

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

COMMONWEALTH OF)
PENNSYLVANIA,)

Plaintiff,)

v.)

Civil Action No. 2:17-cv-04540 (WB)

DONALD J. TRUMP, in his official)
capacity as President of the United States;)

ERIC D. HARGAN, in his official)
capacity as Acting Secretary of Health and)

Human Services; UNITED STATES)
DEPARTMENT OF HEALTH AND)

HUMAN SERVICES; STEVEN T.)
MNUCHIN, in his official capacity as)

Secretary of the Treasury; UNITED)
STATES DEPARTMENT OF THE)

TREASURY; RENE ALEXANDER)
ACOSTA, in his official capacity as)

Secretary of Labor; and UNITED STATES)
DEPARTMENT OF LABOR,)

Defendants.)

**DEFENDANTS' MEMORANDUM IN OPPOSITION TO
PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION**

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INTRODUCTION

This case is about religious liberty and freedom of conscience. In 2010, as part of the Affordable Care Act (“ACA”), Congress enacted a law requiring employers to cover preventive care for women. The law does not mention contraceptive coverage. But the Health Resources and Services Administration (“HRSA”), a division of the Department of Health and Human Services (“HHS”), issued guidelines that required coverage of all FDA-approved contraceptives. At the same time, the government recognized that some employers hold sincere religious objections to contraception, especially certain contraceptives the employers considered to be abortifacients, but decided to exempt only a fraction of those employers—churches and their integrated auxiliaries—from the requirement. Other religious employers remained subject to the mandate and were left either to violate their sincerely held religious beliefs or to be subjected to significant fines.

Years of litigation in dozens of cases followed. In *Burwell v. Hobby Lobby Stores, Inc.*, the Supreme Court held that the “contraceptive mandate imposes a substantial burden on the exercise of religion” that was unlawful under the Religious Freedom Restoration Act (“RFRA”). 134 S. Ct. 2751, 2779 (2014). Rather than extend the church exemption, however, HHS tried “accommodating” religious objectors who did not qualify for that exemption. That decision triggered a new round of multi-district litigation that generated decisions in nine federal courts of appeals. Ultimately, the Supreme Court vacated those decisions and instructed the courts of appeals to give the parties time to try to resolve their differences. *See Zubik v. Burwell*, 136 S. Ct. 1557, 1560 (2016).

On October 6, 2017, in an effort to address serious religious and moral objections and finally bring the litigation to a close, the Departments of HHS, Labor, and the Treasury (“the Agencies”) issued interim final rules (“IFRs”) that keep the Mandate in place, but exempt religious and moral objectors from having to include contraceptive coverage in insurance plans offered to their employees. *See Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the ACA*, 82 Fed. Reg. 47,792 (Oct. 13, 2017) (the “Religious Exemption Rule”); *Moral Exemptions and Accommodations for Coverage of Certain Preventive*

Services Under the ACA, 82 Fed. Reg. 47,838 (Oct. 13, 2017) (the “Moral Exemption Rule”) (collectively also “the Rules”).

The Commonwealth of Pennsylvania seeks to reverse this considered decision, demanding that religious and secular minorities facilitate services to which they deeply object. Pennsylvania argues that the new rules violate the Equal Protection Clause, the Establishment Clause, and the Pregnancy Discrimination Act. And it contends that the rules cannot be squared with the ACA’s purpose “to give women greater access to necessary preventive care and more control over their own health care decisions.” Mem. in Supp. of Pl.’s Mot. for a Prelim. Inj. at 27, ECF No. 8-2 (“PI Mot.”). Those positions, if adopted, would apply equally to sweep away the longstanding exemption for churches and their integrated auxiliaries, exposing churches to the contraceptive mandate for the first time.

Nor does Pennsylvania grapple with the ACA’s existing exemption for grandfathered plans. Under this exemption, the employers of tens of millions of employees have no obligation to cover contraceptive services at all. Pennsylvania ignores the vast scope of this exemption, while overstating the limited effect of the exemptions here. At the same time, the Commonwealth dismisses the benefit of the new rules to employers whose religious obligations or duties of conscience would preclude them from offering coverage to which they object.

The federal government acted lawfully in making a policy choice grounded in respect for religious liberty. Both the ACA and RFRA provide firm statutory authority for the Rules. And it is settled law that the government may accommodate religion without running afoul of the Equal Protection Clause or the Establishment Clause. This case is not about “us[ing] the arm of the state to permit employers to impose their religious beliefs on their female employees” as Pennsylvania would have it. PI Mot. at 1. It is about protecting a narrow class of sincere religious and moral objectors from being forced to facilitate practices that conflict with their beliefs.

But this Court should not reach the merits at all, because the Commonwealth lacks standing. The Commonwealth seeks to enjoin Rules that do not apply to it and that do not affect any identified state residents. Pennsylvania claims to be injured because it has an interest in the

health and safety of its citizens, but it is black-letter law that a state cannot assert the rights of its citizens against the federal government. *See Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 592, 610 n.16 (1982). It also asserts that it will lose funds, but that claim is far too conjectural to support standing to sue. In short, the Commonwealth would prefer that the Agencies had made a different policy choice, but it lacks standing to pursue that policy disagreement in a federal court. In any event, the Commonwealth is in the wrong court; venue is not proper here.

The Commonwealth also meets none of the four parts of the test for preliminary injunctive relief. It has not shown that it faces irreparable harm—or indeed that it faces injury to its own legally cognizable interests at all. Notre Dame, the only entity that Pennsylvania has suggested would drop contraceptive coverage as a result of the Rules, PI Mot. at 46 n.29, has in fact announced that its employees and students will continue to receive contraceptive coverage with no co-payment, *see infra* n.12.

Nor is the Commonwealth likely to succeed on the merits of any of its various claims. It contends that the Agencies should have gone through notice and comment under the Administrative Procedure Act (“APA”) before issuing the Rules, but the Agencies were authorized by statute to issue IFRs—the previous administration did so on this issue three separate times—and in any event met the APA standard of “good cause” to do so. Moreover, any error in this regard would have been harmless, given the tens of thousands of comments that the Agencies have already received in their development of the exemption and accommodation at issue here. Far from being arbitrary and capricious, the Agencies reasonably exercised their rulemaking authority to guide HRSA’s discretion in prescribing required services and to craft a response to problems caused by the Mandate. Pennsylvania’s constitutional and statutory claims fare no better. The Rules do not discriminate on the basis of sex. Whether a woman’s employer or school is exempt from the requirement to offer her cost-free contraceptive services does not turn on her sex, but on whether that entity has a sincere religious or moral objection to the provision of coverage for such services (under a plan otherwise subject to the Mandate). (The ACA does not require coverage of male contraceptive services, and the Mandate has accordingly never included such services.) Nor

do the Rules establish religion, as they have a secular purpose and effect, and do not entangle the government with religion. Indeed, the Rules place religious and moral objections on similar footing.

Finally, the balance of harms and the public interest also weigh against the Court issuing an injunction. The broad position that Pennsylvania advocates would undermine religious exercise and freedom of conscience. The Agencies and the public would also be harmed because the Agencies would be unable to implement the Rules and because, more generally, the public interest in the Agencies being able to regulate as allowed by Congress would be damaged. On the other side of the ledger, although the Commonwealth claims that the Rules are “the ‘exceptions that swallow the rule,’” PI Mot. at 2, the Mandate remains in place for the vast majority of employers.

For these reasons, the Court should deny Pennsylvania’s motion for a preliminary injunction.¹

¹ If the Court rules in Pennsylvania’s favor, Defendants agree with the Commonwealth that an injunction should simply return the parties to the “position tha[t] they were [in] before the rules were issued,” PI Mot. at 17, which is that the Agencies were actively considering policy responses to the *Zubik* remand. In no event should the Court issue a mandatory injunction directing Defendants to *enforce* the contraceptive coverage requirement against objecting employers. Such an injunction could conflict with the Supreme Court’s *Zubik* remand order prohibiting the government from imposing fines and penalties on objecting employers, and would require a significantly higher showing than the Commonwealth could make. *Punnett v. Carter*, 621 F.2d 578, 582 (3d Cir. 1980) (“[W]hen the preliminary injunction is directed not merely at preserving the status quo but, as in this case, at providing mandatory relief, the burden on the moving party is particularly heavy.”). That type of injunction could also inappropriately generate dueling injunctions between this Court and the other district courts that have enjoined the government from enforcing the requirement against certain religious employers. *See, e.g., Newland v. Burwell*, 2015 WL 1757148 (D. Colo. Mar. 16, 2015); *Dordt Coll. v. Sebelius*, 22 F. Supp. 3d 934 (N.D. Iowa 2014); *Sharpe Holdings, Inc. v. U.S. Dep’t of Health & Human Servcs.*, 2013 WL 6858588 (E.D. Mo. Dec. 30, 2013). *See also Wenner v. Texas Lottery Comm’n*, 123 F.3d 321, 326 (5th Cir. 1997) (courts generally should not revisit whether injunctions issued by other courts were proper). An injunction directing the executive branch to enforce a specific law would also generate serious separation of powers concerns. *Cf. Taylor v. Freeman*, 34 F.3d 266, 269–70 (4th Cir. 1994). Finally, because Pennsylvania’s arguments regarding irreparable harm turn on Pennsylvania-specific circumstances, any injunction should not extend nationwide, and should be limited to the parties before this Court. *See Lewis v. Casey*, 518 U.S. 343, 357 (1996) (under Article III, “[t]he remedy” sought must “be limited to the inadequacy that produced the injury in fact that the plaintiff has established”).

BACKGROUND

In March 2010, Congress enacted the ACA. *See* Patient Protection and Affordable Care Act (“PPACA”), Pub. L. No. 111–148, 124 Stat. 119 (2010); Health Care and Education Reconciliation Act, Pub. L. No. 111–152, 124 Stat. 1029 (2010). Section 1001 of the PPACA added section 2713 to the Public Health Service Act (“PHSA”). *See* 42 U.S.C. § 300gg-13. That provision requires group health plans and health insurance issuers that offer group or individual health coverage to provide coverage for certain preventive services without cost-sharing. *Id.* The preventive services that must be covered include, “with respect to women, such additional preventive care and screenings not described in [§ 300gg-13(a)(1)] as provided for in comprehensive guidelines supported by HRSA.” *Id.* at § 300gg-13(a)(4). Congress did not require HRSA to include contraceptive services, and the ACA does not mention such services.

Congress exempted the employers of tens of millions of employees from the preventive services provision. Many are exempt because they sponsor “grandfathered plans,” which are those “in which an individual was enrolled on March 23, 2010” that also comply with certain additional regulations. *See* 26 C.F.R. § 54.9815–1251(a); 29 C.F.R. 2590.715–1251(a); 45 C.F.R. § 147.140(a). Congress required even grandfathered plans to cover certain services, including coverage of preexisting conditions and allowing dependents to remain on plans until age 26, but did not require coverage of preventive services.

The Agencies issued interim final regulations implementing the preventive services coverage provision in 2010. IFRs Relating to Coverage of Preventive Services Under the ACA, 75 Fed. Reg. 41,726, 41,728 (July 19, 2010). Because no HRSA guidelines relating to preventive care and screening for women existed when the ACA was passed, HHS commissioned the Institute of Medicine (“IOM”)² to recommend a set of comprehensive guidelines. *See* Inst. of Med., Clinical Preventive Services for Women: Closing the Gaps 2 (2011), ECF No. 9-4 (“IOM Rep.”);

² IOM was established in 1970 by the National Academy of Sciences and is funded by Congress. IOM Rep. at iv. It is now known as the National Academy of Medicine.

HRSA, Women's Preventive Services: Required Health Plan Coverage Guidelines ("Guidelines"), <http://www.hrsa.gov/womens-guidelines>.

On July 19, 2011, one year after the first IFRs were first issued, IOM published its report. The report recommended that HRSA's women's guidelines include, among other things, "the full range of [FDA]-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity." IOM Rep. at 10-12. FDA-approved contraceptive methods include diaphragms, oral contraceptive pills, emergency contraceptives (such as Plan B and Ella), and intrauterine devices when used to prevent pregnancy.³ See FDA, Birth Control: Medicines to Help You, <https://go.usa.gov/xnWVj>.

On August 1, 2011, HRSA adopted the IOM recommendations in guidelines published on its website. See Guidelines. Simultaneously, the Agencies issued a second set of IFRs specifying that any contraceptive coverage mandate may be subject to an exemption for certain religious employers. See Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the PPACA, 76 Fed. Reg. 46,621, 46,625 (Aug. 3, 2011). Under that exemption, an employer was required to meet each of the following criteria: "(1) The inculcation of religious values is the purpose of the organization; (2) The organization primarily employs persons who share the religious tenets of the organization; (3) The organization serves primarily persons who share the religious tenets of the organization; (4) The organization is a nonprofit organization as described in section 6033(a)(1) and section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended." *Id.* at 46,626. The statutes referenced in the fourth criterion refer to "churches, their integrated auxiliaries, and conventions or associations of churches," as

³ These methods are not covered by the Mandate or the exemptions if they are used to treat medical conditions, because they are not considered preventive care in that event. Section 2713(a)(4) of the PHSA does not apply to non-preventive care provided solely for treatment of an existing condition. See 82 Fed. Reg. at 47,805. Thus, "[w]here a drug approved by the FDA for contraceptive use is prescribed for both a contraceptive use and a non-contraceptive use, the Guidelines (to the extent they apply) would require its coverage." *Id.* n.48. And "[w]here a drug approved by the FDA for contraceptive use is prescribed exclusively for a non-contraceptive and non-preventive use to treat an existing condition, it would be outside the scope of the Guidelines." *Id.*

well as “the exclusively religious activities of any religious order,” that are exempt from taxation under 26 U.S.C. § 501(a). 26 U.S.C. § 6033 (a)(3)(A)(i), (iii); *see also id.* § 6033(a)(1). The Agencies requested comments on the amended interim final regulations and specifically on the definition of a “religious employer.” 76 Fed. Reg. at 46,623.

After considering thousands of comments,⁴ the Agencies issued final regulations that adopted the interim rules’ definition of a religious employer. 77 Fed. Reg. 8,725, 8,726–27 (Feb. 15, 2012). Around the same time, the Agencies announced the creation of a temporary enforcement safe harbor for non-grandfathered plans sponsored by certain non-profit organizations with religious objections to contraceptive coverage that would not qualify as religious employers (and for any associated group health insurance coverage).⁵ Under the safe harbor, the Agencies committed not to take any enforcement action against an employer, group health plan, or group health insurance issuer with respect to a non-exempt, non-grandfathered group health plan that failed to cover some or all recommended contraceptive services. The safe harbor was available to any non-profit organization that certified that it had not provided contraceptive coverage because of the organization’s religious beliefs and that the plan had provided notice to participants that this coverage would not be offered. *Id.*

The safe harbor did not extend to for-profit companies with religious objections to providing contraceptive services or to any companies—for-profit or non-profit—with moral objections to providing such coverage. Therefore, dozens of organizations and individuals filed lawsuits challenging the mandate. Courts around the country began to issue injunctions against the Mandate. *See Archdiocese of St. Louis v. Burwell*, 28 F. Supp. 3d 944, 954 (E.D. Mo. 2014) (citing cases).

⁴ These comments are available at: <https://www.regulations.gov/docket?D=HHS-OS-2011-0023>.

⁵ On February 10, 2012, HHS issued a guidance describing the safe harbor and stating that the Agencies would wait an additional year before enforcing the mandate against certain non-exempt religious organizations. This guidance was later reissued without changing the substance of the policy in order to extend the safe harbor an additional year. *See HHS, Guidance on the Temporary Enforcement Safe Harbor*, at 1 n.1 & 3 (Feb. 10, 2012), <https://go.usa.gov/xnZBN>.

As part of their continuing review of religious objections, the Agencies issued an advance notice of proposed rulemaking (“ANPRM”) in March 2012. Certain Preventive Services Under the ACA, 77 Fed. Reg. 16,501 (Mar. 21, 2012). The ANPRM sought to address alternatives for providing women access to contraceptive services without cost-sharing and for accommodating religious organizations’ liberty interests, *id.* at 16,501–03, and to give “an early opportunity for any interested stakeholder to provide advice and input into the policy development relating to the accommodation to be made” in amendments to the regulations, *id.* at 16,503.

After a comment period, the Agencies issued a Notice of Proposed Rulemaking (“NPRM”). Coverage of Certain Preventive Services Under the ACA, 78 Fed. Reg. 8,456 (Feb. 6, 2013). The NPRM proposed changes to the finalized preventive services provisions and requested comments on its proposals, *id.* at 8,457. In particular, it suggested changing the religious employer exemption to the Mandate “by eliminating the first three prongs of the definition and clarifying the application of the fourth [so that] ... an employer that is ... a nonprofit entity and referred to in section 6033(a)(3)(A)(i) or (iii) of the [Internal Revenue] Code would be considered a religious employer” *Id.* at 8,461. The NPRM also proposed to “establish accommodations for health coverage [through] ... eligible organizations ... with religious objections to contraceptive coverage.” *Id.* at 8,459.

After receiving over 400,000 comments,⁶ the Agencies published final regulations. 78 Fed. Reg. 39,870 (July 2, 2013). As did the NPRM, the 2013 final rules sought to simplify the religious employer exemption by eliminating three criteria and clarifying the remaining criterion. *Id.* at 39,896. They defined a “religious employer” to be “an organization that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (a)(3)(A)(iii) of the Internal Revenue Code of 1986, as amended.” *Id.* at 39,889. That Code provision refers to churches, their integrated auxiliaries, and conventions or associations of churches, and the exclusively religious activities of any religious order. *Id.* The rules sought to ensure “that an otherwise exempt plan is

⁶ The comments on the ANPRM and NPRM are available at: <https://www.regulations.gov/docket?D=CMS-2012-0031>.

not disqualified because the employer's purposes extend beyond the inculcation of religious values or because the employer hires or serves people of different religious faiths." *Id.* at 39,874.

But the 2013 final rules did not extend the religious employer exemption to all objecting organizations. Instead, the rules established an "accommodation" for group health plans established or maintained by "eligible organizations." *Id.* at 39,874–80, 39,896. Under this process, an eligible organization was not required "to contract, arrange, pay, or refer for contraceptive coverage" to which it had religious objections, *id.* at 39,874, but was required to complete a self-certification process stating that it was an eligible organization and to provide a copy of that form to its issuer or third-party administrator ("TPA"). *Id.* at 39,878–79. The organization's health insurance issuer or TPA, after receiving the self-certification, would then be required to provide or arrange separate payments to participants and beneficiaries for contraceptive services without cost sharing, premium, fee, or other charge to participants or beneficiaries, or to the eligible organization or its plan.⁷ *See id.* at 39,875–80.

The 2013 final rules did not resolve the litigation challenging the Mandate. In 2014, the Supreme Court held that, at least as applied to closely-held for-profit corporations with religious objections to providing contraceptive coverage, the Mandate violated the Religious Freedom Restoration Act. *Hobby Lobby*, 134 S. Ct. at 2775. The Court explained that the "contraceptive mandate substantially burden[ed] the exercise of religion" by those employers because it put them to the choice of violating their sincerely held religious beliefs or facing significant fines. *Id.* at 2757. The Court also held that the application of the Mandate to them was not the least restrictive means of achieving a compelling governmental interest, because the accommodation was a less restrictive alternative than applying the Mandate directly. *See id.* at 2779–80. The Court cautioned that it was not deciding "whether an approach of this type complies with RFRA for purposes of all religious claims." *Id.* at 2782.

⁷ For self-insured plans, any costs incurred by a TPA could be reimbursed through an adjustment to Federally-facilitated Exchange (FFE) user fees. *See* 78 Fed. Reg. at 39,880.

Less than one week later, the Court issued an order in a case involving an employer whose objections to the Mandate could not be satisfied by use of the accommodation process. *See Wheaton Coll. v. Burwell*, 134 S. Ct. 2806 (2014). Wheaton College stated it sincerely believed that executing the self-certification process and submitting it to its health insurance issuer or TPA made it materially complicit in providing contraceptive coverage. *Id.* at 2808. The Court accordingly identified an alternative form of accommodation for Wheaton College during the litigation: the college was to “inform[] the Secretary of Health and Human Services in writing that it is a non-profit organization that holds itself out as religious and has religious objections to providing coverage for contraceptive services,” but was not required to use the self-certification form or send copies of that form to its health insurance issuers or administrators. *Id.* at 2807. This alternative form of accommodation would neither affect “the ability of [Wheaton College’s] employees and students to obtain, without cost, the full range of FDA approved contraceptives,” nor preclude the government from relying on the notice it received from Wheaton College “to facilitate the provision of full contraceptive coverage under the Act.” *Id.*

The Agencies responded to these litigation developments through various rulemakings. The Agencies issued a third set of IFRs to augment the regulatory accommodation process in light of the *Wheaton College* order. *Coverage of Certain Preventive Services Under the ACA*, 79 Fed. Reg. 51,092 (Aug. 27, 2014). They also issued a second NPRM to extend the accommodation process to closely held for-profit entities with religious objections to contraceptive coverage in light of the decision in *Hobby Lobby*. *See* 79 Fed. Reg. 51,118 (Aug. 27, 2014). On July 14, 2015, after receiving over 75,000 comments, the Agencies finalized both the August 2014 IFRs and the August 2014 proposed rules. *See* 80 Fed. Reg. 41,318, 41,324 (July 14, 2015).

Meanwhile, the litigation about whether the accommodation process satisfied the government’s RFRA obligations toward non-profit religious entities generated a split among the federal appeals courts, and the Supreme Court granted certiorari in *Zubik v. Burwell* to resolve it. After oral argument, the Court asked the parties to submit supplemental briefs addressing “whether and how contraceptive coverage may be obtained by petitioners’ employees through petitioners’

insurance companies, but in a way that does not require any involvement of petitioners beyond their own decision to provide health insurance without contraceptive coverage to their employees.” 2016 WL 1203818, at *2 (Mar. 29, 2016). In supplemental briefing, the Agencies acknowledged that the accommodation process for eligible organizations with insured plans could operate without any formal self-certification or written notice being submitted by eligible organizations, so long as the organization provided the insurer “any request” to exclude coverage of contraceptives. Suppl. Br. for Resp’ts at 15, *Zubik*, 136 S. Ct. 1557 (No. 14-1418). On May 16, 2016, the Supreme Court issued a *per curiam* opinion vacating the judgments of the courts of appeals and remanding the cases “[i]n light of the ... substantial clarification and refinement in the positions of the parties” in their supplemental briefs. 136 S. Ct. at 1560. The Court stated that it anticipated that, on remand, the courts of appeals would “allow the parties sufficient time to resolve any outstanding issues between them.” *Id.*

The Agencies then issued a Request for Information (“RFI”) seeking public comment on options for modifying the accommodation process in light of the supplemental briefing in *Zubik* and the Court’s remand order. Coverage for Contraceptive Services, 81 Fed. Reg. 47,741 (July 22, 2016). The Agencies explained that they were using the RFI procedure because the issues addressed in the supplemental briefing in *Zubik* affect a wide variety of stakeholders, including many who were not parties to the cases before the Supreme Court. *Id.* at 47,742-43.

In response to the RFI, the Agencies received over 54,000 public comments.⁸ See FAQs About ACA Implementation Part 36 (“FAQs”) (Jan. 9 2017).⁹ On January 9, 2017, the Agencies issued a “FAQ” document noting that, after reviewing these comments and considering various options, the Agencies could not find a way to amend the accommodation so as to satisfy objecting organizations while pursuing the Agencies’ policy goals. See *id.* Thus, the litigation on remand, involving dozens of cases and dozens of plaintiffs, remained unresolved.

⁸ These comments are available at: <https://www.regulations.gov/docket?D=CMS-2016-0123>.

⁹ Available at: <https://go.usa.gov/xnWVG> and <https://go.usa.gov/xnWVs>.

On May 4, 2017, the President issued an “Executive Order Promoting Free Speech and Religious Liberty.” Exec. Order No. 13,798, 82 Fed. Reg. 21,675 (May 4, 2017). Regarding “Conscience Protections with Respect to Preventive-Care Mandate,” that order instructed the Agencies to “consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under section 300gg-13(a)(4) of title 42, United States Code.” *Id.*

“Consistent with the President’s Executive Order and the Government’s desire to resolve the pending litigation and prevent future litigation from similar plaintiffs,” the Agencies concluded that it was “appropriate to reexamine the exemption and accommodation scheme currently in place for the Mandate” and issued the IFRs at issue here on October 6, 2017. Religious Exemption Rule, 82 Fed. Reg. 47,792; *accord* Moral Exemption Rule, 82 Fed. Reg. 47,838. The Agencies have requested public comments on the Rules by December 5, 2017.

The Religious Exemption Rule expands the exemption for non-governmental plan sponsors that object to providing all or a subset of contraceptive services based on sincerely held religious beliefs, as well as institutions of higher education in their arrangement of student health plans, to the extent of these entities’ sincerely held religious beliefs. 45 C.F.R. § 147.132(a)(2). The Moral Exemption Rule provides an exemption for certain non-governmental plan sponsors that object to providing all or a subset of contraceptive services based on sincerely held moral convictions, as well as institutions of higher education in their arrangement of student health plans, to the extent of these entities’ sincerely held moral convictions. *Id.* § 147.133(a)(2).¹⁰

Under the Rules, HRSA remains free to define “contraceptive services” as “contraceptive or sterilization items, procedures, or services, or related patient education or counseling, to the extent specified for purposes of § 147.130(a)(1)(iv).” *See* 82 Fed. Reg. at 47,835; 45 C.F.R.

¹⁰ Each rule also includes an “individual exemption” that allows a willing plan sponsor of a group health plan or a willing health insurance issuer offering group or individual health insurance coverage to provide a separate benefit package option or separate policy, certificate, or contract of insurance to an individual who objects to coverage for contraceptive services based on sincerely held religious beliefs or moral convictions. 45 C.F.R. §§ 147.132(b), 147.133(b).

§ 147.132(c); 45 C.F.R. § 147.133(c). “Contraceptive services” do not include contraceptive services for men, and never have, because the ACA only authorizes HRSA to develop guidelines for “additional preventive care and screenings” to be covered “with respect to women.” 42 U.S.C. § 300gg-13(a)(4); 78 Fed. Reg. at 8,458 n.3 (excluding “services relating to a man’s reproductive capacity, such as vasectomies and condoms” from the definition of “preventive services” that must be provided without cost sharing).¹¹ As under the previous rule, exempt entities are not required to self-certify, but they are still subject to the ERISA disclosure requirements for plan exclusions or reductions in a covered service or benefit. 82 Fed. Reg. at 47,808 & n.54; *id.* at 47,804 & n.32. The Rules also maintain the accommodation process as a voluntary mechanism to provide contraceptive availability for women covered by the plans of exempt entities that choose to use it. 45 C.F.R. § 147.131; 26 C.F.R § 54.9815-2713A; 29 C.F.R. § 2590.715-2713A. On October 6, 2017, HRSA updated its Guidelines to exempt entities and individuals that qualify for exemptions from the Guidelines’ requirements. Guidelines, <http://www.hrsa.gov/womens-guidelines>.

ARGUMENT

I. PENNSYLVANIA LACKS STANDING.

As an initial matter, Plaintiff is not entitled to a preliminary injunction because this Court lacks standing and therefore jurisdiction to adjudicate its claims. *See Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 94 (1998). To establish standing, a plaintiff must show that it has “suffered an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized, and ... (b) actual or imminent, not conjectural or hypothetical.” *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) (citations omitted). The harm must be “distinct and palpable, as opposed to merely abstract.” *N.J. Physicians, Inc. v. President of the United States*, 653 F.3d 234, 238 (3d Cir. 2011) (citation omitted). Allegations of possible future injury do not

¹¹ “Contraceptive services” under the Rules also do not include drugs or methods approved by the FDA for contraceptive use that are prescribed for medical treatment, because 42 U.S.C. § 300gg-13(a)(4) does not apply to non-preventive care provided for treatment of an existing condition. *See* 82 Fed. Reg. at 47,805 & n.48.

suffice; rather, “[a] threatened injury must be certainly impending to constitute injury in fact.” *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990). A plaintiff that “alleges only an injury at some indefinite future time” has not shown an injury in fact; “the injury [must] proceed with a high degree of immediacy, so as to reduce the possibility of deciding a case in which no injury would have occurred at all.” *Lujan*, 504 U.S. at 564 n.2. The standing inquiry is “especially rigorous” where, as here, a plaintiff asks a federal court “to decide whether an action taken by one of the other two branches of the Federal Government was unconstitutional.” *Raines v. Byrd*, 521 U.S. 811, 819-20 (1997).

A. Pennsylvania Has Not Shown that It Will Suffer a Cognizable Proprietary Injury Traceable to the Rules.

The challenged Rules apply to non-governmental employers, not to states. They do not command the Commonwealth to take, or refrain from taking, any action. Accordingly, this case is unlike the most common situation in which states have standing to challenge federal law. *See, e.g., New York v. United States*, 505 U.S. 144 (1992); *Oregon v. Mitchell*, 400 U.S. 112 (1970). Instead, Pennsylvania complains of injury “from the government’s allegedly unlawful regulation (or lack of regulation) of someone else,” making standing “substantially more difficult to establish.” *See Lujan*, 504 U.S. at 562. The Commonwealth nonetheless seeks to challenge the expanded exemptions for religious and moral objections set forth in the Rules based on conjecture about the indirect or incidental financial consequences that allegedly will flow from them. It fails to show that the Rules will result in any injury for the Commonwealth, much less that an injury is “*certainly impending.*” *Id.* at 564 n.2.

1. Pennsylvania’s conjecture about costs associated with the Rules is not cognizable.

Pennsylvania’s first theory of harm is that the expanded exemptions will injure the state’s finances by “forc[ing]” the Commonwealth “to bear additional health care costs, in part, due to an increase in unintended pregnancies.” Compl. ¶ 19, ECF No. 1; *see also id.* ¶¶ 129-39; PI Mot. at 13-16, 38-47. But conclusory allegations that a state’s budget or tax revenues will be harmed in some general way by a federal policy are not sufficient to support standing. *See, e.g., Pennsylvania*

v. Kleppe, 533 F.2d 668, 672-73 (D.C. Cir. 1976); *Wyoming v. U.S. Dep't of the Interior*, 674 F.3d 1220, 1234 (10th Cir. 2012); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

The only specific example the Commonwealth provides of an employer planning to stop providing contraceptive coverage to Pennsylvania residents is Notre Dame, PI Mot. at 13 n.9, which has since announced that its TPA will provide contraceptive coverage to its health plan members at no cost.¹² It also fails to allege that the employees of such an employer would have no other access to contraceptive coverage through, for example, a family member's plan.

Even if state residents do lose coverage as a result of the Rules, Pennsylvania's alleged harms rely on an attenuated chain of causation. It is pure speculation that "[s]ome women who lose their employer-sponsored health coverage for contraceptive care will seek coverage through" programs that are at least partially state-funded, thus requiring increased state spending. *See id.* ¶ 134; PI Mot. at 14, 43. And it requires even further speculation to assume that these gainfully employed women will meet the low-income requirements of these programs. *Id.* The Commonwealth's allegation that the expanded exemptions will result in "an increase in unintended pregnancies" in Pennsylvania, causing its state-funded health programs to incur greater costs, is even more attenuated. Compl. ¶ 136; PI Mot. at 15. The costs of such "unintended pregnancies" would likely be otherwise covered by these employees' health plans. Moreover, the expanded exemptions do not "forc[e]" anyone to forgo contraceptive use, much less do they "forc[e]" eligible individuals to seek subsidized contraception and prenatal care and delivery services from state programs. Pennsylvania's "belie[f] that the Commonwealth has enjoyed increased tax revenue as a result of its female citizens enjoying increased savings borne from the contraceptive mandate" is similarly unavailing. If such hypothetical impacts on state finances were enough to provide a state with Article III standing, a state could challenge virtually any federal policy.¹³ *See Wyoming*, 674

¹² *See* Margaret Fosmoe, *Notre Dame employees will retain access to free birth control*, South Bend Tribune, Nov. 8, 2017 (attached as Ex. A); Tami Luhby, *Notre Dame reverses decision to end birth control coverage*, Nov. 8, 2017 (attached as Ex. B) ("A university spokesman confirmed that students would continue to have access to no-cost birth control, as well.").

¹³ Even if Pennsylvania had alleged a fiscal injury traceable to the expanded exemptions in the Rules, that injury would not suffice to confer the state with standing on behalf of itself. The

F.3d at 1234 (“concrete evidence” of an impact on state finances is needed because of “the unavoidable economic repercussions of virtually all federal policies” (quoting *Kleppe*, 533 F.2d at 672)). *See also State of Iowa ex rel. Miller v. Block*, 771 F.2d 347, 353 (8th Cir. 1985) (“these injuries fail to constitute distinct, palpable injuries to the State as a state”).

2. Pennsylvania cannot base standing on costs triggered by elective state programs.

The Commonwealth alleges that it will suffer injury to “Pennsylvania’s coffers” because it will be “providing contraceptive care services through already over-burdened state programs.” Compl. ¶¶ 134-35; PI Mot. at 3. But a state has suffered no legally cognizable injury if an eligible person applies for a benefit that a state has elected to provide (such as those available through a state’s Family Planning Services, or Title X programs). *See Lujan*, 504 U.S. at 560 (“injury in fact” requires “an invasion of a *legally protected* interest” (emphasis added)). The expanded exemptions do not require Pennsylvania to provide any state benefits to the employees of employers who opt into the exemption; whether to provide such benefits is a decision made by the Commonwealth. Accordingly, costs associated with providing subsidized contraception for state residents whose employers who opt into the exemption is a “self-inflicted injur[y]” that is not traceable to the challenged regulations and is not a cognizable injury under Article III. *See Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 418 (2013); *see also Pennsylvania v. New Jersey*, 426 U.S. 660, 664 (1976) (finding “[t]he injuries to the [states’] fiscs were self-inflicted, resulting from decisions by their respective state legislatures” and “[n]o State can be heard to complain about damage inflicted by its own hand”); *In re McNeil Consumer Healthcare*, 877 F. Supp. 2d 254, 277

Commonwealth’s generalized allegation of harm to the state’s finances or loss of increased tax revenue is not a proprietary interest apart from the interests of its citizens. As explained below, a state cannot sue the federal government asserting a *parens patriae* interest in its citizens’ economic well-being. The Commonwealth cannot circumvent that black-letter legal principle by asserting an interest in tax revenues from its residents that is merely an assertion of *parens patriae* standing by another name. *See City of Rohnert Park v. Harris*, 601 F.2d 1040, 1044-45 (9th Cir. 1979) (alleged “loss of investment profits and tax revenues” by citizens if development did not proceed implicates a *parens patriae* interest); *People ex rel. Hartigan v. Cheney*, 726 F. Supp. 219, 225 (C.D. Ill. 1989) (concluding that alleged decrease in state revenue and increase in social spending did not confer standing on Illinois because they “fall on the taxpayers and citizens of Illinois and not on the state qua state”).

(E.D. Pa. 2012) (plaintiffs could not base standing on costs that “[we]re the result of the plaintiffs’ own choices and [we]re not fairly traceable to the actions of the defendants”).

B. Pennsylvania Cannot Pursue This Litigation on Behalf of the Purported Interests of Its Citizens.

The Commonwealth cannot overcome its failure to show its own standing by asserting a right as *parens patriae* to represent the interests of its citizens. See Compl. ¶¶ 20, 140. As *parens patriae*, a state can sue a private party to protect its “quasi-sovereign interest” in the health and well-being of its citizens. *Snapp*, 458 U.S. at 602-03. But it cannot bring such a suit against the federal government. “It has been settled since *Massachusetts v. Mellon*, 262 U.S. 447, 486 (1923) that a state may not attempt as *parens patriae* to enforce rights of its citizens ‘in respect of their relations with the federal government. In that field it is the United States, and not the State, which represents [its citizens] as *parens patriae* when such representation becomes appropriate; and to the former, and not to the latter, they must look for such protective measures as flow from that status.’” *Pennsylvania v. Porter*, 659 F.2d 306, 317 (3d Cir. 1981) (en banc) (quoting *Mellon*, 262 U.S. at 486); see also *Maiden Creek Assocs. v. U.S. Dep’t of Transp.*, 823 F.3d 184, 193 (3d Cir. 2016). This well-settled rule controls here.

Plaintiff’s invocation of its “quasi-sovereign” interests similarly fails to establish standing. In *Massachusetts v. EPA*, 549 U.S. 497, 522–23 (2007), the Supreme Court allowed the Commonwealth of Massachusetts to sue the federal government to vindicate a claim of a concrete, direct injury to its quasi-sovereign interests; Massachusetts alleged harm to the physical integrity of its “sovereign territory,” damaging its “independent interest in all the earth and air within its domain.” *Id.* at 519. Pennsylvania here alleges no such concrete, direct injury to its own interests. Rather, it alleges “quasi-sovereign” interests only in the health and safety of its residents. Compl. ¶ 140; PI Mot. at 46-47. Again, these are really the interests of its citizens, and the Commonwealth cannot assert those interests as *parens patriae* against the federal government. *Snapp*, 458 U.S. at 602-03. “[T]here is a critical difference between allowing a State ‘to protect her citizens from the

operation of federal statutes’ (which is what *Mellon* prohibits) and allowing a State to assert its rights under federal law (which it has standing to do).” *Massachusetts*, 549 U.S. at 520 n.17.

II. VENUE IS NOT PROPER IN THIS DISTRICT.

There are three possible bases for venue in a suit against a federal agency or officer; suit may be brought in a district in “which (A) a defendant in the action resides, (B) a substantial part of the events or omissions giving rise to the claim occurred, or a substantial part of property that is the subject of the action is situated, or (C) the plaintiff resides if no real property is involved in the action.” 28 U.S.C. § 1391(e)(1). The Commonwealth asserts that venue is proper in this district because it “resides in this district and because a substantial part of the events giving rise to this action occurred in this judicial district.” Compl. ¶ 26. It is wrong on both counts.

The Commonwealth resides in the Middle District of Pennsylvania, not here. Indeed, the Commonwealth has itself so argued. *E.g.*, *Stanton-Negley Drug Co. v. Pa. Dep’t of Pub. Welfare*, No. 07-1309, 2008 WL 1881894, at *4 (W.D. Pa. Apr. 24, 2008) (“Defendants ... argue that venue is improper under § 1391(b)(1) because the Defendant State Officials do not officially reside in the Western District of Pennsylvania, but rather in Harrisburg, which is located in the Middle District of Pennsylvania.”). The courts agree. *See, e.g., id.*; *Gaskin v. Pennsylvania*, No. 94-4048, 1995 WL 154801, at *1 (E.D. Pa. Mar. 30, 1995) (accepting Commonwealth’s argument); *Perkins v. Snider*, No. 94-4785, 1994 WL 530045, at *1 (E.D. Pa. Sept. 2, 1994) (same); *Bentley v. Ellam*, No. 89-5418, 1990 WL 63734, at *1 (E.D. Pa. May 8, 1990) (same); *Hosp. Ambulance Serv., Inc. v. Larson*, No. 86-2041, 1986 WL 506, at *2 (E.D. Pa. Dec. 17, 1986) (same). And for good reason: “It is well settled for venue purposes that the residence of a state agency or state official is the state capitol, even when branch offices of the state agency are maintained in other parts of the state.” *Bentley*, 1990 WL 63734, at *1.

Nor have “a substantial part of the events giving rise to this action occurred in this judicial district.” Compl. ¶ 26. The Commonwealth has filed a facial challenge to two Rules issued by federal agencies headquartered in Washington, D.C. and has not alleged that any specific residents of this district would be affected by the Rules. The only “events or omissions” that “giv[e] rise to

the claim occurred” when the Agencies promulgated the Rules at their headquarters. That cannot support venue here. *See Rogers v. Civil Air Patrol*, 129 F. Supp. 2d 1334, 1339 (M.D. Ala. 2001) (noting events giving rise to facial challenge to federal law occurred where law was enacted); *Seariver Maritime Financial Holdings, Inc. v. Pena*, 952 F. Supp. 455, 462 (S.D. Tex. 1996) (venue would be proper in District of Columbia where challenge is to allegedly unconstitutional enactment of federal statute); *Republican Party of N.C. v. Martin*, 682 F. Supp. 834, 836-37 (M.D.N.C. 1988) (same result under prior version of venue statute). Venue is not appropriate here simply because the effects of the Rules might, one day, be felt here. Section 1391(e) refers in the past tense to events that have already “occurred,” thereby pointedly excluding venue choices based on events that have not yet happened. *See Carr v. United States*, 560 U.S. 438, 448 (2010) (“Congress’ use of a verb tense is significant in construing statutes”); *Reuben H. Donnelly Corp. v. FTC*, 580 F.2d 264, 268 (7th Cir. 1978) (“To base a venue determination on the possibility of some future administrative ruling approaches the question backwards.”). Moreover, courts should focus on the actions of the defendant, not of the plaintiff. *Rogers*, 129 F. Supp. 2d at 1338–39. “[T]he purpose of statutorily specified venue is to protect the defendant against the risk that a plaintiff will select an unfair or inconvenient place of trial.” *See Leroy v. Great W. United Corp.*, 443 U.S. 173, 183-86 (1979). The only events giving rise to this suit occurred in Washington, D.C., not here.

III. PENNSYLVANIA HAS NOT SHOWN THAT PRELIMINARY RELIEF IS NEEDED TO PREVENT IRREPARABLE HARM.

A preliminary injunction is an “extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief.” *Winter v. Nat. Res. Def. Council*, 555 U.S. 7, 22 (2008). “A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest.”

Id. at 20.¹⁴ Pennsylvania does not meet any of these four requirements.

Pennsylvania alleges that it suffers two kinds of harm from the Rules: (1) an injury to its interest as *parens patriae* in the health and well-being of Pennsylvania residents, PI Mot. at 39-43, 46-47, and (2) an injury in the form of increased costs for the Commonwealth, *id.* at 43-46. As explained above, neither allegation states an injury to the Commonwealth at all, let alone an irreparable one.

In any event, a merely economic injury itself does not provide a basis for injunctive relief, and Pennsylvania's effort to circumvent this rule by citing the federal government's sovereign immunity from damages, PI Mot. at 44-45, is unavailing. *See Kinder Morgan Liquids v. Borough of Carteret*, No. 05-4334, 2006 WL 827848, at *3 (D.N.J. Mar. 30, 2006) (rejecting contention that the fact that money damages were allegedly unrecoverable because of sovereign immunity constituted irreparable harm). Pennsylvania cites Judge Walton's decision in *Feinerman v. Bernardi*, 558 F. Supp. 2d 36 (D.D.C. 2008), as support, PI Mot. at 45, but fails to note that Judge Walton later held that *Feinerman* "goes too far" by characterizing such damages as irreparable *per se*. *CoverDyn v. Moniz*, 68 F. Supp. 3d 34, 49 (D.D.C. 2014) (citation omitted). Instead, "[t]he wiser formula requires that the economic harm be significant, even where it is irretrievable because a defendant has sovereign immunity." *Air Transp. Ass'n of Am., Inc. v. Export-Import Bank of U.S.*, 840 F. Supp. 2d 327, 335 (D.D.C. 2012); *see also Save Jobs USA v. Dep't of Homeland Sec.*, 105 F. Supp. 3d 108, 115 (D.D.C. 2015) ("This court concurs with the reasoning in *Air Transport Association* and the other decisions in this District that unrecoverable economic losses do not automatically constitute irreparable harm, but instead must be sufficiently severe to warrant emergency relief.").

Pennsylvania nowhere alleges the sort of "sufficiently severe" economic losses that could justify emergency injunctive relief. Without even an attempt to quantify its irreparable economic

¹⁴ The Third Circuit has interpreted the likelihood of success on the merits requirement to require a showing of "a reasonable probability of eventual success in the litigation." *Reilly v. City of Harrisburg*, 858 F.3d 173, 176 & 179 n.3 (3d Cir. 2017) (citing *Del. River Port Auth. v. Transamerican Trailer Transport, Inc.*, 501 F.2d 917, 920 (3d Cir. 1974)).

harm, it cannot meet its burden of proving irreparable injury. See *In re N. Am. Refractories Co.*, 542 B.R. 350, 358 (Bankr. W.D. Pa. 2015) (explaining that “[t]he key inquiry” in determining whether unrecoverable economic injury will support entry of a preliminary injunction “is whether the unrecoverable economic injury is of such nature or magnitude that it will cause serious or special harm to the plaintiff, for example by threatening the plaintiff’s solvency or requiring it to undergo substantial changes in its operations”); *Instant Air Freight Co. v. C.F. Air Freight, Inc.*, 882 F.2d 797, 802-03 (3d Cir. 1989) (no irreparable injury where movant retained twenty percent of its business and no evidence showed it was “likely to cease its existence”).¹⁵

Additionally, “[t]he irreparable harm alleged must be actual and imminent, not merely speculative.” *Macchione v. Coordinator Adm’r in Wash., D.C.*, 591 F. App’x 48, 49 (3d Cir. 2014). “[A] showing of irreparable harm is insufficient if the harm will occur only in the indefinite future. Rather, the moving party must make a clear showing of *immediate* irreparable harm.” *Campbell Soup Co. v. ConAgra, Inc.*, 977 F.2d 86, 91 (3d Cir. 1992) (citation omitted). See also *Adams v. Freedom Forge Corp.*, 204 F.3d 475, 488 (3d Cir. 2000) (“[T]he risk of irreparable harm must not be speculative.”). As shown by its very language, Pennsylvania’s allegations that “[i]f employers eliminate contraceptive coverage, women will seek coverage from [state-funded] programs,” PI Mot. at 14 (emphasis added), are founded on multiple levels of speculation. Employers that eliminate coverage generally must provide their employees with 60 days’ notice, or at least 30 days’ notice before the start of a plan year, see *id.* at 45–46; 82 Fed. Reg. at 47,829, and Pennsylvania has not identified any employers that have given such notice to Pennsylvania residents, let alone that anyone denied coverage will seek (and be eligible for) state benefits.

Pennsylvania has alleged, at most, a threat of harm that might occur at some indefinite future time, rather than identifying a threatened injury that is imminent and immediate. It alleges that some as-yet unidentified Pennsylvania employers will seek an exemption for all contraception,

¹⁵ *N.J. Retail Merchants Ass’n v. Sidamon-Eristoff*, 669 F.3d 374, 388 (3d Cir. 2012), is not to the contrary; the plaintiffs there were ordered to pay money directly to the state that they could not later recover. Pennsylvania’s claim of economic losses is far more conjectural.

rather than an accommodation, and that, as a result, some women will seek coverage for contraception costs through state-administered programs at some indefinite future date, PI Mot. at 43-44, and that the reduction in employer-based coverage of contraception will some day increase the number of unplanned pregnancies and/or significant health problems, which will lead to state-administered programs incurring greater costs at some time in the future. *Id.* at 44. These allegations do not show that the Commonwealth faces an imminent threat of irreparable harm absent emergency relief, and fail to show a need for urgent relief given that full briefing on the merits could be completed in a matter of months.

IV. PENNSYLVANIA IS UNLIKELY TO SUCCEED ON THE MERITS.

A. Pennsylvania Is Unlikely to Succeed on Its Procedural APA Claim.

Pennsylvania asserts that the Rules should be enjoined because they were issued without notice and comment. Compl. ¶¶ 159-67; PI Mot. at 18-22. This claim is meritless. The Rules were issued pursuant to express statutory authorization—identically worded in each of the statutes governing the three Agencies’ authority to issue the rules at issue here—to “promulgate *any* interim final rules as the Secretary determines are appropriate” to carry out those sections of the Internal Revenue Code, ERISA, and Public Health Services Act which encompass the Act. *See* 26 U.S.C. § 9833; 29 U.S.C. § 1191c; 42 U.S.C. § 300gg-92 (emphasis added). In addition to this express statutory authority, the Agencies had “good cause” under the APA to dispense with notice and comment in order, among other things, to cure ongoing RFRA violations under the previous regulations and to help settle or resolve litigation over the past rules. 82 Fed. Reg. at 47,814. In any event, any error was harmless. The Rules were issued after the Agencies received “more than 100,000 public comments” throughout six years of publishing and modifying these regulations, providing an extensive discussion about whether and by what extent to expand the exemptions at issue here. *Id.*¹⁶

¹⁶ Pennsylvania’s claims against the President fail for the additional reason that no injunctive or declaratory relief is available against the President in the performance of his official duties. *Franklin v. Massachusetts*, 505 U.S. 788, 802–03, 826 (1992) (citation omitted) (“[I]n general this court has no jurisdiction of a bill to enjoin the President in the performance of his official duties.”)

1. The Agencies issued the Rules pursuant to express statutory authority.

The APA's rulemaking provisions generally require that agencies provide notice of a proposed rule, invite and consider public comments, and adopt a final rule that includes a statement of basis and purpose. *See* 5 U.S.C. § 553(b), (c). But the Rules were issued under express statutory authority granting the Agencies discretion to promulgate regulations relating to health coverage on an interim final basis. 82 Fed. Reg. at 47,813 (referring to 26 U.S.C. § 9833; 29 U.S.C. § 1191c; 42 U.S.C. § 300gg-92); *id.* at 47,854 (same). Indeed, three statutes authorize the Secretaries of the Agencies to promulgate “*any interim final rules as the Secretar[ies] determine[] are appropriate.*” 29 U.S.C. § 1191c (emphasis added); 26 U.S.C. § 9833 (emphasis added); 42 U.S.C. § 300gg-92 (emphasis added). These provisions relating to health coverage IFRs are unique; they do not appear in other grants of regulatory authority to agencies. This is the same statutory authority under which the Agencies issued the 2010, 2011, and 2014 IFRs. 75 Fed. Reg. at 41,729-30; 76 Fed. Reg. at 46,624; 79 Fed. Reg. at 51,095; *cf. Real Alternatives, Inc. v. Burwell*, 150 F. Supp. 3d 419, 427 n.6 (M.D. Pa. 2015) (noting that APA notice-and-comment requirements did not apply to the 2011 IFR under this specific statutory authority to issue IFRs). The Agencies have met the APA's only procedural requirements that are applicable here: they have requested comments for a period of sixty days on the IFRs and will not issue final regulations until after receiving and carefully considering these comments. *See* 82 Fed. Reg. 47,792; 82 Fed. Reg. 47,838.

Pennsylvania's contrary position writes this express grant of statutory authority out of the statute. Under the Commonwealth's view, the grant of authority is meaningless; it would merely give the Secretaries the same authority they already possessed. But when Congress sets forth its “clear intent that APA notice and comment procedures need not be followed,” an agency may

(through plurality opinion and concurrence, majority of justices agree with this conclusion); *see also Swan v. Clinton*, 100 F.3d 973, 976 n.1 (D.C. Cir. 1996).

In addition, as to Count I, a state is not a “person” protected by the Due Process Clause of the Fifth Amendment. *See South Carolina v. Katzenbach*, 383 U.S. 301, 323-34 (1966); *Pennsylvania v. Riley*, 84 F.3d 125, 130 n.2 (3d Cir. 1996). As to Count III, Plaintiff cites no case recognizing the standing of a state to bring an Establishment Clause challenge, and it is not clear how a state can suffer “direct, personal contact” with or be “offended and intimidated by” the Rules. *See ACLU-NJ v. Township of Wall*, 246 F.3d 258, 265-66 (3d Cir. 2001).

dispense with those requirements and issue an IFR. *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1237 (D.C. Cir. 1994) (upholding IFR where statute provided for an expedited regulatory process and instructed HHS to issue an IFR followed by public comment); *Asiana Airlines v. FAA*, 134 F.3d 393, 397-98 (D.C. Cir. 1998). The relevant question is “whether Congress has established procedures so clearly different from those required by the APA that it must have intended to displace the norm.” *Id.* at 397. That is precisely the case here. Express authority to issue “any interim final rules *as the Secretar[ies] determine[]* are appropriate” is “clearly different from [procedures] required by the APA,” which impose a standard of good cause, not appropriateness as deemed by the Secretaries.

2. The Agencies had good cause to issue Interim Final Rules.

In any event, the Agencies’ action would have been justified under the APA itself. That Congress “has specifically authorized the Secretaries to promulgate interim final rules,” at a minimum, “provides support towards a finding of ‘good cause’ to proceed without notice and comment.” *Coalition for Parity, Inc. v. Sebelius*, 709 F. Supp. 2d 10, 20 (2010). The APA authorizes agencies to dispense with the notice-and-comment rulemaking procedures “when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor[e] in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.” 5 U.S.C. § 553(b)(3)(B).

Here, good cause existed to issue the Rules without notice and comment. *First*, the Agencies found that any additional delay in issuing the Rules would be contrary to the public interest. 82 Fed. Reg. at 47,814-15; 82 Fed. Reg. at 47,855–56. Prompt guidance would provide entities and individuals facing burdens on their sincerely held religious beliefs and moral convictions with important and urgent relief. The need for this relief was particularly acute for those objecting entities not protected by court injunctions. *Id.* at 47,814; *see also id.* at 47,855. But the Rules also resolve the uncertainty, inconsistency, and costs resulting from the dozens of lawsuits over the Mandate for nearly five years. Plaintiff argues that “[l]itigation over agency rules is a constant,” PI Mot. at 20, but a half decade of litigation (through dozens of lawsuits, including

more than 50 pending at the time the Rules were promulgated) has shown to the Agencies that the proposed accommodation was ineffective and the exemption too narrow.

Indeed, after the *Zubik* remand, the vacated cases were still active and required prompt resolution: the Agencies were filing mandatory status reports on their attempts to find a solution to the objections raised to the accommodation process, the Seventh Circuit directed the government to agree to resolve *University of Notre Dame v. Price* by May 2017 or prepare for oral argument on the merits, No. 13-3853 (ECF No. 130), and plaintiffs in many cases were pressuring the courts to force a resolution, *see, e.g., Wieland v. HHS*, No. 16-3831 (ECF No. 4530941); *E. Tex. Baptist Univ. v. Price*, No. 14-20112 (ECF No. 513968100). The Religious Exemption Rule “provide[s] a specific policy resolution that courts have been waiting to receive from the [Agencies] for more than a year” following *Zubik*. 82 Fed. Reg. at 47,814.

Second, by issuing a detailed RFI after the *Zubik* remand, followed by the IFRs, the Agencies were able to provide accelerated clarity and certainty while also affording opportunity for meaningful public input. *See, e.g., Priests for Life v. U.S. Dep’t of Health & Human Servs.*, 772 F.3d 229, 276 (D.C. Cir. 2014) (finding good cause for the 2014 IFR augmenting the regulatory accommodation process without notice-and-comment);¹⁷ *Serv. Emps. Int’l Union, Local 102 v. Cty. of San Diego*, 60 F.3d 1346, 1352 n.3 (9th Cir. 1994) (finding good cause for an IFR because “the federal courts were issuing conflicting decisions” and the resulting potential liability “may threaten [the state and local governments’] fiscal integrity,” while noting that “the public was not deprived of its input” because by the time of the 1991 IFR, the agency had reviewed public comments submitted in response to an advance notice of proposed rulemaking issued in 1985). *Cf. Mobay Chemical Corp. v. Gorsuch*, 682 F.2d 419, 427 (3d Cir. 1982) (finding that a 1978 ANPRM was not sufficient actual notice because the “generalities” in the ANPRM were “insufficient to alert interested parties to the full extent” of the program in the agency’s 1979 IFRs).

¹⁷ Plaintiff attempts to distinguish *Priests for Life* by arguing that “the process mandated by the [*Wheaton College*] Court had to be implemented immediately,” PI Mot. at 20 n.11, but the *Priests for Life* Court said nothing about the how quickly the government was required to act in response to *Wheaton College*.

Moreover, the clarity provided in these Rules serves the public interest by removing barriers to participation in the insurance market. “As reflected in litigation pertaining to the Mandate, some [grandfathered health plans] wish to make changes to their health plans that will reduce the costs of insurance coverage for their beneficiaries or policyholders, but which would cause the plans to lose grandfathered status.” 82 Fed. Reg. at 47,815. The Rules permit these entities to change their plans and thereby “help reduce the costs of health insurance for such entities and their plan participants.” *Id.* The Rules also remove any deterrent that would discourage persons from organizing entities that would be subject to the Mandate, or from offering health insurance in the first place. *Id.* at 47,814.

Third, the Agencies indisputably demonstrated a willingness to consider public comment, both prior to and following issuance of the Rules. As discussed above, *supra* pp. 5–11, the Agencies received, and considered, multiple rounds of comments on the first set of interim final regulations in 2010; on the interim final regulations that adopted the HRSA guidelines and set forth a religious employer exemption in 2011; on their proposed changes to the religious employer exemption in 2012 and 2013; on the modifications to the accommodation process in 2015; and most recently, on the RFI they issued in July 2016, seeking public comment on options for modifying the accommodation process in light of *Zubik*. *See* 81 Fed. Reg. 47,741. In total, the Agencies have received “more than 100,000 public comments on multiple occasions” on the exemption and accommodation issues. 82 Fed. Reg. at 47,814. After reviewing these thousands of comments, the Agencies could not find a way to amend the accommodation to satisfy everyone. But there is no question that the Agencies have “educate[d] [themselves] before establishing rules and procedures which have a substantial impact on those regulated.” *Texaco, Inc. v. Fed. Power Comm’n*, 412 F.2d 740, 744 (3d Cir. 1969).

The Agencies have also solicited comments for 60 days following issuance of the Rules. *See* 82 Fed. Reg. at 47,792 (requesting comments on or before December 5, 2017); *id.* at 47,838 (same). Their solicitation of post-promulgation comments “suggests that the [Departments have] been open-minded,” with the result that “real ‘public reconsideration of the issued rule’ [is taking]

place.” *Petry v. Block*, 737 F.2d 1193, 1203 (D.C. Cir. 1984) (citation omitted) (finding that, in light of post-promulgation comment period, remand to the agency for further proceedings was unnecessary); *see also Republic Steel Corp. v. Costle*, 621 F.2d 797, 804 (6th Cir. 1980) (upholding rule where agency provided only post-promulgation comment period); *Universal Health Servs. of McAllen, Inc. v. Sullivan*, 770 F. Supp. 704, 721 (D.D.C. 1991) (“[F]ailure to comply with the pre-promulgation procedures of § 553 of the APA may be cured by an adequate later notice if the agency’s mind remain[s] open enough at the later stage.”) (citation omitted). The Agencies’ solicitation of *both* pre-and post-promulgation comments shows that their “mind remains open.”

Finally, the Rules are effective only until final rules are issued. “The interim nature of a challenged rule is a ‘significant factor’ in evaluating an agency’s good cause claim.” *Nat’l Women, Infants, & Children Grocers Ass’n v. Food & Nutrition Serv.*, 416 F. Supp. 2d 92, 107 (D.D.C. 2006) (quoting *Tenn. Gas Pipeline Co. v. FERC*, 969 F.2d 1141, 1144 (D.C. Cir. 1992)); *see also Mid-Tex Elec. Co-op., Inc. v. FERC*, 822 F.2d 1123, 1132 (D.C. Cir. 1987). The Rules, by definition, are temporary regulations. By seeking comments, the Agencies have given interested parties, including Pennsylvania, two full months to review the Rules before the Agencies issue final regulations.

Pennsylvania emphasizes that “[t]he desire to eliminate uncertainty, by itself, cannot constitute good cause.” PI Mot. at 21 (quoting *United States v. Reynolds*, 710 F.3d 498, 510 (3d Cir. 2013)). But the Agencies found multiple bases for good cause here. *See* 82 Fed. Reg. at 47,814-15; *id.* at 47,855-56. The Court’s inquiry into whether an agency has “properly invoked ‘good cause’ proceeds case-by-case, sensitive to the totality of the factors at play.” *Alcaraz v. Block*, 746 F.2d 593, 612 (9th Cir. 1984) (citing *Petry*, 737 F.2d at 1200). Thus, even if a single justification “standing alone” would not constitute good cause, the court must consider whether the “combined effect” suffices. *Nat’l Women Ass’n*, 416 F. Supp. 2d at 107; *Mid-Tex Elec. Coop., Inc.*, 822 F.2d at 1132-33. Each of the factors discussed above, in light of the Agencies’ express statutory interim final rulemaking authority, justified their reliance on the “good cause” exception. *See Nat’l Women Ass’n*, 416 F. Supp. 2d at 104–05.

3. If the lack of formal notice-and-comment was an error, it was harmless.

In any event, any error in forgoing notice and comment was harmless. The APA's judicial review provision instructs courts to take "due account ... of the rule of prejudicial error." 5 U.S.C. § 706. Courts routinely apply this instruction when they determine whether an agency has failed to comply with the APA's notice-and-comment requirement. *See, e.g., Am. Farm Bureau Fed'n v. EPA*, 984 F. Supp. 2d 289, 335 (M.D. Pa. 2013). The burden falls on the party asserting error to demonstrate prejudice. *Shinseki v. Sanders*, 129 S. Ct. 1696, 1706 (2009).

Pennsylvania cannot show prejudice because it, like all interested parties, has had multiple opportunities to comment on the scope of the exemptions and accommodations. *See Priests for Life*, 772 F.3d at 276 (good cause existed for the August 2014 IFR because, among other things, "the regulations the interim final rule modifies were recently enacted pursuant to notice and comment rulemaking, and presented virtually identical issues" and the Agencies would "expose [the] interim rule to notice and comment before its permanent implementation"); *Conservation Law Found. v. Evans*, 360 F.3d 21, 29-30 (1st Cir. 2004). As discussed, the Agencies solicited comments following the issuance of three interim final regulations, one advance notice of proposed rulemaking, and two notices of proposed rulemaking on these issues. *See* 75 Fed. Reg. at 41,726; 77 Fed. Reg. at 16,501. Then, following the *Zubik* remand, on July 22, 2016, the Agencies solicited comments for an additional two months. *See* 81 Fed. Reg. 47,741. And Pennsylvania now has a further opportunity to comment on the expanded exemptions before final rules are issued.

Notably, Pennsylvania does not allege any specific comments that it would have submitted on the Rules. But the thousands of public comments submitted in response to the July 26, 2016 RFI include comments raising Establishment Clause, equal protection, due process, First Amendment, and religious freedom concerns, as well as references to the Civil Rights Act and Section 1554 of the ACA. *See* <https://www.regulations.gov/docket?D=CMS-2016-0123>. Similar comments, addressing each of the claims that Pennsylvania now asserts, were submitted in response to earlier rounds of rulemaking the Agencies have conducted over the past six years. *See* <https://www.regulations.gov/docket?D=HHS-OS-2011-0023> (comments on 2011 IFRs);

<https://www.regulations.gov/docket?D=CMS-2012-0031> (comments on 2012 and 2013 proposed changes to definition of religious employer). The comments also addressed proposals similar to the religious employer exemption that ultimately became the final regulation. *See, e.g.*, 77 Fed. Reg. 8,725; 78 Fed. Reg. at 39,869, 39,874. The Agencies enjoyed the benefit of public comment and “the parties have not been deprived of the opportunity to present relevant information by lack of notice that the issue was there.” *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 236 (D.C. Cir. 2008). The absence of prior notice and comment thus would constitute harmless error.

B. Pennsylvania Is Unlikely to Succeed on Its Substantive APA Claims.

The Commonwealth contends that the Rules are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law” under the APA. Compl. ¶ 169 (quoting 5 U.S.C. § 706(2)(A)); PI Mot. at 22. It argues that the Rules (1) are inconsistent with the ACA which “require[s] that group health plans and insurers provide women with preventive care as provided for in guidelines issued by the HRSA, without any cost-sharing requirements,” PI Mot. at 23-24, Compl. ¶ 170; (2) generally constitute an abuse of discretion and are arbitrary and capricious, PI Mot. at 27-28, Compl. ¶ 175; and (3) are not required by the Religious Freedom Restoration Act, PI Mot. at 24-27, Compl. ¶ 173. These contentions are incorrect.

1. The preventive services requirement provides the Agencies with discretion to extend and modify exemptions for any contraceptive coverage mandate.

Congress has given the Agencies wide discretion to craft minimum requirements for women’s preventive healthcare and screenings. The PHSA, as modified by the ACA, requires that covered group health plans “shall, ... at a minimum provide coverage for ... with respect to women, such additional preventive care and screenings ... as provided for in comprehensive guidelines supported by [HRSA] for purposes of this paragraph.” 42 U.S.C. § 300gg-13(a). Congress has also delegated general regulatory authority to the Agencies to “promulgate such regulations as may be necessary or appropriate to carry out the provisions” of the ACA. 42 U.S.C. § 300gg-92; 26 U.S.C. § 9833; 29 U.S.C. § 1191c. The Agencies acted within the clear authority granted to them under these statutes. *See Chevron U.S.A., Inc. v. Nat’l Res. Def. Council*, 467 U.S.

837, 842-43 (1984) (“If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.”).

To begin, the text and structure of § 300gg-13 of title 42 show a clear grant of authority to the Agencies. Section (a) of that provision identifies four categories of services for which covered health plans must provide coverage without any cost-sharing requirements:

(1) evidence-based items or services that have in effect a rating of “A” or “B” in the current recommendations of the United States Preventive Services Task Force;

(2) immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved; and

(3) with respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration.

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

42 U.S.C. § 300gg-13(a)(1)–(4). Because the recommendations and guidelines noted in subsections (a)(1)–(3) were in existence at the time Congress enacted that statutory provision, but the guidelines described in subsection (a)(4) were not, the reference to such guidelines must be understood as a grant of authority to develop them. The Agencies, as administering agencies of the applicable statutes, and HHS, as the agency within which HRSA is located, have general rulemaking authority to guide that development. *See* 42 U.S.C. § 300gg-92; 28 U.S.C. § 9833; 29 U.S.C. § 1191c; 47 Fed. Reg. 38,409 (Aug. 31, 1982). And since their very first rulemaking on this subject in 2011, the Agencies have consistently interpreted that broad authority to include the power to provide limited exceptions that reconcile the ACA’s preventive-services provision with strongly held religious and moral views on the sensitive issue of contraceptive coverage.

The text of subsection (4) confirms that the Agencies have exercised that authority appropriately through these Rules. The language “as supported ... for purposes of this paragraph [(a)(4)]” makes clear that, unlike the preceding subsections, HRSA would have discretion to

develop guidelines that did not already exist and to define the entities that would be subject to them. 76 Fed. Reg. at 46,623; *see also* 82 Fed. Reg. at 47,794. Moreover, while subsection (a)(3) requires provision of those children’s services “provided for” by HRSA, subsection (a)(4) requires provision of preventive services “as provided for” by HRSA. The use of the word “as” suggests that HRSA may determine not only the services covered, but the manner or reach of that coverage. This context suggests that Congress did not intend to foreclose HRSA from considering strongly-held religious and moral objections in defining the scope of the guidelines.

Even if the statutes were ambiguous, this Court must defer to the Agencies’ resolution of that ambiguity. Nothing in the statutes prohibits the Agencies from creating exemptions. *See Chevron*, 467 U.S. at 843 (“[I]f the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency’s answer is based on a permissible construction of the statute”). The Agencies read the statutes to authorize them to craft or modify exemptions for any contraceptive coverage mandate, and that reasonable construction must prevail.

Pennsylvania rewrites § 300gg-13 to mean that the Guidelines supported by HRSA for paragraph (a)(4) can never allow exemptions. That position would forbid even the longstanding, narrower exemption for churches. And, as noted above, the statute expressly contemplates a policy decision about the types of preventive services for women to be covered under that subsection. Although the statute does not expressly mention exemptions, neither does the statute mention contraception. *See* 42 U.S.C. § 300gg-13(a)(4). Moreover, Congress itself indicated that it did not intend absolutely uniform coverage of preventive services across employers. It carved out an exemption for grandfathered plans—an exemption that does not apply to other provisions of the ACA that the Agencies have termed to be “particularly significant protections,” 75 Fed. Reg. 34,538, 34,540 (June 17, 2010). Thus, “of the 150 million nonelderly people in America with employer-sponsored health coverage, approximately 25.5 million are estimated to be enrolled in grandfathered plans” not subject to the Mandate. 82 Fed. Reg. at 47,794. No federal law requires this exemption ever to be phased out. *Id.*

It is thus “consistent with the policy, purpose, and goals” of the statute for the Agencies to issue rules allowing HRSA to issue Guidelines supporting contraceptive coverage so long as such Guidelines afford exemptions to those with religious or moral objections to providing such coverage. *See* PI Mot. at 27 (citing *Frisby v. U.S. Dep’t of Hous. & Urban Dev.*, 755 F.2d 1052, 1057 (3rd Cir. 1985)). Indeed, the Agencies have long interpreted the statutory language to require that the Guidelines determine both the nature and the extent of coverage. *See* 82 Fed. Reg. at 47,794. From the beginning, the Agencies interpreted Section 300gg-13(a)(4), and the statutes granting the Agencies’ general rulemaking authority, to authorize them to craft exemptions. *See* 76 Fed. Reg. at 46,621 (creating the first religious exemption from the contraceptive coverage requirement in the 2011 IFR). The exemptions have persisted through multiple rulemakings and Administrations, although, consistent with the statutes’ grant of discretionary authority, they have not remained static. For example, in 2013, the definition of “religious employer” was revised by eliminating the three-part test that had been present in the original 2011 IFRs. *See* 78 Fed. Reg. at 39,870, 39,896. The 2013 rules also created the accommodation process, which likewise modifies the application of the statute to employers with religious exemptions. *Id.* The new IFRs represent simply one further exercise of the statutes’ discretionary grant.

2. The Agencies’ rationales for exercising this discretion were not arbitrary.

The arbitrary and capricious standard is highly deferential, and presumes the validity of agency action. *Motor Vehicles Mfrs. Ass’n of U.S., Inc. v. Ruckleshaus*, 719 F.2d 1159 (D.C. Cir. 1983). A court may not substitute its judgment for that of the agency, *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971), but must instead affirm an agency’s decision if a rational basis for that decision “may reasonably be discerned.” *E.g., Bowman Transp., Inc. v. Ark.-Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974). Agency action is not arbitrary or capricious if it “is rational, based on consideration of the relevant factors and within the scope of the authority delegated to the agency by the statute.” *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983). Agency action is not subject to any more searching standard of review simply because it is a change in policy. *FCC v. Fox Television Studios, Inc.*, 556 U.S.

502, 515 (2009). An agency that changes policy “need not demonstrate to a court’s satisfaction, that the reasons for the new policy are *better* than the reasons for the old one.” *Id.* at 515. Instead, it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency believes the new policy to be better. *Id.*

Pennsylvania takes one broad statutory purpose—to increase access to preventive care—and elevates it above all others. “But no legislation pursues its purposes at all costs. Deciding what competing values will or will not be sacrificed to the achievement of a particular objective is the very essence of legislative choice—and it frustrates rather than effectuates legislative intent simplistically to assume that *whatever* furthers the statute’s primary objective must be the law.” *Rodriguez v. United States*, 480 U.S. 522, 525–26 (1987). Notwithstanding Pennsylvania’s claim to the contrary, the Agencies did, in fact, consider the interests advanced by the Women’s Health Amendment; they simply did not construe the Amendment to require them to pursue marginal advances to those interests at the expense of all other goals. The Agencies considered that Congress had not required any provision of contraceptive coverage under the ACA, that Congress had elected not to apply the coverage provision to grandfathered plans, and that they had provided exemptions from the Mandate since its creation.

Rather, the Agencies reevaluated the interests served by the former regulations, and reasonably concluded that the interests served by applying the Mandate to organizations with sincere religious or moral objections to providing contraception coverage did not justify the burden on conscience from requiring them to do so. Congress’s repeated efforts to protect religious beliefs and moral convictions in the health care context weigh in the same direction, as do the facts that many objecting entities are willing to provide coverage of at least some contraceptives and that employees of objecting entities are more likely to share the conscience objections of their employer than are employees of other organizations. 82 Fed. Reg. at 47,799–803; 82 Fed. Reg. at 47,844–48. The Agencies also found that the administrative record was insufficient to overcome these conscience concerns, given the lack of compelling evidence that contraceptive coverage accounts for a significant portion of the preventive services cost gap between men and women, the existence

of numerous federal governmental programs to assist low-income women to access free or subsidized contraception, the inadequate tailoring between the Mandate and women most likely to experience unintended pregnancies, and the lack of compelling evidence that statewide contraceptive coverage mandates actually decreased unintended pregnancies. *Id.* at 47,804. For all of these reasons, although the Agencies decided that the IOM recommendations justified the Mandate in the ordinary course, they concluded that expanded exemptions were needed and appropriate to address serious conscience objections to the Mandate.

Accordingly, rather than rescind the Mandate altogether—which they unquestionably have the authority to do—the Agencies pursued a middle way by accommodating religious belief while ensuring that the vast majority of employees retained coverage. The Rules not only allow HRSA to maintain the mandate for contraceptive coverage for non-exempt plans, *see* 82 Fed. Reg. at 47,807 (“granting exemptions ... does not undermine the Government’s interest in ensuring the provision of such coverage to other individuals who wish to receive it”), they keep the former accommodation process as an optional avenue for eligible employers, 82 Fed. Reg. at 47,806. The Rules expand the kinds of employers who may take advantage of the exemptions, but the exemptions are nonetheless cabined to those with sincere religious and moral beliefs. *Id.*; 82 Fed. Reg. 47,853–54. In doing so, the Rules level the playing field with respect to employers with religious objections. *See* 82 Fed. Reg. 47,801 (“[M]any similar religious organizations are being treated very differently [under the previous rules]”).

Although Pennsylvania warns that “virtually any private employer can opt out” (PI Mot. at 3), the Commonwealth glosses over the fact that only employers with sincerely held religious or moral objections may *lawfully* avail themselves of the exemptions. Any employer feigning such an objection would be vulnerable to litigation brought by employees. Accordingly, the Agencies anticipate that the Rules will only moderately expand the number of employers who take advantage of the exemptions. *See* 82 Fed. Reg. at 47,819 (“We expect that some non-litigating entities will use [the expanded exemption], but ... we believe it might not be very many more.”). Moreover, although Pennsylvania argues that the Rules “allow *employers* ... to decide what preventive

services their insured employees may receive,” PI Mot. at 24, the Rules only allow employers to opt out of providing insurance coverage for contraceptive services; nothing in the Rules allows employers to prevent their employees from obtaining contraceptive services, or from receiving other required preventive services. The Agencies took care not to forsake the interests of the previous regulatory regime, while also protecting religious and moral beliefs.

The Agencies also relied on additional valid considerations. For example, the Agencies properly considered their interest in concluding the extensive litigation over the previous rules. An agency does not act arbitrarily or capriciously where it considers the burdens of ongoing litigation when changing agency policy. *Assoc. Builders & Contractors of Tex., Inc. v. NLRB*, 826 F.3d 215, 229 (5th Cir. 2016). In addition, an Executive Order provides an agency with a valid reason to act, because such Orders carry the weight of the President’s Article II directive power. *See Myers v. United States*, 272 U.S. 52 (1926) (recognizing an implied directive power flowing from Article II’s Appointments Clause, Executive Vesting Clause, and Take Care Clause). An agency certainly has a reasoned basis to enter into a rulemaking where the President has instructed it to do so. *See Sherley v. Sebelius*, 689 F.3d 776, 784 (D.C. Cir. 2012) (an agency “may not simply disregard an Executive Order. To the contrary, as an agency under the direction of the executive branch, it must implement the President’s policy directives to the extent permitted by law”). Here, the President instructed the Agencies to “consider issuing amended regulations, consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under section 300gg-13(a)(4) of title 42, United States Code.” Exec. Order No. 13,798, 82 Fed. Reg. at 21,675.

Finally, the requirements of the ACA, RFRA, and Congress’s historical attention to religious freedom and moral conscience guided the Agencies’ decision to issue the Rules. *See* 82 Fed. Reg. at 47,793, 82 Fed. Reg. at 47,844–46. These considerations were not only proper, but compulsory, as agencies must consider all explicit and implicit statutory factors, *see Overton Park*, 401 U.S. at 412, and may only act within their statutory jurisdiction, *see* 5 U.S.C. § 706(2)(C). Congress has consistently sought to protect religious beliefs and moral convictions in the context

of health care, as the preambles to the Rules demonstrate in detail. *See* 82 Fed. Reg. at 47,792 n.1 (listing multiple statutes protecting religious beliefs from health care mandates), 82 Fed. Reg. at 47,844–46 (explaining a 40-year tradition of protecting moral convictions alongside religious beliefs in certain healthcare contexts). As discussed in § IV.B.1, *supra*, these provisions unambiguously authorize the Agencies to create the exemptions at issue here; but even if the statutes were ambiguous, *Chevron* deference would be owed to the Agencies’ reading of them.

3. RFRA requires the Religious Exemption Rule.

Plaintiff also argues that RFRA does not support the Religious Exemption Rule. PI Br. at 25. To the contrary, the Religious Exemption Rule is required by RFRA: the Mandate as applied to those who object on sincere religious or moral grounds under the Rule, even as modified by the accommodation, imposes a substantial burden on religion, and it is not justified by a compelling government interest.¹⁸ Accordingly, even if the ACA did not permit the Agencies to establish exemptions to the Mandate, RFRA would require them to do so.

Congress enacted RFRA in 1993 in response to *Employment Div., Dept. of Human Resources of Ore. v. Smith*, 494 U.S. 872 (1990), which “held that the Constitution does not require judges to engage in a case-by-case assessment of the religious burdens imposed by facially constitutional laws,” *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 424 (2006). Through RFRA, Congress sought to provide fuller protection for the exercise of religion than the Supreme Court had interpreted the Constitution to provide. Accordingly, with one exception, “[u]nder RFRA, the Federal Government may not, as a statutory matter, substantially burden a person’s exercise of religion, even if the burden results from a rule of general applicability.” *Id.* The exception is this: A law that imposes a substantial burden on the exercise of religion is allowed under RFRA if the government “demonstrates that application of the burden

¹⁸ Pennsylvania argues that RFRA does not support the Moral Exemption, or the abandonment of the accommodation process. But the Agencies never contended that RFRA supported the Moral Exemption Rule (as the Commonwealth admits, PI Mot. at 25), so that argument is a straw man. And the Agencies did not abandon the accommodation process; that process remains available. 82 Fed. Reg. 47,792 (“These rules also leave the ‘accommodation’ process in place as an optional process for certain exempt entities that wish to use it voluntarily.”).

to the person—(1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest.” 42 U.S.C. § 2000bb–1(b).

“[T]he exercise of religion involves not only belief and profession but the performance of (or abstention from) physical acts that are engaged in for religious reasons.” *Hobby Lobby*, 134 S. Ct. at 2770. “[A] substantial burden exists where (1) a follower is forced to choose between following the precepts of his religion and forfeiting benefits otherwise generally available ... versus abandoning one of the precepts of his religion in order to receive a benefit; or (2) the government puts substantial pressure on an adherent to substantially modify his behavior and to violate his beliefs.” *Mack v. Warden Loretto*, 839 F.3d 286, 304 (3d Cir. 2016) (citation omitted).

The compelling interest element “requires the Government to demonstrate that the compelling interest test is satisfied through application of the challenged law ‘to the person’—the particular claimant whose sincere exercise of religion is being substantially burdened.” *Hobby Lobby*, 134 S. Ct. at 2779 (internal citations omitted). Here, the Government does not assert any compelling interest in requiring objecting employers to provide the contraceptives at issue.¹⁹ That, in itself, is dispositive: the Government is not aware of any case in which any court has found a government policy to advance a compelling interest where the Government itself does not claim a compelling interest. And, in any event, even where the Government does assert a compelling interest, courts “loo[k] beyond broadly formulated interests and to scrutiniz[e] the asserted harm of granting specific exemptions to particular religious claimants—in other words, to look to the marginal interest in enforcing the contraceptive mandate in these cases.” *Id.* The existence of numerous exceptions to a law can undercut the conclusion that it furthers a compelling interest. *See, e.g., Williams-Yulee v. Fla. Bar*, 135 S. Ct. 1656, 1668 (2015); *Legatus v. Sebelius*, 988 F. Supp. 2d 794, 810 (E.D. Mich. 2013) (“But in this context, given the multiple tens of millions of Americans that are simply exempt from the HRSA mandate, the court is dubious that the

¹⁹ *Hobby Lobby* assumed without deciding that the Mandate served a compelling interest, and such assumptions do not bind future courts. *Hobby Lobby*, 134 S. Ct. at 2759, 2780; *id.* at 2785 (Kennedy, J., concurring).

Government would be able to prove a *compelling* interest.”).

The Religious Exemption Rule reasonably concludes that the Mandate, even as modified by the accommodation, imposes a substantial burden on the exercise of religion. In *Hobby Lobby*, the Supreme Court held that forcing an entity with a religious objection to choose between abiding by the Mandate or paying potentially stiff financial penalties constitutes a substantial burden on religion. *Hobby Lobby*, 134 S. Ct. at 2779. Although the Court has not held that the accommodation—which requires provision of an opt-out notice to the health insurance issuer, TPA, or HHS to avoid the same potentially onerous fines, 80 Fed. Reg. at 41,318—likewise imposes a substantial burden on the exercise of religion,²⁰ the Agencies have reasonably concluded that it does. The accommodation requires some religious objectors to “act in a manner that they sincerely believe would make them complicit in a grave moral wrong as the price of avoiding a ruinous financial penalty.” *Sharpe Holdings, Inc. v. U.S. Dep’t of Health & Human Servs.*, 801 F.3d 927, 941 (8th Cir. 2015), *cert. granted, judgment vacated sub nom. U.S. Dep’t of Health & Human Servs. v. CNS Int’l Ministries.*, No. 15-775, 2016 WL 2842448 (May 16, 2016). It is not the role of the government “to say that their religious beliefs are mistaken or insubstantial.” *Hobby Lobby*, 134 S. Ct. at 2779. The Agencies have thus reasonably concluded that “requiring certain objecting entities or individuals to choose between the Mandate, the accommodation, or penalties for noncompliance imposes a substantial burden on religious exercise under RFRA.” 82 Fed. Reg. at 47,800.

Pennsylvania incorrectly argues that the Religious Exemption Rule’s conclusion regarding the existence of a substantial burden conflicts with Third Circuit case law. *See* PI Mot. at 25. Pennsylvania recognizes that the Third Circuit’s *Geneva* decision, which addressed whether the

²⁰ *Zubik* presented the question, but the Court vacated and remanded the cases—including the Third Circuit’s decision in *Geneva Coll. v. Secretary*, 778 F.3d 422, 427 (3d Cir. 2015), *vacated and remanded sub nom. Zubik*, 136 S. Ct. at 1561—without deciding it, after the Agencies acknowledged that they could refine their accommodation process by allowing such coverage to be offered through their insurance companies without any formal notice from the petitioners, so long as the organization provided the insurer “any request” to exclude coverage of contraceptives. *See* 136 S. Ct. at 1560.

accommodation eliminated the substantial burden for religious objectors, was *vacated* by the Supreme Court in *Zubik*, 136 S. Ct. at 1560-61. But Pennsylvania asserts that the decision in *Real Alternatives, Inc. v. Secretary*, 867 F.3d 338 (3d Cir. 2017), “reaffirmed” that “the accommodation process did not impose a substantial burden.” PI Mot. at 25. That is an overstatement. The panel in *Real Alternatives* stated that the Supreme Court had not overruled the reasoning of *Geneva* and that the panel still believed that *Geneva* was correctly decided. *Real Alternatives*, 867 F.3d at 360-62. But the panel recognized that the vacated *Geneva* opinion is no longer controlling precedent. *Id.* And the panel’s statement is *dicta*, because the case before it did not question whether the Mandate, even as modified by the accommodation, imposed a substantial burden on objecting employers or schools. *Id.* Rather, the *Real Alternatives* panel determined that the accommodation imposed no substantial burden on *employees*—a claim that “is distinct from an *employer’s* RFRA claim objecting to the mandated provision of contraceptive services that was found to be meritorious in [*Hobby Lobby*].” *Real Alternatives*, 867 F.3d at 355 & n.17 (emphasis added).

Both the vacated *Geneva* opinion and the *Real Alternatives dicta* inappropriately dismissed the plaintiffs’ claims of a substantial burden on their religious beliefs. The *Geneva* panel went astray when it questioned the correctness of the plaintiffs’ religious opinions. The plaintiffs had contended that the act of notifying their issuers would make them complicit in the provision of contraceptive services, and the panel erred in substituting its own view of the plaintiffs’ religious doctrine to conclude that that act would not violate their religious beliefs. *See Geneva*, 778 F.3d 435–42. It is not the role of the government “to say that their religious beliefs are mistaken or insubstantial.” *Hobby Lobby*, 134 S. Ct. at 2779. Thus, the Court should “decline to question the Individual Plaintiffs’ religious beliefs under the guise of adjudicating substantial burden. [It should] respect their convictions and conclude that the Contraceptive Mandate—which forces them, under threat of monetary penalty, to sign up for and participate in a system that violates their devoutly held beliefs about human life—is a substantial burden on their exercise of religion.” *Real Alternatives*, 867 F.3d at 385 (Jordan, J., dissenting); *see also Sharpe Holdings, Inc.*, 801 F.3d at 941 (“It is not our role to second-guess CNS and HCC’s honest assessment of a difficult and

important question of religion and moral philosophy, namely, the circumstances under which it is wrong for a person to perform an act that is innocent in itself but that has the effect of enabling or facilitating the commission of an immoral act by another.”) (citation omitted).

Not only does the Religious Exemption Rule reasonably identify a substantial burden, but it also reasonably concludes that there is no compelling interest that justifies the imposition of this burden. The focus here is not on the governmental interests served by the Mandate in general, but on the governmental interests served by applying the Mandate to the small percentage of employers with sincere religious or moral objections to it. *Hobby Lobby*, 134 S. Ct. at 2779. The Rule’s preamble discusses the Agencies’ rationale for determining that there is no compelling interest for this small percentage of employers, 82 Fed. Reg. at 47,800–06; what follows is a synopsis highlighting some of the reasons discussed in the Rule.²¹

First, Congress has never required private employers to offer contraceptive coverage. 82 Fed. Reg. at 47,800–01. These services are absent from paragraph (a)(4), and from any part of the ACA’s provisions defining required benefits. That Congress left open the possibility that contraceptive services would not be covered at all undermines any argument that the government has a compelling interest to require a small subset of employers to provide such coverage over their sincere religious or moral objections. And the fact that Congress left it up to HHS (acting through HRSA) to decide whether contraceptive services should be covered *at all* indicates that HHS’s judgment about whether the inclusion of those services meets the extremely high compelling-interest standard warrants particular deference.

Second, the underinclusiveness of the ACA undermines the claim of a compelling interest in the provision of cost-free contraceptives under the Mandate to that small subset of employers. *Hobby Lobby*, 134 S. Ct. at 2780 (“The objecting parties contend that HHS has not shown that the

²¹ The Commonwealth argues that the Rule’s conclusion on this score contradicts *Hobby Lobby*. PI Mot. at 26. But *Hobby Lobby* did not *decide* that the Mandate served a compelling interest, rather, it explicitly *assumed* that the Mandate served such an interest. *Hobby Lobby*, 134 S. Ct. at 2780, 2786. Such assumptions do not bind future courts. See *United States v. Verdugo-Urquidez*, 494 U.S. 259, 272 (1990); *Tristani ex rel. Karnes v. Richman*, 652 F.3d 360, 362 (3d Cir. 2011).

mandate serves a compelling government interest, and it is arguable that there are features of ACA that support that view.”). The ACA did not extend the Mandate to employees covered by grandfathered plans, though it did require grandfathered plans to comply with other health reform provisions that provide what HHS has described as “particularly significant protections.” 75 Fed. Reg. at 34,540. A requirement can in theory serve a compelling interest even if it is subject to exemptions. But this more limited application of the Mandate, as compared to other “reform provisions,” suggests that the need for cost-free contraceptive services coverage is not a compelling interest when weighed against specific concerns, such as those of the small subset of employers with religious or moral objections. See *Hobby Lobby*, 134 S. Ct. at 2780; *Legatus v. Sebelius*, 988 F. Supp. 2d at 810.

Third, the scope of the pre-existing religious and church-plan exemptions undercuts the argument that there is a compelling interest in requiring objecting entities to facilitate the provision of cost-free contraceptive coverage. The Agencies have already exempted from the mandate all “religious employers” and their related auxiliaries. 78 Fed. Reg. at 39,873–74. Moreover, entities that participated in self-insured church plans were effectively exempt because the government lacks the authority to make the TPA of a self-insured church plan provide contraceptive services. *Roman Catholic Archbishop of Wash. v. Sebelius*, 19 F. Supp. 3d 48, 82–83 (D.D.C. 2013), *aff’d in part, vacated in part sub nom. Priests for Life*, 772 F.3d 229, *vacated and remanded sub nom. Zubik v. Burwell*, 136 S. Ct. 1557 (2016). These already significant exemptions were broadened even further when the Supreme Court recently confirmed that self-insured church plans can include a plan that is not established or maintained by a church (or by a convention or association of churches), but is maintained by “an organization ... the principal purpose or function of which is the administration or funding of a plan or program for the provision of retirement benefits or welfare benefits, or both, for the employees of a church or a convention or association of churches, if such organization is controlled by or associated with a church or a convention or association of churches.” *Advocate Health Care Network v. Stapleton*, 137 S. Ct. 1652, 1656–57 (2017). These broad pre-existing exemptions undercut any claim in a compelling interest in the provision of cost-

free contraceptive services by employers with sincere religious objections to doing so. *See Williams-Yulee*, 135 S. Ct. at 1668.

Fourth, the Agencies have now determined, in their expert judgment, that the administrative record in support of the Mandate does not contain adequate evidence to meet the high standard of proving a compelling interest in providing cost-free contraceptive services by objecting employers. The Agencies explained that the evidence regarding the effect of the Mandate on women’s health is significantly more “uncertain[] and ambigu[ous] ... than the Departments previously acknowledged.” 82 Fed. Reg. at 47,805; *see also id.* at 47,803–05. For example, a recent study by the Guttmacher Institute to determine whether the Mandate changed contraceptive use patterns concluded that the Institute had ““observed no changes in contraceptive use patterns among sexually active women.”” 82 Fed. Reg. at 47,804 (quoting Jonathan M. Bearak & Rachel K. Jones, *Did Contraceptive Use Patterns Change after the Affordable Care Act? A Descriptive Analysis*, 27 *Women’s Health Issues* 316 (2017) (attached as Ex. C)). The Agencies did not take the view that contraceptive coverage has no benefits at all, but simply that the evidence is sufficiently ambiguous to support the conclusion that the compelling interest standard’s high evidentiary bar is not met, and religious objectors should be exempted. The Agencies’ view of this medical evidence is accorded deference because it falls within the ambit of HHS’s expertise. *N.J. Env’tl. Fed’n v. U.S. Nuclear Regulatory Comm’n*, 645 F.3d 220, 228 (3d Cir. 2011) (highest deference is owed to agency conclusions about scientific matters within their area of expertise). There is no compelling interest, then, in applying the Mandate to those employers that will qualify for the expanded religious exemption.²²

4. At a minimum, the Religious Exemption Rule was a permissible response to the substantial burden on religious exercise imposed by the Mandate.

Even if this Court determines that RFRA does not *require* the expansion of the religious

²² And even if there is a compelling interest, there aren’t other equally “least restrictive” means that better advance that interest. After reviewing over 54,000 public comments on the RFI and considering various options, the Agencies could not find a way to amend the accommodation so as to satisfy objecting eligible organizations while pursuing the Agencies’ policy goals. *See* FAQs.

exemption—or opts not to resolve that question here—it should hold that, at a minimum, RFRA *authorized* the Agencies to adopt the Religious Exemption Rule. The Supreme Court’s decision in *Hobby Lobby* makes clear that, absent some form of exemption or accommodation, the Mandate imposes a substantial burden on employers with religious objections to providing contraceptive coverage. 134 S. Ct. at 2775. Previously, the Agencies “attempted to develop an accommodation that would either alleviate the substantial burden imposed on religious exercise or satisfy RFRA’s requirements for imposing that burden.” 82 Fed. Reg. at 47,806. But the Agencies’ attempts did not resolve the sincere religious objections asserted by dozens of employers, and instead led to half a decade of RFRA litigation and serial regulatory amendments. *Id.* at 47,814. Those efforts imposed significant costs on the Agencies and the courts—as well as on regulated entities and their plan participants and beneficiaries, who were left uncertain about their legal rights and obligations.

Under the circumstances, the Agencies reasonably determined that rather than engaging in further efforts to “revis[e] the accommodations previously offered”—an approach that would have entailed continued litigation in dozens of cases, with no foreseeable end—a broader exemption was “the most appropriate administrative response” to the substantial burden identified in *Hobby Lobby*. *Id.* at 47,806. The Agencies emphasized that they would have adopted the Religious Exemption Rule “[e]ven if RFRA does not compel [it].” *Id.*

That independent ground identified by the Agencies provides a fully sufficient basis for upholding the Religious Exemption Rule. Under *Hobby Lobby*, RFRA required the Agencies to take *some* action to respond to the substantial burden imposed by the unmodified mandate. 134 S. Ct. at 2775. Pennsylvania essentially asserts that because (in its view) the prior administrative accommodation did not violate RFRA, the Agencies were required to maintain it. But even if Pennsylvania were right that the accommodation did not violate RFRA, it identifies no legal authority *requiring* the Agencies to respond to the substantial burden identified in *Hobby Lobby* with an accommodation rather than a broader exemption. No such authority exists. “RFRA does not ... prescribe the accommodation that the government must adopt” in response to a substantial burden; instead, it leaves agencies with a measure of “discretion to fashion an appropriate and

administrable response to respect religious liberty interests implicated by their own regulations.” 82 Fed. Reg. at 47,806. And allowing agencies to choose to respond to a substantial burden on religious exercise with an exemption rather than an accommodation is particularly appropriate here, where the Agencies have already attempted an accommodation and that accommodation has been the subject to widespread legal challenges that have divided the courts and that (at an absolute minimum) raise serious questions about its validity.

Pennsylvania’s contrary approach would place agencies in an impossible position. Agencies are often presented with claims that statutory or regulatory requirements substantially burden the exercise of religion. On Pennsylvania’s view, an agency faced with such a claim would apparently be legally prohibited from affording an exemption unless it concluded that that no possible accommodation short of an exemption would be possible and consistent with RFRA. That is a recipe for protracted and unnecessary litigation. It is also inconsistent with the Supreme Court’s recognition in analogous contexts that an entity faced with potentially conflicting legal obligations should be afforded some leeway. For example, the Court has held that, under Title VII, an employer may “engage in intentional discrimination for the asserted purpose of avoiding or remedying an unintentional disparate impact” if the employer has “a strong basis in evidence to believe it will be subject to disparate-impact liability if it fails to take the race-conscious, discriminatory action.” *Ricci v. DeStefano*, 557 U.S. 557, 585 (2009). Critically, the Court did not require the employer to prove that it *actually would* “be subject to disparate-impact liability.” The Court explained that the more flexible standard it adopted “appropriately constrains employers’ discretion in making race-based decisions” but was not “so restrictive that it allows employers to act only when there is a provable, actual violation”—a standard that would have left employers in an untenable position. *Id.* at 583. So too here. Particularly where, as in this case, administrative agencies are faced with substantial claims that RFRA compels an exemption—claims that have been accepted by many courts—the agencies should be permitted to adopt that exemption even if the courts might ultimately have concluded that some form of accommodation would have been consistent with RFRA.

C. Pennsylvania Is Unlikely to Succeed on Its Title VII and Pregnancy Discrimination Act Claim.

The Commonwealth contends that the Rules violate Title VII’s prohibition on pregnancy-related sex discrimination and, therefore, are “not in accordance with law” under the APA, 5 U.S.C. § 706(2)(A). PI Mot. at 28-32. Not so.

Title VII prohibits “employer[s]” from discriminating against an employee or job applicant “because of” or “on the basis of” “sex.” 42 U.S.C. § 2000e-2(a), (b). It extends similar prohibitions to employment agencies and labor organizations. § 2000e-2(b), (c). In 1978, Congress enacted the Pregnancy Discrimination Act, 92 Stat. 2076, which modified the definition of sex-based discrimination to specify, in relevant part, that “because of sex’ ... include[s] ... because of or on the basis of pregnancy, childbirth, or related medical conditions.” 42 U.S.C. § 2000e(k). Title VII prohibits, absent a showing of good cause, both explicitly sex-based distinctions (disparate treatment) as well as distinctions that have a disproportionate effect on one sex (disparate impact). *Id.*; see *E.E.O.C. v. Metal Serv. Co.*, 892 F.2d 341, 346–47 (3d Cir. 1990). To establish a prima facie case of disparate impact in a sex discrimination case, a plaintiff must essentially show “a significant statistical disparity,” *Ricci*, 557 U.S. at 587, in the effect of a regulation on men and women. But the defendant can rebut the suggestion of invidious discrimination by demonstrating that the distinction is required as a matter of “business necessity” or, in the case of the government, the “public interest.” *Id.*; *Tex. Dep’t of Hous. & Cmty. Affairs v. Inclusive Communities Project, Inc.*, 135 S. Ct. 2507, 2518 (2015) (“a business justification— or, in the case of a governmental entity, an analogous public interest”).

As a threshold matter, APA relief is unavailable on this claim. A plaintiff may bring an APA claim only if there is no other adequate legal remedy available. 5 U.S.C. § 704. But, if the Title VII argument had any merit, an adequate remedy would be available: a Title VII suit against allegedly discriminating employers who avail themselves of the exemptions. See *Wash. Legal Found. v. Alexander*, 984 F.2d 483, 486 (D.C. Cir. 1993) (discrimination suits against third parties provide an adequate alternative remedy).

More fundamentally, however, the Rules do not engage in sex discrimination because the Rules do not draw distinctions on the basis of sex or pregnancy. Pennsylvania asserts that “[b]ecause the Rules permit employers to unilaterally opt out of the Contraceptive Care Mandate, and the Contraceptive Care Mandate affects only women affected by pregnancy and related medical conditions, the Rules allow employers to discriminate on the basis of sex.” PI Mot. at 28. It adds, “[s]ince the capacity to become pregnant – and, therefore, the need for contraception if one wishes to prevent pregnancy – is a sex-based characteristic, differential coverage *is* discrimination on the basis of sex.” *Id.* at 31. These arguments are meritless.

The Rules do not authorize sex discrimination because, while they allow certain employers to omit contraceptive coverage, they do not require them to do so. If, as Pennsylvania claims, an employer’s omission of contraceptive coverage violates Title VII, it is still illegal even with the Rules in place. The Rules do not purport to negate any Title VII protections.

In fact, however, the Rules do not draw sex-based distinctions. Rather, they draw coverage distinctions based on whether an employer religiously or morally objects to facilitating the provision of contraceptives. That the Rules relate to contraceptives for women does not establish that they discriminate on the basis of sex. Contraceptives are used by both men and women, and though the Rules expand the exemption for female contraceptives, male contraceptives remain completely uncovered under federal law. *See In Re Union Pac. R.R. Emp’t Practices Litig.*, 479 F.3d 936, 940–42 & n.1 (8th Cir. 2007) (holding that Title VII “does not require coverage of contraception because contraception is not a gender-specific term like potential pregnancy, but rather applies to both men and women”). Thus, the Rules do not violate Title VII’s prohibition on sex-based disparate treatment. *Healey v. Southwood Psychiatric Hosp.*, 78 F.3d 128, 131 (3d Cir. 1996) (disparate treatment encompasses facially discriminatory conduct). Nor do they run afoul of Title VII’s disparate impact rules. The Rules do not have a disproportionate impact on women because no male may receive contraceptive services covered pursuant to 42 U.S.C. § 300gg-13(a)(4), whereas female contraceptive services are covered except where an exemption applies.

Even if the Rules had did have statistically disproportionate effect on women, they still

would not violate Title VII. First, the Rules are supported by the public interest (the equivalent, in this context, of business necessity), rebutting the Commonwealth's prima facie case. As noted earlier, the Government has a legitimate interest in accommodating sincerely held religious and moral beliefs, and the Rules fulfill this interest by alleviating the burden imposed by the Mandate. Second, considerations under RFRA compelled the Agencies to issue the Religious Exemption Rule, *see* § IV.B.3, and this statute takes precedence over any obligations imposed by Title VII. 42 U.S.C. § 2000bb-3 (“This chapter applies to all Federal law, and the implementation of that law, whether statutory or otherwise, and whether adopted before or after November 16, 1993.”).

D. Pennsylvania Is Unlikely to Succeed on Its Equal Protection Claim.

The Commonwealth argues that the Rules violate the equal protection component of the Fifth Amendment's Due Process Clause. PI Mot. at 32-34. It lacks standing to bring this claim, *see supra n.16*, and the claim is meritless for much the same reason as the Title VII claim is. The Rules do not draw a sex-based distinction, nor do they otherwise discriminate on the basis of sex. Rather, the Rules distinguish between employers and institutions that have religious or moral objections to (all or certain) contraceptive services, and those that do not. In other words, whether a woman has coverage under the exemptions depends on whether the woman's employer has a sincere religious or moral objection; it has nothing to do with the fact that she is a woman. That distinction is subject to rational basis review, and the distinction is rational: It recognizes—and protects—the sincerely held views of those who object to facilitating the provision of some or all contraceptive services, while requiring those who have no such objection to pay for those services.

The Due Process Clause of the Fifth Amendment “contains within it [a] prohibition against denying to any person the equal protection of the laws.” *United States v. Windsor*, 133 S. Ct. 2675, 2695 (2013) (citations omitted). When faced with a claim of discrimination on the basis of sex, courts assess (i) whether the classification is facially based upon sex and, if not, (ii) whether there are other factors—such as the purpose of the law or the existence of a disparate impact—that demonstrate an invidious intent to discriminate on the basis of sex. *See Personnel Adm'r of Mass. v. Feeney*, 442 U.S. 256, 274 (1979). With regard to “this second inquiry, [that] impact provides

an important starting point, but purposeful discrimination is the condition that offends the Constitution.” *Id.* (citations omitted). Sex-based distinctions are subject to intermediate scrutiny, meaning that the distinction must be substantially related to an important governmental interest. *Wengler v. Druggists Mut. Ins. Co.*, 446 U.S. 142, 150 (1980). All other distinctions that do not target a protected class or burden a fundamental right are subject to rational-basis review. *Heller v. Doe*, 509 U.S. 312, 319–20 (1993). Under this standard, “a classification must be upheld ... if there is any reasonably conceivable state of facts that could provide a rational basis for the classification,” regardless of the actual basis for the distinction. *Id.* at 320 (citation omitted).

The Rules do not draw any sex-based distinction. Consistent with the ACA, the Rules do *not* require health plans to cover male contraceptives, but do allow HRSA generally to require coverage for female contraceptives, while providing an exemption for those with conscience objections. *See* 78 Fed. Reg. at 8,458 n.3 (excluding “services relating to a man’s reproductive capacity, such as vasectomies and condoms”). Any distinctions in coverage among women are not premised on sex, but on whether the employer, other plan sponsor, or institution of higher education objects, for religious or moral reasons, to facilitating the provision of contraceptives. So, if a woman works for Employer A, who objects and elects to use the exemption rather than the accommodation, her contraceptives will not be covered by her health plan, but if she later takes a job with Employer B, who does not object (and who offers a plan that otherwise is covered by the preventive services mandate), then her contraceptives will be covered. The sex of the employee does not explain the difference in coverage; the objection of the employer does. Men receive no better treatment. To the contrary, as noted, there is no federal requirement for any plan to cover male contraceptives, nor could there be. The statutory provision requiring coverage for additional preventive services supported by HRSA pertains only to such services for “women.” 42 U.S.C. § 300gg-13(a)(4). Any sex-based distinction is a function of the statute, not the Rules.

No other factor reflects any invidious intent to discriminate on the basis of sex. Consider first the purpose. The stated purpose is sex neutral: to “better balance the Government’s interest in ensuring coverage for contraceptive and sterilization services in relation to the Government’s

interests, including as reflected throughout Federal law, [in] provid[ing] conscience protections for individuals and entities with sincerely held religious beliefs [or moral convictions] in certain health care contexts, and [in] minimiz[ing] burdens in our regulation of the health insurance market.” 82 Fed. Reg. at 47,793, 47,839. This purpose finds support in the history of the Rules. The Rules were not written on a blank slate, but instead against the backdrop of years of litigation and negotiation between the Agencies and religious and moral objectors, who, prior to this rule, struggled to find common ground with the government. *See, e.g., Hobby Lobby*, 134 S. Ct. at 2764 n.10; *Zubik*, 136 S. Ct. at 1560. Next, consider the impact. The Rules affect the requirement to provide coverage of women’s contraceptive services and not men’s, but only because 42 U.S.C. § 300gg-13(a)(4) does not authorize a male contraceptive services mandate in the first place. 78 Fed. Reg. at 8,458 n.3. In short, the Rules do not discriminate on the basis of sex.

Because the Rules do not create sex-based distinctions, they are subject to rational basis review. They satisfy this “extremely low” threshold, *United States v. Pollard*, 326 F.3d 397, 408 (3d Cir. 2003), because they are rationally related to legitimate government interests, *Lyng v. Int’l Union*, 485 U.S. 360, 370 (1988). The Religious Exemption Rule accommodates religion by “provid[ing] conscience protections for individuals and entities with sincerely held religious beliefs in certain health care contexts.” 82 Fed. Reg. at 47,793. And the accommodation of religious beliefs is a legitimate government interest, as the Supreme Court recognized in *Cutter v. Wilkinson*, 544 U.S. 709, 720 (2005). The Rule is rationally related to this interest because, by providing an exemption for religious objectors, it alleviates a burden on the exercise of religion.

The Moral Exemption Rule also has a rational basis. It is designed to protect “sincerely held moral convictions” by exempting those with such convictions from facilitating the provision of contraceptive services. 82 Fed. Reg. at 47,839. The government may permissibly accommodate deeply held moral, but not religious, convictions. *See Welsh v. United States*, 398 U.S. 333, 340 (1970) (individual qualified as a religious conscientious objector to the draft if he or she “deeply and sincerely holds beliefs that are purely ethical or moral in source and content but that nevertheless impose upon him a duty of conscience to refrain from participating in any war at any

time, those beliefs certainly occupy in the life of that individual ‘a place parallel to that filled by ... God’ in traditionally religious persons”) (plurality opinion)); *United States v. Seeger*, 380 U.S. 163 (1965) (similar holding); *Doe v. Bolton*, 410 U.S. 179, 197–98 (1973). Indeed, Congress has repeatedly legislated conscience protections in sensitive health contexts, including the provision of contraceptive services. The Commonwealth agrees that it is legitimate to protect non-religious moral beliefs. *See* 18 Pa. Stat. and Cons. Stat. Ann. § 3213 (West) (conscience clause permitting medical professionals and facilities to opt out of providing abortions).

E. Pennsylvania Is Unlikely to Succeed on Its Establishment Clause Claim.

Plaintiff alleges that the Rules violate the Establishment Clause. Compl. ¶¶ 153-58; PI Mot. at 34-38. Specifically, Plaintiff alleges that the Rules intend to and do have the effect of advancing religious interests. Compl. ¶ 155; PI Mot. at 36. This allegation has no merit. The Rules’ protections of entities and individuals with objections to providing contraception based on religious beliefs and moral convictions do not run afoul of the Establishment Clause. The Rules do not themselves promote or subsidize a religious belief or message, as demonstrated most clearly by the fact that their application is not limited to religious entities or persons. Instead of establishing religion, the Rules free entities and individuals with religious or moral objections to the provision of contraception to act as they otherwise would in the absence of government-imposed regulations. The Rules represent a constitutional exercise of executive authority to alleviate unjustified significant burdens on the exercise of moral convictions and religious beliefs.

When government relieves such burdens, it does not violate the Establishment Clause; rather, “it follows the best of our traditions.” *Zorach v. Clauson*, 343 U.S. 306, 314 (1952). “[I]n commanding neutrality the Religion Clauses do not require the government to be oblivious to impositions that legitimate exercises of state power may place on religious belief and practice.” *Bd. of Educ. of Kiryas Joel Vill. Sch. Dist. v. Grumet*, 512 U.S. 687, 705 (1994). Rather, “government may (and sometimes must) accommodate religious practices.” *Corp. of the Presiding Bishop of the Church of Jesus Christ of Latter-Day Saints v. Amos*, 483 U.S. 327, 334 (1987) (quoting *Hobbie v. Unemp. Appeals Comm’n of Fla.*, 480 U.S. 136, 144-45 (1987)). And

“‘there is room for play in the joints between’ the Free Exercise and Establishment Clauses, allowing the government to accommodate religion beyond free exercise requirements, without offense to the Establishment Clause.” *Cutter*, 544 U.S. at 713. Thus, the Supreme Court has upheld a broad range of accommodations against Establishment Clause challenges, including the exemption of religious organizations from Title VII’s prohibition against discrimination in employment on the basis of religion, *see Amos*, 483 U.S. at 335-39; a state property tax exemption for religious organizations, *see Walz v. Tax Comm’n of N.Y.*, 397 U.S. 664, 672–80 (1970); and a state program releasing public school children during the school day to receive religious instruction at religious centers, *see Zorach*, 343 U.S. at 315.

The Supreme Court and the Third Circuit continue to apply the three-part test articulated in *Lemon v. Kurtzman*, 403 U.S. 602 (1971), to evaluate Establishment Clause challenges to government acts seeking to accommodate the practice of religious beliefs. *See Amos*, 483 U.S. at 335; *Stratechuk v. Bd. of Educ., S. Orange-Maplewood Sch. Dist.*, 587 F.3d 597, 604 (3th Cir. 2009). The *Lemon* test requires that government actions (1) have “a secular legislative purpose,” (2) have a “principal or primary effect” that “neither advances nor inhibits religion,” and (3) do not “foster excessive government entanglement with religion.” *Lemon*, 403 U.S. at 612-13 (citations and internal punctuation omitted). The Rules easily satisfy that test.

1. The Rules have a secular purpose.

With respect to *Lemon*’s first prong—that the government act serves a secular legislative purpose—the Supreme Court has recognized that it is a permissible legislative purpose to alleviate significant governmental interference with the exercise of religion. *Amos*, 483 U.S. at 335; *see also Williams v. Bitner*, 285 F. Supp. 2d 593, 600 (M.D. Pa. 2003) (*Amos* recognized that “ensuring fair treatment for *all* individuals, regardless of belief, is a valid secular objective”). This was the precise aim of the executive branch in promulgating the Religious Exemption Rule. *See* 82 Fed. Reg. at 47,793 (purpose of the Rules is “to better balance the Government’s interest in ensuring coverage for contraceptive and sterilization services in relation to the Government’s interests, including as reflected throughout federal law, to provide conscience protections for individuals

and entities with sincerely held religious beliefs in certain health care contexts, and to minimize burdens in our regulation of the health insurance market”). And the aim of the executive branch in promulgating the Moral Exemption Rule was patently secular: the accommodation of moral convictions is *not* based in religion. 82 Fed. Reg. at 47,844.

The first prong of the *Lemon* test “does not mean that the law’s purpose must be unrelated to religion – that would amount to a requirement that the government show a callous indifference to religious groups, and the Establishment Clause has never been so interpreted.” *Amos*, 483 U.S. at 335 (quoting *Zorach*, 343 U.S. at 314). Rather, this prong “mandates only that [the government’s] main goal not be to support a particular viewpoint.” *Williams*, 285 F. Supp. 2d at 600. “Under *Lemon*, if the [governmental action] has *some* secular purpose, then it survives the first prong.” *Doe v. Indian River Sch. Dist.*, 653 F.3d 256, 283 (3d Cir. 2011) (citation omitted). Courts are “normally deferential” to the government’s articulation of a secular purpose as long as it is “sincere and not a sham.” *Stratechuk*, 587 F.3d at 604 (citation omitted).

Here, nothing in the Rules shows any intent to advance a particular faith or to promote religion in general.²³ Instead, the Rules alleviate substantial hardships faced by entities and individuals in providing health insurance. That the Rules apply to entities and individuals with secular, non-religious moral beliefs regarding the provision of contraception confirms that the Rules possess a secular purpose.²⁴ *See also Geneva Coll. v. Sebelius*, 929 F. Supp. 2d 402, 437-40 (W.D. Pa. 2013) (rejecting Establishment Clause challenge to ACA’s exemption).

²³ Plaintiff does not explain why an “abrupt change in policy” would “demonstrate[] [a] clear religious objective.” PI Mot. at 37. Indeed, every religious accommodation is a change in policy, in favor of permissible lifting of a previous government burden on religion. Moreover, this change was not abrupt, but rooted in a seven-year process involving multiple rounds of proposed rules and thousands of comments.

²⁴ Plaintiff misplaces its reliance on two cases relating to the display of Ten Commandments monuments. *See* PI Mot. at 35, 36-37 (citing *McCreary Cty. v. ACLU of Ky.*, 545 U.S. 844, 860 (2005), and *Van Orden v. Perry*, 545 U.S. 677, 683 (2005)). This case does not concern religiously-themed displays on government property, where contextual concerns play a decisive role in evaluating Establishment Clause challenges. *See Newdow v. Rio Linda Union Sch. Dist.*, 597 F.3d 1007, 1022 (9th Cir. 2010) (“Although a display containing the Ten Commandments was at issue in both cases, the Court upheld the display in *Van Orden*, but invalidated it in *McCreary County*. The words displayed were the same, but the context made all the difference[.]”).

2. The effect of the Rules is neither to advance nor inhibit religion.²⁵

The second prong of the *Lemon* test requires that a law’s “principal or primary effect ... neither advance[] nor inhibit[] religion.” *Lemon*, 403 U.S. at 612. The Supreme Court has made clear that removing barriers to the exercise of religious freedom does not advance religion; to the contrary, “there is ample room for accommodation of religion under the Establishment Clause.” *Amos*, 483 U.S. at 338. The Rules do not promote or subsidize a religious belief or message; instead, they merely free entities and individuals with objections to contraception based on religious beliefs and moral convictions to practice those beliefs and convictions as they otherwise would in the absence of certain government-imposed regulations. *See Geneva Coll.*, 929 F. Supp. 2d at 438 (religious-employer exemption to contraceptive-coverage mandate did not “run afoul of the Establishment Clause because it does not make distinctions based upon religious affiliation” and “does not single out one particular religious denomination or religion”).

3. The Rules do not foster excessive government entanglement with religion.

The Rules satisfy the third and final prong of *Lemon* because they do not “entangle the State in an unlawful fostering of religion.” *Hobbie v. Unemployment Appeals Comm’n of Fla.*, 480 U.S. 136, 145 (1987). In *Amos*, the Supreme Court upheld a statutory provision that exempted religious groups from Title VII’s prohibition against religious discrimination, stating that “[i]t cannot be seriously contended that [the statute] impermissibly entangles church and state; the statute effectuates a more complete separation of the two” *Amos*, 483 U.S. at 339. The Rules operate in a similar manner: they reduce state interference with religious exercise. By relieving

²⁵ The Third Circuit has occasionally applied “the ‘endorsement test,’ a modification of the *Lemon* test” in Establishment Clause cases. *Stratechuk*, 587 F.3d at 608. This alternative test “dispenses with *Lemon*’s ‘entanglement’ prong and, combining an objective version of *Lemon*’s ‘purpose’ prong with its ‘effect’ prong, asks whether a reasonable observer familiar with the history and context of a religious display would perceive it as a government endorsement of religion [and] ... whether the government action has the effect of communicating a message of government endorsement or disapproval of religion.” *Id.* at 608–09 (citations and internal punctuation omitted). “Whether ‘the endorsement test’ is part of the inquiry under *Lemon* or a separate inquiry apart from it, the import of the test is the same. [The Court] must determine whether, under the totality of the circumstances, the challenged practice conveys a message favoring or disfavoring religion.” *Id.* at 609. The Rules satisfy this test; in light of the totality of the circumstances, the Rules do not convey a message of government endorsement of religion.

religious institutions from certain government-imposed burdens, the Rules in fact achieve a more complete separation of church and state. In rejecting a similar challenge to the religious-employer exemption to the Mandate, another court in this Circuit explained: “The risk of entanglement in the present case is not excessive, because the government is not providing anything to the covered organizations.” *Geneva Coll.*, 929 F. Supp. 2d at 440. So too here.

Pennsylvania’s reliance on cases such as *Estate of Thornton v. Caldor, Inc.*, 472 U.S. 703 (1985), and *Santa Fe Independent Sch. Dist. v. Doe*, 530 U.S. 290 (2000), is similarly misplaced. PI Mot. at 37–38. *Estate of Thornton* involved a statute that “compel[led] people to act in the name of ... religion” by requiring private employers to permit employees to take off work on their chosen Sabbath day, *Estate of Thornton*, 472 U.S. at 708, and *Santa Fe* involved an allegation of government-sponsored speech that endorsed a religion. By contrast, the Rules neither compel nor encourage any action on private employers’ part. Rather, they leave room for private employers to exercise their religion by declining to provide contraceptive coverage if doing so would conflict with the employers’ religious beliefs or moral convictions. This lifting of a *government-imposed* burden on religious exercise is permitted under the accommodation doctrine referenced in *Amos*. See *Tex. Monthly, Inc. v. Bullock*, 489 U.S. 1, 18 n.8 (1989) (plurality opinion). In addition, *Estate of Thornton* involved government interference with private contracts. By contrast, the Rules involve a benefit that the government need not have required at all. The Establishment Clause should not be interpreted to require the government to broadly withdraw benefits.

V. THE BALANCE OF EQUITIES AND PUBLIC INTEREST MAKE INJUNCTIVE RELIEF INAPPROPRIATE.

The balance of hardships and the public interest weigh against issuing an injunction here. Where the government is a party, these two inquiries merge. *Nken v. Holder*, 556 U.S. 418, 435 (2009). There is inherent harm to an agency in preventing it from implementing regulations that Congress found to be in the public interest to direct that agency to develop. *Cornish v. Dudas*, 540 F. Supp. 2d 61, 65 (D.D.C. 2008); see also *Richenberg v. Perry*, 73 F.3d 172, 173 (8th Cir. 1995). Furthermore, although it is true that “it is always in the public interest to prevent the

violation of a party's constitutional rights," *Am. Freedom Def. Init. v. S.E. Penn. Transp. Auth.*, 92 F. Supp. 3d 314, 331 (E.D. Pa. 2015) (emphasis added), the Commonwealth has not asserted a violation of any of its own constitutional rights in this case.

Nor has the Commonwealth explained that any harm to it outweighs the public interest. Eligible religious organizations have long been able to claim an exemption to the Mandate—this rule simply equalizes the availability of those exemptions for others with sincerely held beliefs. *See* 82 Fed. Reg. at 47,794–95. An injunction would undermine the critical public interest in protecting religious liberty. Moreover, the government, the public, and the individual employers with burdened beliefs have a strong interest in seeing the Agencies exercise their statutory mandate with the discretion Congress intended.

CONCLUSION

The Court should deny Pennsylvania's motion for a preliminary injunction.

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CERTIFICATE OF SERVICE

I hereby certify that, on November 16, a copy of the forgoing document was electronically filed with the Clerk of the Court using the CM/ECF system which will send notification of such filing to all counsel of record.

DATED this 16th day of November, 2017.

/s/ Elizabeth L. Kade
ELIZABETH L. KADE