amended Complaint for Declaratory and Injunctive Relief (4:17-cv-05783-HSG)

1 In passing the Contraceptive Equity Act, the California Legislature concluded that 45. 2 providing contraception will result in overall savings in the health care industry due to reduced 3 office visits, reduced unintended pregnancies, and therefore, reduced prenatal care, abortions, and 4 labor and delivery costs. In fact, the California Health Benefits Review Program (CHBRP) 5 anticipated that there would be substantial cost savings, including \$213 million in savings to 6 private employers, \$86 million in savings to individuals, and \$7 million in savings to CalPERS. 7 CHBRP also anticipated a cost savings of \$56 million for Medi-Cal managed care. In addition to 8 these fiscal benefits, there is huge benefit to California's public health. CHBRP estimated that 9 access to and increased contraceptive use under this Act would result in 51,298 averted 10 unintended pregnancies and 20,006 fewer abortions.

46. California's Contraceptive Equity Act, however, only applies to state-regulated health
plans. It does not apply to self-funded health plans, through which 61 percent of covered workers
are insured. Self-funded health plans are governed by the Federal Employee Retirement Income
Security Act of 1974 (ERISA) and are regulated by the U.S. Department of Labor, Employee
Benefits Security Administration.

47. The California Health Care Foundation estimates that as of 2015, 6.6 million
Californians were covered by a self-funded employer health plan. Therefore, the IFRs could
affect over 6 million California women. These women will be left unprotected and the IFRs
threaten California's ability to guarantee health and welfare to its residents by a virtual denial of
free access to contraceptive coverage to women.

21 48. In California, if women do not receive cost-free contraceptive coverage from their 22 employer, California risks having to absorb the financial and administrative burden of ensuring 23 access to contraceptive coverage. Due to the IFRs, California women will be forced to utilize the 24 state's Family Planning, Access, Care, and Treatment (Family PACT) program provided they 25 meet certain eligibility requirements. Family PACT is administered by the Office of Family 26 Planning (OFP), an entity within the California Department of Health Care Services, which is 27 charged by the California Legislature to make available to citizens of the State who are of 28 childbearing age comprehensive medical knowledge, assistance, and services relating to the 14

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planning of families. Family planning allows women to decide for themselves the number,
 timing, and spacing of their children.

49. Family PACT is available to eligible low-income (under 200 percent of federal
poverty level) men and women who are residents of California. Currently, the program serves 1.1
million eligible men and women of childbearing age through a network of 2,200 public and
private providers. Services include comprehensive education, assistance, and services relating to
family planning. These Californians have no other source of health care coverage for family
planning services (or they meet the criteria specified for eligibility) and they have a medical
necessity for family planning services.

50. The 2,200 clinic and private practice clinician provider entities enroll women in
Family PACT across the state. Family PACT clinician providers include private physicians in
non-profit community-based clinics, obstetricians and gynecologists, general practice physicians,
family practice, internal medicine, and pediatrics. Medi-Cal licensed pharmacies and laboratories
also participate by referrals from enrolled Family PACT clinicians.

51. Planned Parenthood is one example of a Family PACT provider that enrolls women
into the program. Planned Parenthood currently serves approximately 850,000 patients a year
through 115 health centers. California reimburses Planned Parenthood for family planning
services provided. For every dollar Planned Parenthood spends on family planning services, the
federal government contributes 77.49 cents while the state spends 22.51 cents.

52. Because health facilities, including but not limited to Planned Parenthood, will likely
see a spike in patients seeking contraceptive coverage, California will be fiscally impacted
through increased enrollment in Family PACT.

DELAWARE

23

53. Delaware had the highest unintended pregnancy rate in the country in 2010, at a rate
of 62 such pregnancies per 1,000 women aged 15-44. These unintended pregnancies cost the
State and the federal government \$94.2 million. Limiting or removing access to contraception as
contemplated by the IFRs will result in an increase in the rate of unintended pregnancies in the
State of Delaware, which adds a fiscal and administrative burden on the State in the form of

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increased enrollment in state-funded or sponsored family planning programs. In Delaware, 71
 percent of unintended pregnancies are paid for by the State.

3 54. In 2000, the Delaware General Assembly passed legislation, Senate Bill 87 (the 4 "Delaware Contraceptive Equity Act"), requiring all group and blanket health insurance policies 5 delivered or issued for delivery in the State, and which provided coverage for outpatient 6 prescription drugs, to provide coverage for all FDA-approved prescription contraceptives and 7 other outpatient services related to the use of such drugs and devices. In passing the legislation, 8 the Delaware General Assembly sought to provide equity in health care coverage by providing 9 women with insurance coverage for contraceptive-related services and costs not previously 10 covered.

55. Unlike other states' contraceptive equity legislation, the Delaware Contraceptive
Equity Act does not prohibit cost sharing altogether. Rather, cost sharing is permissible if similar
cost sharing provisions are imposed on other non-contraceptive related healthcare coverage. The
result of enforcing the IFRs is the removal in Delaware of the guaranteed free access to
contraceptive coverage for women provided for under the ACA.

16 56. The Delaware Contraceptive Equity Act only applies to state-regulated health plans.
17 It does not apply to self-funded health plans, through which over thirty percent of Delawareans
18 are insured. Self-funded health plans are governed by ERISA and are regulated by the U.S.
19 Department of Labor, Employee Benefits Security Administration.

57. In Delaware, if women do not have guaranteed free access to contraceptive coverage
from their employers as a result of the IFRs, the financial and administrative burden of providing
access to such services may fall back on the State through the increased enrollment in Medicaid
or State-funded programs aimed at providing contraceptives to women who are otherwise unable
to access or afford such coverage elsewhere.

58. Under Title X of the Public Health Services Act, the Division of Public Health (DPH)
within the Delaware Department of Health and Social Services offers a wide range of
reproductive health services and supplies to women in the State of Delaware. Family planning

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services provided by DPH include family planning counseling, birth control supplies, counseling,
 education, and referral services, and testing for sexually transmitted diseases.

59. DPH services are available to eligible low-income (under 250 percent of the federal
poverty level) Delawareans. Fees for these services and supplies are based on income, and for
Delawareans with income at or below 100 percent of the federal poverty level these services are
provided at no charge. In 2016, DPH provided services under the Title X program to 18,824
eligible Delawareans.

8 60. Planned Parenthood of Delaware (PPDE) is a non-profit 501(c)(3) organization that
9 works to provide reproductive health care services across the State of Delaware. PPDE currently
10 serves approximately 8,000 patients each year in three health centers and at mobile sites. PPDE
11 primarily serves low-income patients with limited access to health care services, and in fiscal year
12 2017, PPDE provided contraception to nearly 5,600 patients.

13 61. Delaware reimburses PPDE for family planning services it provides, either through
14 the Medicaid program or Title X. For every dollar PPDE spends on family planning services, the
15 federal government contributes 90 cents and the state spends 10 cents.

62. Because DPH and other publicly-funded service providers like PPDE will likely see a
spike in the number of Delawareans seeking contraceptive coverage as a result of the IFRs,
Delaware will be fiscally impacted through increased enrollment in its family planning programs.

19 Delaware will also be fiscally impacted by any increase in unintended pregnancies as a result of

20 the IFRs, the majority of which are paid for by the State.

21

MARYLAND

63. Maryland has the fourth highest unintended pregnancy rate in the country. In 2010,
71,000 or 58 percent of all pregnancies were unintended. Of those unplanned pregnancies that
resulted in births, 58.2 percent were publicly funded, costing Maryland \$180.9 million.

64. In 1998, the Maryland Legislature mandated contraceptive coverage for certain Stateregulated plans. In 2016, it built upon this earlier law in enacting the Maryland Contraceptive
Equity Act. The Maryland Contraceptive Equity Act, which goes into effect January 2018,

28 extends the contraceptive coverage requirements under the ACA by expanding the number of

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1 contraception options available without co-payment, requiring coverage of over-the-counter 2 contraceptive medications, providing for coverage of up to 6-months dispensing of birth control, 3 and expanding vasectomy coverage without cost-sharing and deductible requirements. With the 4 contraceptive mandate in 1998 and the Maryland Contraceptive Equity Act in 2016, the State has 5 demonstrated its long-standing commitment to ensuring access to contraceptive coverage.

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65. Maryland's contraceptive coverage law applies only to State-regulated health plans. It does not apply to self-insured commercial health plans, through which 50 percent of covered Marylanders are insured. The Maryland Insurance Administration estimates that as of 2016, 1.46 million Marylanders were covered by a self-insured commercial health plan.

10 66. Maryland funds three statewide programs that provide access to contraception. Due 11 to the IFRs, Maryland women who lose contraceptive coverage may be forced to rely on these 12 statewide programs, creating an administrative and financial burden on the State.

13 67. The Maryland Title X Program supported 71,823 individuals across Maryland in 2016. The program provides family planning related services on a sliding fee scale for 14 15 participants with incomes up to 250 percent of federal poverty level. The program covers the 16 uninsured and underinsured who need wrap-around services. Through these services, Maryland 17 assisted women in preventing 15,000 unintended pregnancies in 2014. As a result of the IFRs, 18 more women who are insured will seek wrap-around family planning services from the Title X 19 Program. The Program has a finite budget of \$9.9 million, which includes \$6 million in State 20 funds and \$3.9 million in federal funds. Maryland will be unable to meet the additional demand 21 for services without a significant increase in funding, and a failure to fund will lead to an increase 22 in unintended pregnancies. Both scenarios create a negative fiscal impact on Maryland.

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The Medicaid Family Planning Waiver Program provides contraceptive coverage to 68. 24 women up to 200 percent of the federal poverty level. In 2016, the average monthly enrollment 25 was 12,852 individuals. Program expenditures were \$3.2 million in fiscal 2016, with a split of 10 26 percent/90 percent in State and federal funding, respectively. This program provides coverage for 27 the uninsured as well as wrap-around coverage for the underinsured. With the IFRs, more women

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with insurance will likely seek coverage for contraceptives under the Medicaid Family Planning
 Waiver Program. Maryland will be fiscally impacted through increased enrollment.

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3 69. Medicaid and the Maryland Children's Health Program (MCHP) cover family 4 planning services. Maryland covers individuals up to 138 percent of the federal poverty level in 5 Medicaid and 300 percent federal poverty level in MCHP. As a result of the IFRs, more women 6 in low income jobs may seek Medicaid coverage for themselves or MCHP coverage for their 7 children as a result of the loss of contraception coverage in their employers' plans. Thus, 8 financial burden of coverage would shift to the State. Most adults and children receive their 9 coverage through the managed care program called HealthChoice. In calendar year 2015, 10 HealthChoice expenditures for family planning were \$33.7 million in total funds. Family 11 planning services are generally covered under a 10 percent/90 percent split of State and federal 12 funds.

13 70. Women who lose coverage may also simply seek services at Planned Parenthood and
14 other community-based providers. These providers generally offer services on a sliding fee scale
15 for low-income patients. Under a sliding fee scale, the provider pays for a portion of the services.
16 These providers may not have the financial capacity to absorb the cost of care for an influx of
17 patients who have lost contraceptive coverage.

18 71. Finally, women may simply choose to forgo seeking contraceptive and related
19 services if they do not have the means to pay for it, thereby risking unintended pregnancy and
20 other poor health outcomes related to reproductive care. Because the State pays for delivery
21 services for certain low-income women who are uninsured, the State bears a financial risk when
22 women lose contraceptive coverage. In 2010, the State paid for 19,000 unintended pregnancies
23 that resulted in birth. The State is also obligated to pay for newborn care, which can be expensive
24 if there are complications, when those newborns are enrolled in MCHP.

25

NEW YORK

26 72. New York has one of the highest rates of unintended pregnancy in the nation. In
27 2010, the rate of unintended pregnancies was 61 per 1,000 women. Fifty-five percent of all
28 pregnancies in New York State were unintended in 2010.

73. The risk of unintended pregnancy is greatest for the most vulnerable women in New
York: young, low-income, minority women, without high school or college education. In New
York in 2010, the percent of births that resulted from an unintended pregnancy was twice as high
among African-American women, and about 1.5 times higher among Hispanic women, compared
to Caucasian women. Young women with some college education had half as many unintended
pregnancies as high school graduates and one third that of non-graduates. Unmarried young
women with no high school diploma had the highest unintended pregnancy rate.

8 74. In 2010, 59,000, or approximately 70 percent, of unplanned births in New York were
9 publicly funded. In 2010, the federal and New York State governments together spent \$1.5
10 billion on births, abortions, and miscarriages resulting from unintended pregnancies; of this,
11 \$937.7 million was paid by the federal government, and \$601.1 million was paid by the New
12 York. In that same year, the total public costs for unintended pregnancies in New York was \$380
13 per woman aged 15–44.

14 New York has protected women's access to contraceptive coverage both through 75. 15 legislation and law enforcement. In 2003, New York enacted the Women's Health and Wellness 16 Act (WHWA), which requires plans governed by New York State law ("fully insured plans" or 17 "state regulated plans") to cover contraceptives for female members. N.Y. Pub. Health L. § 602 18 (2003). Stating that "access to contraceptive services is essential to women's health and 19 equality," the New York State Assembly cited the extensive evidence of contraception use's 20 efficacy, and the consequent improvements in public health and the wellbeing of women and their 21 families. The Assembly noted that "all New Yorkers, regardless of economic status, should have 22 timely access to contraception and the information they need in order to protect their health, plan 23 their families and their future."

After the ACA's preventive requirements became effective and plans were required
to provide contraceptives with no cost sharing, in 2015 the New York Attorney General
investigated allegations that health plans were not adhering to these requirements, with the result
that plans corrected any failures, and refunded those members who had paid in error.

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77. In January 2017, the New York State Department of Financial Services issued Regulation 62, requiring that state regulated plans not impose cost sharing for contraceptives on plan members. New York is one of only eight states that require no cost sharing.

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78. New York's WHWA and Regulation 62 do not apply to self-funded health insurance plans. Those plans are governed by ERISA and are regulated by the U.S. Department of Labor, Employee Benefits Security Administration, and have over the years increasingly covered a growing percentage of New York members.

8 79. As a result of the IFRs, New York employers will qualify for expanded exemptions
9 and not need to make any accommodation for women to access health plan coverage for
10 contraceptives. While some of these women may be able to pay for their contraceptive care,
11 many others will likely seek state-funded programs to provide free or low-cost contraceptives.
12 These costs will be borne by New York State.

80. A variety of New York State programs help to provide family planning services for
hundreds of thousands of women in New York. For example, publicly supported family planning
centers in New York in 2014 served 390,350 female contraceptive clients, and helped avert
94,500 unintended pregnancies the same year, which would have resulted in 45,900 unplanned
births and 34,100 abortions. In 2010, publicly funded family planning services in New York
helped save the federal and state governments approximately \$830 million.

19 81. New York State's Family Benefit program covers women up to 223 percent of the
20 federal poverty line. In 2016, over 300,000 New York women and men received services through
21 the New York Department of Health's family planning programs. Women in low-income jobs
22 whose employers choose exemption from contraceptive coverage may qualify for this program,
23 thereby shifting the costs of contraceptives for these women to New York State.

82. New York State's Children's Health Insurance Plan (CHIP) provides coverage for the
children of women up to 400 percent of the federal poverty line. In 2016, there were
approximately 684,625 children up to 19 years old enrolled in New York's CHIP program, and
the state spent approximately \$156 million on the program. Women whose employers avail
themselves of this broad exemption may turn to the CHIP program for contraceptive coverage for

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their preteen and teenage children; a demographic particularly at risk for unintended pregnancy.
 These costs would be borne by New York State.

- 83. In addition, women whose health plans no longer cover contraceptive care may turn
 to providers like Planned Parenthood. But such providers, and Planned Parenthood in particular,
 may be unable to satisfy the demand for contraceptive services, because Planned Parenthood
 clinics are increasingly at risk of exclusion from federal funding programs including Medicaid,
 with the result that some clinics may be forced to close.
- 8 84. Finally, some women without available contraceptive coverage, will forgo
 9 contraceptive care altogether or consistent contraceptive care, with the consequence of increases
 10 in unintended pregnancies together with all of the attendant costs, including health care risks to
 11 women and children many of which will be borne by New York State.
 - <u>VIRGINIA</u>

13 85. In Virginia, prior to the ACA, 54 percent of all pregnancies were unintended in 2010.
14 Of those unplanned pregnancies that resulted in births, 45.4 percent were publicly funded, costing
15 Virginia \$194.6 million on unintended pregnancies.

16 86. In contrast to the other States, Virginia does not have a state law Contraceptive
17 Equity Act. Accordingly, there is no general state-based legal framework to ensure that
18 employers and insurers provide contraception coverage for women under self-funded health plans
19 *or* state-regulated health plans. The IFRs will therefore have an even broader impact on the
20 Commonwealth of Virginia directly, as well as on its population because they could affect every
21 women who obtains health care through her employer.

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87. Of the almost 2 million women in Virginia between the ages of 15 and 49, 66 percent obtain their health insurance coverage from employer-sponsored plans.

24 88. CoverVirginia's Plan First is Virginia's limited benefit family planning program that
25 covers all birth control methods provided by a clinician and some birth control methods obtained
26 with a prescription, such as contraceptive rings, patches, birth control pills, and diaphragms. 12
27 VAC 30-30-20. Plan First also covers family planning and education.

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89. Individuals are eligible for Plan First if they are not eligible for full benefits under
 Medicaid or the Family Access to Medical Insurance Security (FAMIS) Plan, are legally residing
 in Virginia, and meet certain income limits. Even those with private insurance may nevertheless
 be eligible for Plan First.

90. Plan First eligibility is set by income limits that are a function of family size and
monthly income level. In general, families with income below 200 percent of the applicable
federal poverty guideline are eligible. As of October 1, 2017, 115,895 individuals were enrolled
in Plan First. The total spent on Plan First in State Fiscal Year 2017 (July 1, 2016 through June
30, 2017) was \$7,142,414.

91. Plan First providers include 1,185 physicians, 1,230 pharmacies, 67 hospitals, and
hundreds of other providers, such as clinics. Two of the top five providers of Plan First services
are the University of Virginia Hospital and the Medical College of Virginia Hospital, both part of
state-supported health systems.

92. Because eligible women denied no-cost coverage from employers and/or insurers
exploiting the "moral" or "religious" exceptions of the IFRs will likely seek access to state funded
alternatives, Virginia will be fiscally impacted through increased enrollment in Plan First.

93. Additionally, state providers, such as the Medical College of Virginia Hospital and
the University of Virginia Hospital, do not recover 100 percent of the cost of the care they
provide under Plan First. Accordingly, an increase in women seeking services from these two
hospital systems under Plan First will have an additional impact on Virginia's financial
obligations through the institutions themselves.

94. In 2016, the Virginia Department of Health (VDH) served 47,869 family planning
clients, of whom 30.2 percent were insured and 69.8 percent were uninsured. According to VDH,
the state has approximately 19,000 teen pregnancies, 9,500 unintended pregnancies, and 20,000
abortions annually.

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II. PRIOR REGULATORY FRAMEWORK PROVIDING ACA CONTRACEPTIVE-COVERAGE REQUIREMENT AND PROTECTING RELIGIOUS EXERCISE

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95. In implementing the ACA, HHS contemplated laws protecting religious exercise. To that end, although the ACA requires coverage of women's preventive health care, the regulations provided adequate protections for certain employers that objected to providing their female employees with contraceptive coverage based on their religious beliefs. The two exceptions originally implemented were for: (1) religious organizations and (2) nonprofits with religious objections. The regulations permitted religious employers such as churches to seek an "exemption" from the contraceptive-coverage requirement. *See* 45 C.F.R. § 147.131(a) (HHS regulation). Non-profits with religious objections were also allowed to opt out of the contraceptive-coverage requirement via an "accommodation," by which the nonprofit employer

12 96. Following three rounds of notice-and-comment rulemaking to develop and refine the
 accommodation regulations, which generated hundreds of thousands of public comments, the
 federal government enacted the "accommodation" process, which furthers the government's
 compelling interest in ensuring that women covered by every type of health plan receive full and
 equal health coverage, including contraceptive coverage, while safeguarding the religious rights
 of specific employers.

certifies its objection and the insurer is then responsible for separate contraceptive coverage.

This process resulted in a relatively seamless mechanism for women, whose 97. 19 employers obtained the religious accommodation to continue to receive their ACA contraceptive 20 coverage and helped the government ensure that no woman went without birth control as a result. 21 See 80 FR 41318 (July 14, 2015) (prior regulation); 45 C.F.R. § 147.131(c)-(d) (prior regulation). 22 This scheme ensured that those employees would not be adversely affected by their employees' 23 decision to opt out. 45 C.F.R. § 147.131(c)-(d). At the same time, it ensured that certain 24 employers who had religious objections could avoid providing for or paying for this coverage. 25 Thus, this scheme struck a good balance for both the employer and the employee. 26

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98. The religious accommodation was later expanded to include certain closely-held forprofit organizations with religious objections to providing contraceptive care, consistent with the

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1	Supreme Court's decision in Burwell v. Hobby Lobby Stores, Inc., 134 S. Ct. 2751 (2014); 80 FR
2	41318 (July 14, 2015); 45 C.F.R. § 147.131(b)(4). Further, in response to the Supreme Court's
3	decision, an organization could use an alternative process of providing notice of its religious
4	objections to providing for contraceptive coverage. Instead of filing a form with HHS or sending
5	a copy of the executed form to its health insurance provider or third party administrator, the non-
6	profit organization could simply notify HHS in writing of its objection to covering contraceptive
7	coverage. Wheaton College v. Burwell, 134 S. Ct. 2806 (2014); 80 FR 41318.
8 9	III. NEW REGULATORY FRAMEWORK ILLEGALLY EXPANDS THE ABILITY OF Employers to Opt-Out of Providing Cost-Free Contraceptive Coverage under the ACA
10	99. Without any notice, opportunity to comment, or evidence-based expert guidance, on
11	October 6, 2017, Defendants promulgated sweeping new IFRs impeding women's access to cost-
12	free contraceptive coverage as required by the ACA.
13	100. Prior to promulgating the IFRs, Defendants failed to meet or convene publically any
14	women's, medical, or public health organizations that emphasize access to health care. For
15	example, Defendants did not meet with the American Academy of Pediatrics, the American
16	Association of Family Physicians, the American College of Physicians, the National Association
17	of Nurse Practitioners in Women's Health, the National Partnership for Women and Families, or
18	the Planned Parenthood Federation of America, among others. Defendants only met with
19	organizations like the Heritage Foundation, Church Alliance, and the Ethics & Religious Liberty
20	Commission of the Southern Baptist Convention.
21	101. The new IFRs vastly expand the scope of entities that may be exempt from the
22	contraceptive-coverage requirement. They cast a wide net beyond religious organizations to any
23	employer or individual or insurer, regardless of corporate structure or religious affiliation. This
24	eviscerates the federally-backed religious accommodation, which balances the interest of
25	employers wishing to opt-out of providing contraceptive coverage for employees while also
26	ensuring seamless access to care for women. Further, this exemption has been extended to not
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28	25
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only a religious objection, but also to a new *moral* objection to the contraceptive-coverage
 requirements.

3 102. The IFRs, thus, expand the *Hobby Lobby* decision to nearly any business, non-profit
4 or for-profit, with a moral objection against providing women access to contraceptive coverage,
5 further frustrating the scheme and purpose of the ACA.

6 103. Additionally, under the new IFRs, employers seeking to be exempt from providing 7 contraceptive coverage do not need to certify their objection to the coverage requirement. Rather, 8 the employer can simply inform their employees they will no longer cover contraception benefits 9 and counseling as part of their employer health care coverage. This is a significant change. By 10 contrast, the prior federal regulations provided a process for women to be notified of their 11 employers' decision to opt out and to maintain receive contraceptive coverage as a religious 12 "accommodation" ensuring that employers who religiously objected to providing this coverage 13 did not have to facilitate the provision of contraceptives. The federal government thereby ensured 14 that there was a balance between the compelling interest that all women have access to their 15 federally entitled benefit under the ACA, while also creating a religious accommodation for those 16 employers that sought not to provide this coverage. The new IFRs eliminate the requirement of 17 accommodation such that women whose employers opt for an exemption will not longer continue 18 to receive this federally entitled coverage.

19 104. Further, these new IFRs create an entirely new "moral exemption" standard, which 20 was not previously contemplated by the federal government, or given definitions or boundaries by 21 the IFRs. Employers can simply make use of the new moral exemption, without informing their 22 employees or the federal government. Thus, a whole new universe of employers can avail 23 themselves of this moral exemption, which is left undefined, and which does not even require an 24 accommodation process, and thereby vastly expands the number of women who will lose access 25 to contraceptive care. Without the federal back stop or guidance over a federal entitlement, these 26 women will simply be left without contraceptive coverage and with nowhere to go. The States 27 will be forced to fill this gap.

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1 105. In short, under the new IFRs, exempted entities do not need to certify any objection to 2 the contraceptive-coverage requirement to the federal government, which all but ensure that 3 women across the country will go without birth control access as the ACA intended. 4 106. These IFRs could impact 6.6 million Californians who receive their health care 5 through a self-insured employer health plan, and therefore do not receive the benefit of 6 California's Contraceptive Equity Act. 7 107. There are at least 25 California employers, with 54,879 employees who will likely 8 seek an exemption or accommodation. Thus, an unknown but substantial number of California 9 women will be affected by these IFRs, and under these new IFRs, California anticipates that this 10 number will vastly expand, eviscerating the ability of these women to access cost-free 11 contraceptive coverage through their health plan. Consequently, they will turn to publicly funded 12 clinics or California's wrap-around family program, Family PACT, to obtain the contraceptive 13 coverage that is no longer being provided by employers or insurers, or being tracked by the 14 federal government to ensure women maintain access as envisioned by the ACA. 15 108. There are at least 5 Maryland employers, with 6,460 employees who will likely seek 16 an exemption or accommodation. Thus, an unknown but substantial number of Maryland women 17 will be affected by these IFRs, and under these new IFRs, Maryland anticipates that this number 18 will vastly expand, eviscerating the ability of these women to access cost-free contraceptive 19 coverage through their health plan. Consequently, they will turn to publicly funded clinics or 20 Maryland's Title X Program or Medicaid Family Planning Program, to obtain the contraceptive 21 services no longer being provided by employers or insurers, or being tracked by the federal 22 government to ensure women maintain access as envisioned by the ACA. 23 109. Based on publicly available data, the IFRs could impact approximately 1.16 million 24 women in New York State who are currently covered by self-funded employer plans and thus 25 subject to the vast reach of the new IFRs. 26 110. There are also several employers in the State of New York that challenged the ACA's 27 contraception coverage mandate and accommodation provisions in court. Hobby Lobby Stores, 28 Inc., the lead plaintiff in the Supreme Court case challenging the contraception mandate, *Burwell* 27

v. *Hobby Lobby*, 573 U.S. (2014), is a for-profit national arts and crafts store chain, which
 has twelve store locations and approximately 600 employees in New York.

111. Two academic institutions located in New York also brought legal action against the
accommodation provisions: The Christian and Missionary Alliance, which challenged the
accommodation provisions, has an affiliate liberal arts college located in New York, Nyack
College, which has approximately 2,500 students and approximately 1,200 employees. Biola
University also brought a legal challenge to the contraception mandate, and its Master of Divinity
graduate program, the Charles Feinberg Center for Messianic Jewish Studies, is located in New
York. Biola University has approximately 1,000 students.

10 112. Upon information and belief, these entities would likely avail themselves of the IFRs'
11 broad exemption criteria and not provide their substantial number of employees and students with
12 insurance plans with contraceptive care coverage.

13 113. There are at least 10 Virginia employers, with 3,853 employees who will likely seek 14 an exemption or accommodation. Thus, an unknown but considerable number of Virginia women 15 will be affected by these IFRs, and under these new IFRs, Virginia anticipates that this number 16 will vastly expand, eviscerating the ability of these women to access cost-free contraceptive 17 coverage through their health plan. Consequently, they will turn to publicly funded clinics or 18 Virginia's wrap-around family program, Plan First, to obtain the contraceptive coverage that is no 19 longer being provided by employers or insurers, or being tracked by the federal government to 20 ensure women maintain access as envisioned by the ACA.

21 114. The IFRs themselves estimate that, based on 2010 census data, between 31,700 and 22 120,000 women will be harmed nationally. Based on the IFRs' own numbers, approximately 23 12.6 percent of such harm will be inflicted upon California (approximately 4,000 – 15,000 24 women); .3 percent of national harm will be inflicted upon Delaware (approximately 91 - 34025 women); 1.9 percent of national harm will be inflicted upon Maryland (approximately 600-2,200 26 women); 6.5 percent of national harm will be inflicted upon New York (approximately 2,000-27 7,700 women); and 2.6 percent of national harm will be inflicted upon Virginia (approximately 28 800-3,100 women).

115. By promulgating the IFRs, the States' concrete interest in ensuring access to contraceptive coverage is violated.

3 FIRST CAUSE OF ACTION 4 (Violation of APA; 5 U.S.C. § 553) 5 116. Paragraphs 1 through 115 are realleged and incorporated herein by reference. 6 117. The APA generally requires agencies to provide the public notice and an opportunity 7 to be heard before promulgating a regulation. An agency wishing to promulgate a regulation 8 must publish in the Federal Register a notice of proposed rulemaking that includes "(1) a 9 statement of the time, place, and nature of public rule making proceedings; (2) reference to the 10 legal authority under which the rule is proposed; and (3) either the terms or substance of the 11 proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b). After the 12 notice has issued, "the agency shall give interested persons an opportunity to participate in the rulemaking through submission of written data, views, or arguments with or without opportunity 13 14 for oral presentation." Id. § 553(c). 15 118. In narrow circumstances, the APA exempts agencies from this notice and comment 16 process where they can show "good cause" that the process would be either "impracticable, 17 unnecessary, or contrary to the public interest." Id. § 553(b)(B). The burden is on the agency to 18 demonstrate good cause, and courts have interpreted the exception narrowly. See, e.g., Lake 19 *Carriers' Ass'n v. EPA*, 652 F.3d 1, 6 (D.C. Cir. 2011).

20 119. Defendants have not and cannot demonstrate good cause for failing to give any notice
21 to the public or allowing for public comment prior to effectuating these new IFRs.

120. Notice and comment is particularly important in legally and factually complex
circumstances like those presented here. Notice and comment allows affected parties—including
states—to explain the practical effects of a rule before it is implemented, and ensures that the
agency proceeds in a fully informed manner, exploring alternative, less harmful approaches. In
the area of women's health care, it is particularly important to have an adequate notice and
comment given that women have been relying on this benefit since 2012.

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1	121. Because Defendants failed to follow section 553's notice and comment procedures,		
2	the regulations are invalid.		
3	SECOND CAUSE OF ACTION		
4	(Violation of APA; 5 U.S.C. § 706)		
5	122. Paragraphs 1 through 121 are realleged and incorporated herein by reference.		
6	123. The APA requires courts to "hold unlawful and set aside" agency action that is		
7	"(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;		
8	(B) contrary to constitutional right, power, privilege, or immunity; (C) in excess of statutory		
9	jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706 (2).		
10	124. By promulgating theses new IFRs, without proper factual or legal basis, Defendants		
11	have acted arbitrarily and capriciously, have abused their discretion, have acted otherwise not in		
12	accordance with law, have taken unconstitutional and unlawful action in violation of the APA,		
13	and have acted in excess of statutory jurisdiction and authority. Defendants' violation causes		
14	ongoing harm to the States and their residents.		
15	THIRD CAUSE OF ACTION		
16	(Violation of the Establishment Clause)		
17	125. Paragraphs 1 through 124 are realleged and incorporated herein by reference.		
18	126. The First Amendment provides that "Congress shall make no law respecting an		
19	establishment of religion, or prohibiting the free exercise thereof." U.S. Const., amend. I. "The		
20	clearest command of the Establishment Clause is that one religious denomination cannot be		
21	officially preferred over another." Larson v. Valente, 456 U.S. 228, 244 (1982); see also		
22	McCreary County, Kentucky v. ACLU, 545 U.S. 844, 875 (2005) ("the government may not favor		
23	one religion over another, or religion over irreligion").		
24	127. The new IFRs privilege religious beliefs over secular beliefs as a basis for obtaining		
25	exemptions under the ACA.		
26	128. In contrast, the prior regulations only allowed an exemption for churches and an		
27	accommodation for non-profits and closely-held for-profit companies with religious objections.		
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	30		
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1 This was narrowly tailored to accommodate religious beliefs and still provide essential women's 2 health care services. 3 129. By promulgating the new IFRs, Defendants have violated the Establishment Clause 4 because the IFRs do not have a secular legislative purpose, the primary effect advances religion, 5 especially in that they place an undue burden on third parties – the women who seek birth control, 6 and the IFRs foster excessive government entanglement with religion. 7 130. The IFRs also ignore the compelling interest of seamless access to cost-free birth 8 control. This crosses the line from acceptable accommodation to religious endorsement. Further, 9 the IFRs essentially coerce employees to participate in or support the religion of their employer. 10 131. Defendants' violation causes ongoing harm to the States and their residents. 11 FOURTH CAUSE OF ACTION 12 (Violation of the Equal Protection Clause) 13 132. Paragraphs 1 through 131 are realleged and incorporated herein by reference. 14 133. The Equal Protection Clause of the Fifth Amendment prohibits the federal 15 government from denying equal protection of the laws. 16 134. The new IFRs specifically target and harm women. The ACA contemplated 17 disparities in health care costs between women and men, and some of these disparities were 18 rectified by the cost-free preventive services provided to women. The expansive exemptions 19 created by the new IFRs undermine this action and adversely target and are discriminatory to 20 women. 21 135. The new IFRs, together with statements made by Defendants concerning their intent 22 and application, target individuals for discriminatory treatment based on their gender, without 23 lawful justification. 24 136. By promulgating the new IFRs, Defendants have violated the equal protection 25 guarantee of the Fifth Amendment of the U.S. Constitution. 26 137. Defendants' violation causes ongoing harm to the States and their residents. // 27 28 31 First Amended Complaint for Declaratory and Injunctive Relief (4:17-cv-05783-HSG)

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1	PRAYER FOR RELIEF		
2	WHEREFORE, the States respectfully request that this Court:		
3	1. Issue a declaratory judgment that the IFRs are void for failing to comply with the notice		
4	and comment requirements of the APA;		
5	2. Issue a declaratory judgment that the IFRs are arbitrary and capricious, not in		
6	accordance with law, and Defendants acted in excess of statutory authority in promulgating them;		
7	3. Issue a declaratory judgment that the IFRs violate the Establishment Clause;		
8	4. Issue a declaratory judgment that the IFRs violate the Equal Protection Clause;		
9	5. Issue a preliminary injunction prohibiting the implementation of the IFRs;		
10	6. Issue a mandatory injunction prohibiting the implementation of the IFRs;		
11	7. Award the States' costs, expenses, and reasonable attorneys' fees; and,		
12	8. Award such other relief as the Court deems just and proper.		
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