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The Contraceptive Coverage Requirement and Legal Challenges Five Years After *Hobby Lobby*

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SUMMARY

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The Contraceptive Coverage Requirement and Legal Challenges Five Years After *Hobby Lobby*

When Congress enacted the Patient Protection and Affordable Care Act (ACA) in 2010, it required employment-based health plans and health insurance issuers to cover certain preventive health services without cost sharing. Those services, because of agency guidelines and rules, would soon include contraception for women. The "contraceptive coverage requirement," or "contraceptive mandate" as it came to be known, was heavily litigated in the years to follow. These challenges primarily concerned (1) what types of employers and institutions should be exempt from the requirement based on their religious or moral objections to contraception; (2) what procedures the government can require for an entity to invoke a religious-based accommodation; and (3) how much authority federal agencies have to create exceptions to the coverage requirement. As originally formulated, only houses of worship and similar entities were exempt from the requirement, but the government later added an accommodation process for certain religious nonprofit organizations.

On June 30, 2014, the Supreme Court held in *Burwell v. Hobby Lobby Stores, Inc.* that the contraceptive coverage requirement violated federal law insofar as it did not also accommodate the religious objections of closely held, for-profit corporations. The law at issue in that case—the Religious Freedom Restoration Act of 1993 (RFRA)—prohibits the federal government from "substantially burden[ing] a person's exercise of religion" except under narrow circumstances. Since *Hobby Lobby*, the agencies tasked with implementing the ACA have faced numerous hurdles in their attempts to accommodate the interests of sincere objectors while minimizing disruptions to the provision of cost-free contraceptive coverage to women. The lower courts split on whether the accommodation process—which required eligible objecting entities to notify their insurers or the government that they qualified for an exemption—substantially burdened the objectors' exercise of religion. Initially, most circuit courts rejected the view that such an accommodation triggered, facilitated, or otherwise made objectors complicit in the provision of coverage, denying their RFRA claims. After consolidating some of these cases for review, the Supreme Court ultimately vacated and remanded the decisions when the government and the objecting parties suggested that a solution might be reached so that the objectors' insurers could provide the required coverage without notice from the objecting parties.

However, following a change in presidential administration, the implementing agencies reevaluated and reversed their position on the legality of the then-existing accommodation process, concluding that it violated RFRA when applied to certain entities. The agencies opted to automatically exempt most nongovernmental entities that objected to providing coverage for some or all forms of contraception on religious or moral grounds. These expanded exemptions sparked a new round of litigation based on claims that the agencies exceeded their authority under the ACA or violated federal requirements for promulgating new rules. Federal courts have preliminarily enjoined the government from implementing the expanded exemptions. At the same time, the government is largely precluded from relying on the prior accommodation process as a result of a nationwide injunction issued by a federal district court.

From a legal perspective, Congress has several options for clarifying the scope of the contraceptive coverage requirement, including through amendments to the ACA and RFRA. For now, the implementing agencies and the courts will likely continue to grapple with the extent of the mandate and its compliance with RFRA and other legal protections.

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When Congress enacted the Patient Protection and Affordable Care Act (ACA) in 2010, it required employment-based health plans and health insurance issuers to cover certain preventive health services without cost sharing.[1] Those services, because of agency guidelines and rules, would soon include contraception for women.[2] The federal contraceptive coverage requirement—sometimes called the "contraceptive mandate"[3]—has generated significant public policy and legal debates. Proponents of the requirement have stressed a need to make contraception more widely accessible and affordable to promote women's health and equality.[4] Opponents have centrally raised religious freedom–based objections to paying for or otherwise having a role in the provision of coverage for some or all forms of contraception.[5] The Supreme Court first took up a challenge to the contraceptive coverage requirement in 2014 in *Burwell v. Hobby Lobby Stores, Inc.*[6] In *Hobby Lobby*, the Court held that the requirement did not properly accommodate the religious objections of closely held corporations.[7]

Since *Hobby Lobby*, legal challenges to the contraceptive coverage requirement have continued, leaving the scope and enforceability of the requirement in an uncertain legal posture. The lower federal courts divided over the legality of an accommodation process instituted in 2013 that shifted the responsibility to provide coverage from an objecting employer to its insurer once the employer certified its religious objections.[8] In 2017, citing the uncertain legal footing of that accommodation, the Trump Administration decided to automatically exempt most nongovernmental entities from the coverage requirement based on their religious or moral

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[1] *See* Pub. L. No. 111-148, tit. I, subtit. A, § 1001, subtit. G, § 1562(e)–(f), 124 Stat. 119, 131, 270 (Mar. 23, 2010). Cost sharing refers to out-of-pocket charges that the insured individual has to pay, such as a copayment, coinsurance, or deductible. *See* Ctrs. for Medicare & Medicaid Servs., *Cost Sharing*, HEALTHCARE.GOV, https://www.healthcare.gov/glossary/cost-sharing/ (last visited Sept. 23, 2019) (stating that cost sharing "generally includes deductibles, coinsurance, and copayments, or similar charges").

[2] *E.g.*, Health Res. & Servs. Admin., *Women's Preventive Services Guidelines*, HRSA, https://www.hrsa.gov/womens-guidelines/index.html (last updated Sept. 2018); Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 76 Fed. Reg. 46,621 (Aug. 3, 2011) (effective Aug. 1, 2011).

[3] *E.g.*, Burwell v. Hobby Lobby Stores, Inc., 573 U.S. 682, 692 (2014); Pennsylvania v. President United States, 930 F.3d 543, 556 (3d Cir. 2019).

[4] *See, e.g.*, INST. OF MED., CLINICAL PREVENTIVE SERVICES FOR WOMEN: CLOSING THE GAPS 104–07, 109–10 (2011) (finding that contraception and contraceptive counseling are effective interventions to reduce unintended pregnancies and promote healthy spacing between pregnancies); Brief of Amici Curiae American College of Obstetricians and Gynecologists et al. in Support of the Government at 1, Burwell v. Hobby Lobby Stores, Inc., 573 U.S. 682 (2014) (Nos. 13-354, 13-356) (stating the organizations' belief that "increased access to the full range of FDA-approved prescription contraceptives is an essential component of effective health care for women and their families"); Brief for the National Women's Law Center and Sixty-Eight Other Organizations as Amici Curiae in Support of the Government at 3, *Hobby Lobby*, 573 U.S. 682 (Nos. 13-354, 13-356) (arguing that "by addressing gender gaps in health insurance and remedying the sex disparities inherent in failing to provide health insurance coverage for contraception and related services, the contraception regulations advance the compelling governmental interest in ending gender discrimination and promoting gender equality").

[5] *See, e.g.*, Petition for a Writ of Certiorari at 1, Little Sisters of the Poor Home for the Aged v. Burwell (Zubik v. Burwell), 136 S. Ct. 1557 (2016) (No. 15-105) (stating that the "Little Sisters sincerely believe that all the available compliance methods would make them morally complicit in grave sin"); Brief for Respondents at 9–10, *Hobby Lobby*, 573 U.S. 682 (Nos. 13-354, 13-356) (explaining that Hobby Lobby objected on religious grounds to covering four particular contraceptive methods).

[6] 573 U.S. 682.

[7] *Id.* at 736.

[8] *See* Massachusetts v. HHS, 923 F.3d 209, 215 (1st Cir. 2019) (noting that "[n]ine circuits considered the issue from late 2014 to early 2016," with eight holding that the accommodation process "did not substantially burden religious exercise" and one holding that it did).

objections.[9] However, more than 15 states filed or joined lawsuits challenging the expanded exemptions.[10] Federal courts have preliminarily enjoined the government from implementing the expanded exemptions while those challenges proceed.[11] At the same time, the government is largely precluded from relying on the prior accommodation process as a result of a nationwide injunction issued by a federal district court.[12]

This report begins by explaining the statutory and regulatory framework for the federal contraceptive coverage requirement. It then recaps the Supreme Court's decision in *Hobby Lobby* before discussing the agency actions taken in response to that decision and subsequent Supreme Court rulings and executive action. Next, the report discusses court cases involving challenges to the coverage exemptions and accommodations, including cases pending in federal district or appellate courts in the First, Third, Fifth, and Ninth judicial circuits.[13] The report concludes with some considerations for Congress, including broadly identifying legal options for clarifying the scope of the contraceptive coverage requirement.

The Contraceptive Coverage Requirement

The federal contraceptive coverage requirement stems from the Patient Protection and Affordable Care Act but was developed and modified by subsequent agency guidelines and rules.[14] Before the ACA, various federal and state requirements dictated whether a health plan needed to cover contraceptive services.[15] Although more than half of the states required plans covering prescription drugs to include contraception,[16] access was typically subject to cost-sharing requirements.[17] The scope of religious exemptions from these state requirements varied.[18]

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[9] *See* Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,792, 47,799, 47,809, 47,835 (Oct. 13, 2017) (effective Oct. 6, 2017) [hereinafter Religious Exemption IFR]; Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 82 Fed. Reg. 47,838, 47,862 (Oct. 13, 2017) (effective Oct. 6, 2017) [hereinafter Moral Exemption IFR].

[10] *See* Pennsylvania v. Trump, 351 F. Supp. 3d 791, 803 (E.D. Pa. 2019) (challenge by Pennsylvania and New Jersey); California v. HHS, 351 F. Supp. 3d 1267, 1279 (N.D. Cal. 2019) (challenge by California, Connecticut, Delaware, Hawaii, Illinois, Maryland, Minnesota, New York, North Carolina, Rhode Island, Vermont, Virginia, Washington, and the District of Columbia); Massachusetts v. HHS, 301 F. Supp. 3d 248, 250 (D. Mass. 2018) (challenge by Massachusetts).

[11] *See* Pennsylvania v. President United States, 930 F.3d 543, 576 (3d Cir. 2019) (upholding the district court's nationwide preliminary injunction); California v. HHS, 351 F. Supp. 3d 1267, 1301 (N.D. Cal. 2019) (granting a preliminary injunction limited to the plaintiff-states), *appeal filed and argued sub nom.* California v. Azar, Nos. 19-15150 et al. (9th Cir. 2019).

[12] *See* DeOtte v. Azar, No. 4:18-cv-00825-O, 2019 U.S. Dist. LEXIS 137849, at *45–54 (N.D. Tex. June 5, 2019).

[13] Subsequent references to a particular circuit in this report refer to the U.S. Court of Appeals for that circuit.

[14] *See* Burwell v. Hobby Lobby Stores, Inc., 573 U.S. 682, 697–98 (2014) (noting that "Congress itself . . . did not specify what types of preventive care must be covered" under the ACA but authorized "a component of HHS" to make that decision, which it did in consultation with "a nonprofit group of volunteer advisers," subject to exemptions set out in agency guidelines and rules).

[15] *See* INST. OF MED., *supra* note 4, at 47, 51–52 (providing background on federal and state laws about preventive services coverage).

[16] *Id.* at 51, 108 (citing BLUE CROSS BLUE SHIELD ASS'N, STATE LEGISLATIVE HEALTHCARE AND INSURANCE ISSUES: 2010 SURVEY OF PLANS (2010) and GUTTMACHER INST., INSURANCE COVERAGE OF CONTRACEPTIVES (2011)).

[17] *See* Laurie Sobel et al., Issue Brief, *State and Federal Contraceptive Coverage Requirements: Implications for Women and Employers*, KFF (Mar. 29, 2018) ("While a number of states had contraceptive equity laws that required plans to cover some or all methods, cost-sharing typically applied.").

[18] *See* Nat'l Conf. of State Legislatures, *Insurance Coverage for Contraception Laws*, NCSL (Feb. 2012),

Moreover, each state's law extended "only to insurance plans that [were] sold to employers and individuals in [that] state."[19] It did not apply to *self-insured* employer-sponsored health plans (also known as self-funded plans) in which nearly 60% of covered workers were enrolled.[20] Self-insured plans are governed by the Employee Retirement Income Security Act of 1974 (ERISA),[21] a federal law that generally did not require coverage for specific preventive services before the ACA.[22] Nevertheless, whether as a matter of law or industry practice, "most private insurance and federally funded insurance programs" offered some form of insurance coverage for contraception before the federal contraceptive coverage requirement.[23]

With the enactment of the ACA, Congress required certain employment-based health plans and health insurance issuers (insurers)[24] to cover various preventive health services without cost

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http://www.ncsl.org/research/health/insurance-coverage-for-contraception-state-laws.aspx (stating that 21 states "offer exemptions from contraceptive coverage, usually for religious reasons, for insurers or employers in their policies"); Susan J. Stabile, *State Attempts to Define Religion: The Ramifications of Applying Mandatory Prescription Contraceptive Coverage Statutes to Religious Employers*, 28 HARV. J. L. & PUB. POL'Y 741, 748 (2005) ("Most, but not all, of the state statutes that mandate prescription contraceptive coverage contain some exclusion for churches and other religious organizations. Those exclusions are framed in various ways."); Inimai M. Chettiar, Comment, *Contraceptive Coverage Laws: Eliminating Gender Discrimination or Infringing on Religious Liberties?*, 69 U. CHI. L. REV. 1867, 1878 (2002) ("Some state laws have no religious exemptions. Additionally, some exemptions apply to employers, others to insurers, and some to both. Other exemptions only apply to a specific group of employers or insurers. Some exemptions apply to any religious employer or insurer that has religious beliefs against contraception and elects to invoke the exemption.").

[19] INST. OF MED., *supra* note 4, at 51.

[20] *Id.* at 48, 51; *see also* Massachusetts v. HHS, 923 F.3d 209, 218 (1st Cir. 2019) (stating that two Massachusetts laws adopting contraceptive coverage requirements for employer-sponsored health plans did "not apply to self-insured plans, because such plans come under [ERISA] (which preempts state regulation)"). With self-insured plans, "the employer itself collects premiums from enrollees and takes on the responsibility of paying employees' and dependents' medical claims" and may "contract for insurance services such as enrollment, claims processing, and provider networks with a third party administrator." Ctrs. for Medicare & Medicaid Servs., *Self-Insured Plan*, HEALTHCARE.GOV, https://www.healthcare.gov/glossary/self-insured-plan/ (last visited Sept. 23, 2019).

[21] *See* FMC Corp. v. Holliday, 498 U.S. 52, 61, 64 (1990) (interpreting ERISA's preemption provisions to "exempt self-funded ERISA plans from state laws that 'regulate insurance,'" concluding that "if a plan is insured, a State may regulate it indirectly through regulation of its insurer and its insurer's insurance contracts; if the plan is uninsured, the State may not regulate it" (quoting 29 U.S.C. § 1144)); *see generally Health Plans & Benefits: ERISA*, U.S. DEPARTMENT OF LABOR, https://www.dol.gov/general/topic/health-plans/erisa (last visited Sept. 23, 2019) ("In general, ERISA does not cover group health plans established or maintained by governmental entities, churches for their employees, or plans which are maintained solely to comply with applicable workers compensation, unemployment, or disability laws.").

[22] INST. OF MED., *supra* note 4, at 48–49.

[23] *Id.* at 108; *see also* KAISER FAMILY FOUND. ET AL., EMPLOYER HEALTH BENEFITS: 2010 ANNUAL SURVEY 1, 186, 196 (2010) (stating that 63% of nonfederal private and public employers reported "that their plan with the largest enrollment cover[ed] prescription contraceptives, such as birth control pills, patches, implants, shots, IUDs, or diaphragms," and that 31% did not know whether their largest plan covered contraceptives).

[24] ACA's preventive health services requirement applies to a "group health plan and a health insurance issuer offering group or individual health insurance coverage." 42 U.S.C. § 300gg-13(a). Certain plans, such as "short-term limited duration insurance" and grandfathered health plans, are not subject to the requirement. *See id.* § 300gg-91 (stating that "'individual health insurance coverage' . . . does not include short-term limited duration insurance"); *id.* § 18011 (stating, in a section pertaining to "grandfathered health plans," that certain amendments the ACA made that included the preventive health services coverage requirement do not apply to "a group health plan or health insurance coverage in which an individual was enrolled on the date of enactment" (March 23, 2010) "regardless of whether the individual renews such coverage after such date"); Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Patient Protection and Affordable Care Act, 75 Fed. Reg. 34,538, 34,540 (Jun. 17, 2010) (noting that "grandfathered health plans are not required to comply with . . . [the ACA's] requirement that preventive health services be covered without any cost sharing").

sharing.[25] One ACA provision specifically requires coverage "with respect to women" for "preventive care and screenings . . . as provided for in comprehensive guidelines supported by the Health Resources and Services Administration [(HRSA)]" within the U.S. Department of Health and Human Services (HHS).[26] To implement this requirement, HHS commissioned a study by the Institute of Medicine (IOM)[27] "to review what preventive services are necessary for women's health and well-being."[28] In its final report, the IOM recommended that HRSA consider including the "full range of Food and Drug Administration [(FDA)]-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity."[29] Among other reasons, IOM concluded that "[s]ystematic evidence reviews and other peer-reviewed studies provide evidence that contraception and contraceptive counseling are effective at reducing unintended pregnancies," which HHS had identified as a specific national health goal.[30] HRSA adopted the IOM's recommendation, including in HRSA's 2011 *Women's Preventive Services Guidelines* (HRSA guidelines) "all" FDA-approved contraception[31] "as prescribed."[32]

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[25] *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, tit. I, subtit. A, § 1001, 124 Stat. 119, 131 (Mar. 23, 2010) (codified at 42 U.S.C. § 300gg-13(a)) (requiring "at a minimum" coverage for, among other things, certain immunizations as well as "preventive care and screenings" for infants, children, and adolescents). The ACA incorporated the preventive health services coverage requirements into ERISA and the Internal Revenue Code. *See id.* at tit. I, subtit. G, § 1562(e), 124 Stat. 119, 270 (codified at 29 U.S.C. § 1185d); *id.* at tit. I, subtit. G, § 1562(e), 124 Stat. 119, 270 (codified at 26 U.S.C. § 9815). ERISA is a federal law implemented by the Department of Labor that provides minimum standards for group health plans offered by private-sector employers, as well as health insurance issuers offering coverage in the group market. *See Health Plans & Benefits: ERISA*, U.S. DEPARTMENT OF LABOR, https://www.dol.gov/general/topic/health-plans/erisa (last visited Sept. 23, 2019). The Department of the Treasury administers and enforces the Internal Revenue Code, and its provisions governing preventive services also apply to group health plans and health insurance issuers in the group market. *See* 26 C.F.R. § 54.9815-2713 (setting out the preventive health services coverage requirements with respect to group health plans and issuers offering group health insurance coverage).

[26] 42 U.S.C. § 300gg-13(a)(4).

[27] IOM, which is now called the National Academy of Medicine, is a nonprofit organization affiliated with the National Academies of Sciences and Engineering that advises on matters of health. *About the National Academy of Medicine*, NATIONAL ACADEMY OF MEDICINE, https://nam.edu/about-the-nam/ (last visited Sept. 23, 2019).

[28] *Women's Preventive Services Guidelines*, HRSA, https://www.hrsa.gov/womens-guidelines/index.html (last updated Sept. 2018).

[29] INST. OF MED., *supra* note 4, at 109–10.

[30] *Id.* at 104, 109 (citing HHS, *Healthy People 2020: Topics & Objectives*, HEALTHYPEOPLE.GOV, http://www.healthypeople.gov/2020/topicsobjectives2020/default.aspx (accessed Apr. 19, 2011)); *see generally* HHS, *Healthy People 2020: Family Planning*, HEALTHYPEOPLE.GOV, https://www.healthypeople.gov/2020/topics-objectives/topic/family-planning (last accessed Sept. 12, 2019) (summarizing the family planning goal to "[i]mprove pregnancy planning and spacing, and prevent unintended pregnancy").

[31] For brevity, this report refers to the FDA-approved "contraceptive methods, sterilization procedures, and patient education and counseling" referenced in the HRSA guidelines as "contraception," "contraceptives," or "contraceptive services."

[32] *Women's Preventive Services Guidelines*, HRSA, https://www.hrsa.gov/womens-guidelines/index.html (last updated Sept. 2018). Other covered services included gestational diabetes screening for pregnant women, lactation support and counseling, annual HIV counseling and screening for sexually active women, and domestic violence screening and counseling. *Id.* HRSA amended its guidelines in 2016 based on a review by a panel of "clinician, academic, and consumer-focused health professional organizations." *Women's Preventive Services Guidelines*, HRSA, https://www.hrsa.gov/womens-guidelines-2016/index.html (last updated Oct. 2017). The panel continued to recommend "the full range of female-controlled [FDA]-approved contraceptive methods" (listed in the updated HRSA guidelines) as well as "follow-up care" and "instruction in fertility awareness-based methods . . . for women desiring an alternative method." *Id.*

The HRSA guidelines applied to plan years beginning on or after August 1, 2012.[33] However, they exempted certain "religious employers"—houses of worship and certain related entities that primarily employed and served persons who shared their religious tenets.[34] In 2012, HHS announced a temporary "safe harbor" from government enforcement of the coverage requirement for certain nonexempt, nonprofit organizations with religious objections to covering some or all forms of contraception.[35] Subsequent rules called such nonprofits "eligible organizations."[36]

On July 2, 2013, following a notice and comment period, HHS, the Department of Labor (DOL), and the Department of the Treasury (the Departments)[37] jointly issued a final rule (2013 Rule) to "simplify and clarify the religious employer exemption" and "establish accommodations" for eligible organizations.[38] The rule continued to authorize HRSA to provide an automatic exemption to the coverage requirement for houses of worship.[39] However, it no longer required those employers to have "the inculcation of religious values" as their purpose or to "primarily" employ and serve "persons who share [their] religious tenets" to qualify for the exemption.[40]

The 2013 Rule also established an accommodation process for "eligible organizations"[41]—essentially, nonprofit, religious organizations with religious objections to some or all forms of

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[33] *Women's Preventive Services Guidelines*, HRSA, https://www.hrsa.gov/womens-guidelines/index.html (last updated Sept. 2018).

[34] *See* Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 76 Fed. Reg. 46,621, 46,623 (Aug. 3, 2011) (effective Aug. 1, 2011) (authorizing HRSA to exempt "religious employers," defined as entities with "the inculcation of religious values as [their] purpose," that "primarily" employ and serve "persons who share [their] religious tenets," and that qualify for certain nonprofit statuses under the Internal Revenue Code for "churches, their integrated auxiliaries, and conventions or associations of churches, as well as to the exclusively religious activities of any religious order"); Religious Exemption IFR, *supra* note 9, at 47,795 (noting that HRSA exercised its discretion to adopt a religious employer exemption the same day that the Departments issued their 2011 rule authorizing such an exemption).

[35] Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act, 77 Fed. Reg. 8,725, 8,728 (Feb. 15, 2012) (finalizing the "religious employer" exemption from the 2011 interim rule without change and establishing a one-year safe harbor for other objecting nonprofits); *see also* CTR. FOR CONSUMER INFO. & INS. OVERSIGHT, CTRS. FOR MEDICARE & MEDICAID SERVS., GUIDANCE ON THE TEMPORARY ENFORCEMENT SAFE HARBOR FOR CERTAIN EMPLOYERS, GROUP HEALTH PLANS AND GROUP HEALTH INSURANCE ISSUERS WITH RESPECT TO THE REQUIREMENT TO COVER CONTRACEPTIVE SERVICES WITHOUT COST SHARING UNDER SECTION 2713 OF THE PUBLIC HEALTH SERVICE ACT, SECTION 715(A)(1) OF THE EMPLOYEE RETIREMENT INCOME SECURITY ACT, AND SECTION 9815(A)(1) OF THE INTERNAL REVENUE CODE (2013), https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/preventive-services-guidance-6-28-2013.pdf (extending the 2012 safe harbor to plan years beginning before Jan. 1, 2014).

[36] Coverage of Certain Preventive Services Under the Affordable Care Act, 78 Fed. Reg. 39,870, 39,871 (July 2, 2013) [hereinafter 2013 Rule].

[37] Unless otherwise noted, each of the regulations discussed in this report was promulgated by all three departments.

[38] 2013 Rule, *supra* note 36, at 39,870.

[39] *Id.* at 39,896; *see also* U.S. DEP'T OF LABOR, FAQS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION PART 36, at 6 (2017), https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf (referring to religious employers as "automatically exempt").

[40] 2013 Rule, *supra* note 36, at 39,873–74. Specifically, the 2013 Rule defined "religious employer" as "an organization that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Internal Revenue Code of 1986, as amended." *Id.* at 39,896. That section of the Tax Code, in turn, referred to "churches, their integrated auxiliaries, and conventions or associations of churches, as well as to the exclusively religious activities of any religious order." *Id.* at 39,871. The amended definition of "religious employer" took effect for plan years beginning on or after August 1, 2013. *Id.* at 39,870.

[41] To qualify as an eligible organization, an entity must (1) oppose providing coverage for some or all of the required contraceptive services "on account of religious objections"; (2) be a nonprofit entity that holds itself out as a religious organization; and (3) comply with the rule's self-certification requirements. 2013 Rule, *supra* note 36, at 39,896.

contraception.[42] The accommodation also extended to student health plans arranged by eligible institutions of higher education.[43] Eligible organizations could comply with the contraceptive coverage requirement by completing a self-certification form provided by HHS and DOL and sending copies of this form to their insurers or third-party administrators (TPAs), as applicable.[44] For insured plans, the rule required the issuers, upon receipt of a certification, to "[e]xpressly exclude contraceptive coverage" (or the subset of objected-to methods) from the applicable plans but separately pay for any required, excluded contraceptive services for the enrolled individuals and their beneficiaries.[45] For self-insured plans, the rule stated that the TPA, upon receipt of a certification, would become the "plan administrator" for contraceptive benefits under ERISA and responsible for providing contraceptive coverage.[46] In addition, the certification provided to the TPA would become "an instrument under which the plan is operated."[47] The rule required the insurer or TPA, rather than the objecting organization, to notify plan participants that separate payments would be made for contraception and that the organization would not be administering or funding such coverage.[48]

RFRA and the *Hobby Lobby* Decision

Numerous organizations filed lawsuits challenging the contraceptive coverage requirement and the accommodation process.[49] Among other claims, these plaintiffs argued that the requirement violated the Religious Freedom Restoration Act of 1993 (RFRA).[50] RFRA is a federal statute enacted in response to *Employment Division v. Smith*,[51] a 1990 Supreme Court decision holding that the Free Exercise Clause of the First Amendment does not require the government to exempt religious objectors from generally applicable laws.[52] Except under narrow circumstances, RFRA

[42] The accommodation took effect for plan years beginning on or after January 1, 2014. 2013 Rule, *supra* note 36, at 39,870.

[43] 2013 Rule, *supra* note 36, at 39,881.

[44] *Id.* at 39,872, 39,894–96. As previously noted, some employers with self-insured plans contract with TPAs to manage enrollment, process claims, or provide other insurance services. *See* Ctrs. for Medicare & Medicaid Servs., *Self-Insured Plan*, HEALTHCARE.GOV, https://www.healthcare.gov/glossary/self-insured-plan/ (last visited Sept. 23, 2019).

[45] 2013 Rule, *supra* note 36, at 39,896.

[46] *Id.* at 39,880, 39,894. The TPA could make the required payments itself or arrange for an issuer or other entity to do so. *Id.* at 39,895.

[47] *Id.* at 39,894.

[48] *Id.* at 39,893.

[49] *See* Pennsylvania v. Trump, 351 F. Supp. 3d 791, 800 (E.D. Pa. 2019) (noting that during the promulgation of the 2013 rule, "a host of legal challenges to the Contraceptive Mandate progressed through the federal courts, several of which eventually reached the Supreme Court").

[50] Pub. L. No. 103-141, 107 Stat. 1488 (1993) (codified as amended at 42 U.S.C. §§ 2000bb–2000bb-4). *E.g.*, Conestoga Wood Specialties Corp. v. Sec'y of HHS, 724 F.3d 377, 380 (3d Cir. 2013), *rev'd sub nom.* Burwell v. Hobby Lobby Stores, Inc., 573 U.S. 682, 736 (2014); E. Tex. Baptist Univ. v. Sebelius, 988 F. Supp. 2d 743, 747 (S.D. Tex. 2013), *rev'd sub nom.* E. Tex. Baptist Univ. v. Burwell, 793 F.3d 449, 463 (5th Cir. 2015), *vacated sub nom.* Zubik v. Burwell, 136 S. Ct. 1557 (2016) (per curiam); Roman Catholic Archdiocese of N.Y. v. Sebelius, 987 F. Supp. 2d 232, 236–37 (E.D.N.Y. 2013).

[51] *See* 42 U.S.C. § 2000bb (congressional findings and declaration of purpose).

[52] 494 U.S. 872, 881 (1990). In *Smith*, the Court concluded that denying unemployment benefits to individuals who "ingested peyote for sacramental purposes at a ceremony of the Native American Church" did not violate the Free Exercise Clause because peyote use was a crime in the state. *Id.* at 874, 890. The Court rejected the argument that the government must exempt religious use from the general prohibition unless it could demonstrate a "compelling interest" in applying the law to such use. *Id.* at 882–86 (reasoning that to require an individual to comply with an "across-the-

prohibits the federal government from "substantially burden[ing] a person's exercise of religion even if the burden results from a rule of general applicability."[53] RFRA allows such a burden only if the government shows that applying the burden to the person (1) furthers "a compelling governmental interest"; and (2) "is the least restrictive means" of furthering that interest.[54] This "strict scrutiny" standard, particularly the "least restrictive means" requirement, is "exceptionally demanding."[55] Thus, in challenges by religious objectors to the application of generally applicable laws, RFRA extends "far beyond" what the "Court has held is constitutionally required."[56]

The initial challenges to the contraceptive coverage requirement centered on two emerging issues: (1) whether for-profit corporations were "persons" protected by RFRA;[57] and (2) whether requiring employers to cover contraception to which they objected on religious grounds violated RFRA.[58] The Supreme Court took up both issues as they related to closely held corporations in *Burwell v. Hobby Lobby Stores, Inc.*, issuing a decision on June 30, 2014.[59]

The challengers in *Hobby Lobby*, which included the owners of the "nationwide chain" of arts-and-crafts stores of the same name, objected to providing health insurance coverage for four of the 20 FDA-approved methods of contraception included in the coverage requirement.[60] In their view, "life begins at conception" and "facilitat[ing] access" to methods of contraception that "may operate after the fertilization of an egg" would violate their religious beliefs.[61] The challengers argued that requiring them to provide insurance coverage for such contraception violated RFRA.[62]

The Supreme Court held that Hobby Lobby, though a corporation, was a "person" covered by RFRA.[63] Although RFRA itself did not define "person," the first section of the *U.S. Code*, commonly known as the Dictionary Act, defined the term to include "corporations" for the purpose of "'determining the meaning of any Act of Congress, unless the context indicates

board criminal prohibition" only when it "coincide[s] with his religious beliefs, except where the State's interest is 'compelling'" would permit that individual "by virtue of his beliefs, 'to become a law unto himself'" and contravene "constitutional tradition" (internal citation omitted)).

[53] 42 U.S.C. § 2000bb-1(a).

[54] *Id.* § 2000bb-1(b).

[55] Burwell v. Hobby Lobby Stores, Inc., 573 U.S. 682, 728 (2014); *see also* Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal, 546 U.S. 418, 430 (2006) (referring to RFRA's "strict scrutiny test").

[56] *Hobby Lobby*, 573 U.S. at 706.

[57] *See* Hobby Lobby Stores, Inc. v. Sebelius, 568 U.S. 1401, 1403–04 (2012) ("This Court has not previously addressed similar RFRA or free exercise claims brought by closely held for-profit corporations and their controlling shareholders alleging that the mandatory provision of certain employee benefits substantially burdens their exercise of religion. . . . [A]nd no court has issued a final decision granting permanent relief with respect to such claims.").

[58] *See E. Tex. Baptist Univ.*, 988 F. Supp. 2d at 746–47 ("One set of cases, filed by for-profit employers, is before the Supreme Court. A second set of cases, filed by nonprofit religious organizations, includes this case." (footnote omitted)).

[59] *Hobby Lobby*, 573 U.S. at 682. Although definitions of closely held corporations vary, a closely held corporation typically is characterized by a small number of stockholders, such as a family-owned company that is not publicly traded. *See* Frequently Asked Questions, Entities, IRS, https://www.irs.gov/faqs/small-business-self-employed-other-business/entities/entities-5 (last visited Sept. 23, 2019) (giving a general definition of closely held corporation).

[60] *Hobby Lobby*, 573 U.S. at 702–03.

[61] *Id.* at 701–03, 720 (noting that the four methods to which these parties objected included "two forms of emergency contraception commonly called 'morning after' pills and two types of intrauterine devices").

[62] *Id.* at 701, 704.

[63] *Id.* at 708, 719.

otherwise.'"[64] The Court reasoned that "nothing in RFRA" suggested a meaning other than the Dictionary Act definition.[65] Specifically, the majority rejected HHS's argument that for-profit corporations could not "exercise" religion, reasoning that they could do so through "[b]usiness practices that are compelled or limited by the tenets of a religious doctrine."[66]

The Court then proceeded to analyze whether the contraceptive coverage requirement "substantially burden[ed]" the challengers' exercise of religion.[67] The Court accepted their argument that providing coverage for certain forms of contraception would violate their sincerely held religious beliefs because it might enable or facilitate the "destruction of an embryo."[68] According to the majority, "federal courts have no business addressing" whether "the religious belief asserted in a RFRA case is reasonable."[69] The more limited judicial role, the Court said, is to determine whether the "line drawn" by the religious objectors "reflects 'an honest conviction.'"[70] Because no party disputed the sincerity of the employers' convictions, the Court focused its inquiry on whether the burden imposed by the coverage requirement was substantial.[71] The Court concluded that it was, because the requirement would force the challengers to either violate their religious beliefs or face "severe" economic consequences.[72]

The Court next considered whether the contraceptive coverage requirement nonetheless satisfied RFRA's strict scrutiny standard.[73] The Court assumed, for purposes of its analysis, that applying the coverage requirement to petitioners served a "compelling governmental interest" in "guaranteeing cost-free access to the four challenged contraceptive methods."[74] However, the Court concluded that the least restrictive means standard was not satisfied because HHS had "at its disposal" the accommodation process it provided to nonprofit organizations with religious objections which, in the Court's view, did not "impinge on" the challengers' religious beliefs and

[64] *Id.* at 707 (quoting 1 U.S.C. § 1); *see also id.* at 706 (reasoning that Congress "employ[ed] a familiar legal fiction" when it "included corporations within RFRA's definition of 'persons'").

[65] *Id.* at 708.

[66] *Id.* at 710. For five Members of the Court, HHS's concession that RFRA applied to nonprofit corporations "effectively dispatche[d] any argument" that the term "person" in RFRA did not apply to closely held corporations. *Id.* at 708. However, HHS and two of the four dissenting Justices argued that for-profit corporations could not "exercise" religion because religious exercise "is characteristic of natural persons, not artificial legal entities." *See id.* at 751–52 (Ginsburg, J., dissenting) ("Until this litigation, no decision of this Court recognized a for-profit corporation's qualification for a religious exemption from a generally applicable law, whether under the Free Exercise Clause or RFRA.").

[67] *Id.* at 719 (majority opinion).

[68] *Id.* at 720, 724.

[69] *Id.* at 724.

[70] *Id.* at 725 (quoting Thomas v. Review Bd. of Ind. Employ. Sec. Div., 450 U.S. 707, 716 (1981)).

[71] *Id.* at 720–23, 726.

[72] *Id.* at 720, 726. Specifically, the Court observed that failure to provide the required coverage would trigger a statutory tax of $100 per affected individual per day while "dropping insurance coverage altogether" could result in penalties of $2,000 per employee per year. *Id.* at 720 (citing 26 U.S.C. §§ 4980D, 4980H).

[73] *Id.* at 726.

[74] *Id.* at 728. *But cf. id.* at 727 (suggesting that "one of the biggest exceptions, the exception for grandfathered plans," undercut the government's rationale because that exception "simply [served] the interest of employers in avoiding the inconvenience of amending an existing plan").

"serve[d] HHS's stated interests equally well."[75] Accordingly, the Court held that applying the contraceptive coverage requirement to closely held corporations violated RFRA.[76]

On July 14, 2015, the Departments finalized a rule in response to the *Hobby Lobby* decision that extended the accommodation previously reserved for religious nonprofits to for-profit entities that are "not publicly traded, [are] majority-owned by a relatively small number of individuals, and object[] to providing contraceptive coverage based on [their] owners' religious beliefs."[77]

Legal Challenges to the Accommodation Process and Agency Responses

When the Court handed down its decision in *Hobby Lobby*, a separate line of legal challenges to the contraceptive coverage requirement involving the accommodation process remained unresolved by the High Court.[78] In one such case, a Christian college argued that the process, which required objecting entities to submit a certification form called EBSA Form 700 to their insurers or TPAs, itself burdened its exercise of religion in violation of RFRA and the First Amendment.[79] The college believed that submitting the required form would "make it morally complicit in the wrongful destruction of human life."[80]

As shown in **Figure 1**, EBSA Form 700 had two pages: the first required the organization to certify compliance with the criteria for obtaining the accommodation and the second contained a notice to TPAs.

[75] *Id.* at 728, 730–31. Four dissenting Justices argued that the contraceptive coverage requirement did not place a "substantial" burden on the employers' religious exercise because it only required them to "direct money into undifferentiated funds that finance a wide variety of benefits under comprehensive health plans," which, by law, "must offer contraceptive coverage without cost sharing" among other preventive services. *Id.* at 760 (Ginsburg, J., dissenting). But any decision to use contraception, the dissent emphasized, was with the individual covered by the plan, not the employer or the government. *Id.* at 760–61. In the dissent's view, "[n]o tradition, and no prior decision under RFRA, allow[ed] a religion-based exemption when the accommodation would be harmful to others" pointing to "the very persons the contraceptive coverage requirement was designed to protect." *Id.* at 764.

[76] *Id.* at 736 (majority opinion). Given that holding, the Court concluded that it was unnecessary to reach the Free Exercise claim raised by some of the challengers. *Id.*

[77] Coverage of Certain Preventive Services Under the Affordable Care Act, 80 Fed. Reg. 41,318, 41,324 (July 14, 2015) (effective Sept. 14, 2015) (summarizing the eligibility criteria for closely held corporations); *see id.* at 41,346 (defining "closely held for-profit entity" for purposes of the revised definition of "eligible organization").

[78] *See, e.g.*, Wheaton Coll. v. Burwell, 573 U.S. 943 (2014) (temporarily enjoining the government from enforcing the contraceptive coverage requirement against the college pending additional briefing and "further order of the Court"); Eternal Word TV Network, Inc. v. Sec'y of HHS, 756 F.3d 1339, 1340 (11th Cir. 2014) (granting the network's motion for an injunction pending appeal); Univ. of Notre Dame v. Sebelius, 743 F.3d 547, 562 (7th Cir. 2014) (affirming the district court's denial of Notre Dame's motion to preliminarily enjoin the 2013 rules), *vacated sub nom.* 135 S. Ct. 1528 (2015) (remanding the case "in light of *Burwell v. Hobby Lobby Stores, Inc.*").

[79] *See* Wheaton Coll. v. Burwell, 50 F. Supp. 3d 939, 942–43 (N.D. Ill. 2014), *aff'd*, 791 F.3d 792 (7th Cir. 2015).

[80] *Id.* (internal quotation marks omitted).

Figure 1. Self-Certification Form/EBSA Form 700

EBSA FORM 700-- CERTIFICATION
(To be used for plan years beginning on or after January 1, 2014)

This form is to be used to certify that the health coverage established or maintained or arranged by the organization listed below qualifies for an accommodation with respect to the federal requirement to cover certain contraceptive services without cost sharing, pursuant to 26 CFR 54.9815-2713A, 29 CFR 2590.715-2713A, and 45 CFR 147.131.

Please fill out this form completely. This form must be completed by each eligible organization by the first day of the first plan year beginning on or after January 1, 2014, with respect to which the accommodation is to apply, and be made available for examination upon request. This form must be maintained on file for at least 6 years following the end of the last applicable plan year.

Name of the objecting organization	
Name and title of the individual who is authorized to make, and makes, this certification on behalf of the organization	
Mailing and email addresses and phone number for the individual listed above	

I certify that, on account of religious objections, the organization opposes providing coverage for some or all of any contraceptive services that would otherwise be required to be covered; the organization is organized and operates as a nonprofit entity; and the organization holds itself out as a religious organization.

Note: An organization that offers coverage through the same group health plan as a religious employer (as defined in 45 CFR 147.131(a)) and/or an eligible organization (as defined in 26 CFR 54.9815-2713A(a); 29 CFR 2590.715-2713A(a); 45 CFR 147.131(b)), and that is part of the same controlled group of corporations as, or under common control with, such employer and/or organization (within the meaning of section 52(a) or (b) of the Internal Revenue Code), may certify that it holds itself out as a religious organization.

I declare that I have made this certification, and that, to the best of my knowledge and belief, it is true and correct. I also declare that this certification is complete.

_____
Signature of the individual listed above

_____
Date

The organization or its plan must provide a copy of this certification to the plan's health insurance issuer (for insured health plans) or a third party administrator (for self-insured health plans) in order for the plan to be accommodated with respect to the contraceptive coverage requirement.

Notice to Third Party Administrators of Self-Insured Health Plans

In the case of a group health plan that provides benefits on a self-insured basis, the provision of this certification to a third party administrator for the plan that will process claims for contraceptive coverage required under 26 CFR 54.9815-2713(a)(1)(iv) or 29 CFR 2590.715-2713(a)(1)(iv) constitutes notice to the third party administrator that the eligible organization:

(1) Will not act as the plan administrator or claims administrator with respect to claims for contraceptive services, or contribute to the funding of contraceptive services; and

(2) The obligations of the third party administrator are set forth in 26 CFR 54.9815-2713A, 29 CFR 2510.3-16, and 29 CFR 2590.715-2713A.

This certification is an instrument under which the plan is operated.

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 1210-0150. Each organizations that seeks to be recognized as an eligible organization that qualifies for an accommodation with respect to the federal requirement to cover certain contraceptive services without cost sharing is required to complete this self-certification from pursuant to 26 CFR 54.9815-2713A(a)(4) in order to obtain or retain the benefit of the exemption from covering certain contraceptive services. The self-certification must be maintained in a manner consistent with the record retention requirements under section 107 of the Employee Retirement Income Security Act of 1974, which generally requires records to be retained for six years. The time required to complete this information collection is estimated to average 50 minutes per response, including the time to review instructions, gather the necessary data, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: U.S. Department of Labor, Employee Benefits Security Administration, Office of Policy and Research, 200 Constitution Avenue, N.W., Room N-5718, Washington, DC 20210 or email ebsa.opr@dol.gov and reference the OMB Control Number 1210-0150.

Source: Dep't of Labor, EBSA Form 700, http://www.dol.gov/ebsa/pdf/preventiveserviceseligibleorganizationcertificationform.pdf [https://web.archive.org/web/20140712052413/http://www.dol.gov/ebsa/pdf/preventiveserviceseligibleorganizationcertificationform.pdf].[81]

After a federal district court denied the college's motion to preliminarily enjoin the enforcement of the contraceptive coverage requirement,[82] the college sought emergency relief from the Supreme Court.[83] On July 3, 2014, three days after deciding *Hobby Lobby*, the Supreme Court ruled that while the college's case was on appeal to the Seventh Circuit, the college did not need to comply with the contraceptive coverage requirement or complete EBSA Form 700 so long as it "inform[ed] 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."[84]

On August 27, 2014, "consistent with the *Wheaton* order," HHS issued an interim rule that provided eligible organizations an alternative to EBSA Form 700.[85] Pursuant to this rule, organizations could opt to notify HHS, rather than their insurers or TPAs, of their eligibility for the exemption and their objections to providing coverage for some or all forms of FDA-approved

[81] For additional versions of this form, see Dep't of Labor, Emp. Benefits Sec. Admin., *Coverage of Preventive Services*, DOL.GOV, https://www.dol.gov/agencies/ebsa/laws-and-regulations/laws/affordable-care-act/for-employers-and-advisers/coverage-of-preventive-services (click on "EBSA Form 700—Revised August 2014" or "EBSA Form 700—Revised September 2017") (last visited Sept. 23, 2019).

[82] *Wheaton Coll.*, 50 F. Supp. 3d at 952.

[83] *See* Wheaton Coll. v. Burwell, 573 U.S. 943 (2014) (temporarily enjoining enforcement of the contraceptive coverage requirement against the college pending further briefing and consideration by the Court).

[84] Wheaton Coll. v. Burwell, 573 U.S. 958, 958–59 (2014).

[85] Coverage of Certain Preventive Services Under the Affordable Care Act, 79 Fed. Reg. 51,092, 51,094 (Aug. 27, 2014) (effective Aug. 27, 2014).

contraception.[86] This option (the "alternative notice process") required organizations to provide HHS with their insurers' or TPAs' names and contact information.[87] After receiving the notice, those Departments would send a "separate notification" to each issuer or TPA, which, for self-insured plans, would designate the TPA as the plan administrator and constitute "an instrument under which the plan is operated."[88] The model notice that HHS issued with the interim rule appears in **Figure 2**.[89]

Figure 2. Model Notice to Secretary of HHS

MODEL NOTICE

Date: _____

To the Secretary of Health and Human Services:

The following eligible organization has a religious objection to providing coverage of [ ] all or [ ] a subset of contraceptive services required to be covered under PHS Act section 2713, as added by the Affordable Care Act, and incorporated into ERISA section 715 and Code section 9815. *If the eligible organization objects to providing coverage of a subset of contraceptive services, insert a description of the services for which the eligible organization objects to providing coverage:*

_____.

(1) Name of eligible organization: _____
Contact information: _____
Eligible organization is a: [ ] Non-profit entity; OR [ ] Other eligible organization

(2) Service provider information:

(a) Plan name	(b) Service provider name	(c) Service provider contact information	(d) Service provider category	(e) Plan type (if applicable)
			[ ]Issuer or [ ]TPA	[ ]Church plan [ ]Student plan
			[ ]Issuer or [ ]TPA	[ ]Church plan [ ]Student plan
			[ ]Issuer or [ ]TPA	[ ]Church plan [ ]Student plan
			[ ]Issuer or [ ]TPA	[ ]Church plan [ ]Student plan

(3) Information being submitted is (check one):
[ ] Original information; OR [ ] Updated information.
If updated information is being provided, specify the date upon which the updated information was, or will be, effective and what has changed: _____.

_____
Signature of authorized representative of eligible organization Date

_____
Typed name of authorized representative of eligible organization

Source: *The Center for Consumer Information & Insurance Oversight*, CMS.GOV, https://www.cms.gov/cciio/resources/Regulations-and-Guidance/index.html#Prevention (click on "August 22, 2014 Model Notice to Secretary of HHS" under "Prevention") (last visited Sept. 23, 2019).

[86] *Id.*

[87] *Id.* at 51,095.

[88] *Id.* at 51,098–51100.

[89] The Departments issued a final rule that included the alternative notice process on July 14, 2015. *See* Coverage of Certain Preventive Services Under the Affordable Care Act, 80 Fed. Reg. 41,318, 41,323 (July 14, 2015) (effective Sept. 14, 2015) ("These final regulations continue to allow eligible organizations to choose between using EBSA Form 700 or the alternative process consistent with the *Wheaton* interim order.").

After these changes in the law, the Seventh Circuit affirmed the district court's decision to deny the college a preliminary injunction.[90] The appellate court reasoned that the college did not have to provide certain forms of contraception in its student benefit plans so long as it notified *either* its TPA *or* the government of its objection to providing that coverage.[91] Although the government would designate the college's preexisting TPA to provide the required coverage, the court reasoned that the plan instrument became the "government's plan" rather than the college's plan.[92] The court also rejected the college's argument that complying with the accommodation process would render it "complicit" in providing the contraception to which it objected.[93] Writing for the court, Judge Richard Posner reasoned that "it is the *law*, not any action on the part of the college," that requires the TPA to provide coverage once the college has registered its objection.[94] Accordingly, the court concluded that the college was unlikely to prevail on its RFRA claim.[95]

The Seventh Circuit was not the only appellate court to uphold the accommodation process amid requests for injunctive relief. Appellate courts in eight circuits in total concluded (at least as a preliminary matter while litigation proceeded on the merits) that the process did not impose a substantial burden on the challengers' exercise of religion.[96] They rejected the view that providing notice to insurers or TPAs, or to HHS, "triggered" the provision of contraception, making the plaintiffs partially responsible for an act that violated their beliefs.[97] Like the Seventh Circuit, they reasoned that the ACA, not the transmission of EBSA Form 700 or the notice to HHS, was the reason the applicable plans provided coverage for contraception without cost sharing.[98] Some

[90] Wheaton Coll. v. Burwell, 791 F.3d 792, 801 (7th Cir. 2015).

[91] *Wheaton Coll.*, 791 F.3d at 795.

[92] *Id.* at 796–98, 800.

[93] *Id.* at 796.

[94] *Id.*

[95] *Id.* at 800.

[96] *See* Massachusetts v. HHS, 923 F.3d 209, 215 n.6 (1st Cir. 2019) (noting that "the Second, Third, Fifth, Sixth, Seventh, Tenth, Eleventh, and D.C. Circuits held that the Accommodation did not substantially burden religious exercise" and citing the relevant decisions); *see, e.g.*, Little Sisters of the Poor Home for the Aged v. Burwell, 794 F.3d 1151, 1195 (10th Cir. 2015) (deciding in a consolidated appeal that the "ministerial act to opt out is not a substantial burden on religious exercise, nor are the collateral requirements of the scheme"); E. Tex. Baptist Univ. v. Burwell, 793 F.3d 449, 459 (5th Cir. 2015) (stating that "[b]ecause RFRA confers no right to challenge the independent conduct of third parties, we join our sister circuits in concluding that the plaintiffs have not shown a substantial burden on their religious exercise"); Geneva Coll. v. Sec'y of HHS, 778 F.3d 422, 442 (3d Cir. 2015) (concluding that because "the self-certification procedure does not cause or trigger the provision of contraceptive coverage, appellees are unable to show that their religious exercise is burdened"); *Geneva Coll.*, 778 F.3d at 428 n.3 (further concluding that "the alternative compliance mechanism set forth in the August 2014 regulations poses no substantial burden"); Priests for Life v. HHS, 772 F.3d 229, 237 (D.C. Cir. 2014) (concluding in a consolidated appeal that "the challenged regulations do not impose a substantial burden . . . under RFRA" because "[a]ll Plaintiffs must do to opt out is express what they believe and seek what they want via a letter or two-page form").

[97] *See, e.g.*, *Geneva Coll.*, 778 F.3d at 441 (reasoning that instead of "'triggering' the provision of contraceptive coverage to the appellees' employees and students, EBSA Form 700 totally removes the appellees from providing those services"); *E. Tex. Baptist Univ.*, 793 F.3d at 461 (reasoning that the "acts that violate [the plaintiffs'] faith are the acts of the government, insurers, and third-party administrators, but RFRA does not entitle them to block third parties from engaging in conduct with which they disagree").

[98] *See, e.g.*, *E. Tex. Baptist Univ.*, 793 F.3d at 459 (reasoning that the "ACA already requires contraceptive coverage" and nothing in that law "suggests the insurers' or third-party administrators' obligations would be waived if the plaintiffs refused to apply for the accommodation"). *But cf. Little Sisters of the Poor Home for the Aged*, 794 F.3d at 1210 (Baldock, J., dissenting in part) (arguing that five circuits either failed to recognize or failed to appreciate "a critical distinction" in the accommodation scheme: "[I]n the *insured* health plan context, 'a health insurance issuer . . . would be obligated to provide contraceptive coverage under the ACA whether or not [the insured non-profit] delivered the Form or notification to HHS.' But in the *self-insured* context, a TPA would be '*authorized* and obligated to provide

appellate judges dissented from their panel's decision or a denial of rehearing by the full circuit court, including now–Supreme Court Justices Neil Gorsuch and Brett Kavanaugh.[99]

The Eighth Circuit was the first appellate court to hold that the accommodation process violated RFRA.[100] In that case, the district court had preliminarily enjoined the government from enforcing the contraceptive coverage requirement against two nonprofit employers that offered self-insured plans.[101] The Eighth Circuit read *Hobby Lobby* to require it to "accept [the plaintiffs'] assertion that self-certification under the accommodation process—using either [EBSA] Form 700 or HHS Notice—would violate their sincerely held religious beliefs."[102] And it reasoned that providing the notice resulted in the provision of contraceptive coverage even if the plaintiffs did not have to arrange for or subsidize that coverage.[103] The court then concluded that the process was not the least-restrictive means of serving the government's interest in providing women with access to cost-free contraception.[104] In particular, it observed that the government could require objecting organizations to notify HHS of their objections without providing "the detailed information and updates" required under the alternative notice process.[105] The court also found that the government failed to demonstrate why it could not reimburse employees for their purchase of contraceptives directly or pursue other ways to make contraception more widely available.[106]

After the Eighth Circuit rendered its decision but before the government sought the Supreme Court's review, the Supreme Court consolidated and granted certiorari in seven other cases involving RFRA challenges to the accommodation process under the caption *Zubik v. Burwell*.[107] However, on May 16, 2016, the Supreme Court vacated the *Zubik* decisions and remanded the cases to the circuit courts in light of the "significantly clarified view of the parties."[108] The Court explained that in response to its request for additional briefing after oral argument, the government confirmed that "contraceptive coverage could be provided to petitioners' employees, through petitioners' insurance companies" without requiring the petitioners to notify their insurers

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the coverage . . . *only if* the religious non-profit . . . opts out.'" (internal citations omitted) (quoting from the majority opinion and adding emphasis)).

[99] *See* Little Sisters of the Poor Home for the Aged v. Burwell, 799 F.3d 1315, 1317 (10th Cir. 2015) (Hartz, J., dissenting from the denial of rehearing en banc, joined by Kelly, Tymkovich, & Gorsuch, JJ.) (reasoning that because the plaintiffs "sincerely believe that they will be violating God's law if they execute the documents required by the government" and because "the penalty for refusal to execute the documents may be in the millions of dollars," it could not "be any clearer that the law substantially burdens the plaintiffs' free exercise of religion"); Priests for Life v. HHS, 808 F.3d 1, 15 (D.C. Cir. 2015) (Kavanaugh, J., dissenting from the denial of rehearing en banc) (reasoning that "under *Hobby Lobby*, the regulations substantially burden the religious organizations' exercise of religion because the regulations require the organizations to take an action contrary to their sincere religious beliefs (submitting the form) or else pay significant monetary penalties").

[100] *See* Sharpe Holdings, Inc. v. HHS, 801 F.3d 927, 946 (8th Cir. 2015), *vacated and remanded sub nom.* HHS v. CNS Int'l Ministries, 136 S. Ct. 2006 (2016) (granting certiorari, vacating and remanding in light of *Zubik v. Burwell*).

[101] *Id.* at 932.

[102] *Id.* at 941.

[103] *Id.* at 942–43.

[104] *Id.* at 944.

[105] *Id.*

[106] *Id.* at 945.

[107] Order of Nov. 6, 2015, Zubik v. Burwell, 136 S. Ct. 1557 (2016) (Nos. 14-1418 et al.) (granting petitions and consolidating cases); *see also* Petition for a Writ of Certiorari, HHS v. CNS Int'l Ministries, 136 S. Ct. 2006 (2016) (No. 15-775) (filed Dec. 15, 2015).

[108] Zubik v. Burwell, 136 S. Ct. 1557, 1560 (2016) (per curiam).

or HHS in the manner previously required.[109] The petitioners, in turn, confirmed that an insurer's independent provision of contraceptive coverage to the petitioners' employees would not burden the petitioners' religious exercise.[110] The Court instructed the appellate courts on remand to afford the parties "an opportunity to arrive at an approach going forward that accommodates petitioners' religious exercise while at the same time ensuring that women covered by petitioners' health plans 'receive full and equal health coverage, including contraceptive coverage.'"[111] It also enjoined the government from taxing or penalizing the petitioners based on a failure to provide notice, reasoning that the petitioners apprised the government of their religious objections through the litigation itself.[112] The Court expressly declined to opine on whether the existing accommodation process substantially burdened the petitioners' religious exercise or nonetheless complied with RFRA's strict scrutiny standard.[113]

Executive Action After *Zubik*

Following the Supreme Court's remand, the executive branch took additional actions on the contraceptive coverage requirement. The Departments solicited and reviewed public comments on options to further revise the process.[114] However, as of January 9, 2017, the Departments had not identified a "feasible approach . . . [to] resolve the concerns of religious objectors, while still ensuring that the affected women receive full and equal health coverage, including contraceptive coverage."[115] At that time, the Departments maintained that the existing accommodation process was "consistent with RFRA."[116]

Following a change in presidential administrations, on May 4, 2017, President Donald J. Trump issued an executive order directing the Departments to "consider issuing amended regulations,

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[109] *Id.* at 1559–60. Although the government indicated that such an approach might be feasible for insured plans, it stated that such a process "would not work" for self-insured plans, because TPAs, unlike issuers, have no independent, preexisting legal obligation to provide coverage. Supplemental Brief for the Respondents at 14–16, *Zubik*, 136 S. Ct. 1557 (Nos. 14-1418 et al.). In order to properly designate a TPA as the plan administrator, the government reasoned, it needed the objecting party to either send EBSA Form 700 directly to the TPA, which makes this designation, or provide HHS with the TPA's name so that HHS could make the designation in a separate notice to the TPA (i.e., per the alternative notice process). *Id.* at 16–17.

[110] *Zubik*, 136 S. Ct. at 1560. The petitioners indicated that their RFRA objections "would be fully addressed" if the coverage offered by the issuer or another commercial insurer (in the case of a self-insured plan) was "*truly* independent of petitioners and their plans—i.e., provided through a separate policy, with a separate enrollment process, a separate insurance card, and a separate payment source, and offered to individuals through a separate communication." Supplemental Brief for Petitioners at 1, *Zubik*, 136 S. Ct. 1557 (Nos. 14-1418 et al.).

[111] *Zubik*, 136 S. Ct. at 1560 (quoting Supplemental Brief for the Respondents at 1, *Zubik*, 136 S. Ct. 1557 (Nos. 14-1418 et al.)).

[112] *Id.* at 1561.

[113] *Id.* at 1560.

[114] U.S. DEP'T OF LABOR, FAQS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION PART 36, at 4 (Jan. 9, 2017), https://www.dol.gov/sites/default/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-36.pdf (noting the receipt of over 54,000 comments).

[115] *Id.* The Departments reasoned that an approach described by the *Zubik* Court—one in which objecting employers notified their insurers of their religious objections to providing coverage in the course of negotiating contracts for employee benefits—did not appear to be acceptable to certain parties to that litigation and objecting employers who submitted comments. *Id.* at 5. The Departments further reasoned that eliminating written notice altogether would raise significant "administrative and operational challenges" that could compromise coverage for women. *Id.* at 4–7. Moreover, according to the Departments, requiring "separate contraceptive-only coverage" might produce conflicts with state contract and insurance laws. *Id.* at 8.

[116] *Id.* at 4.

consistent with applicable law, to address conscience-based objections to the preventive-care mandate promulgated under [42 U.S.C. §] 300gg-13(a)(4)"—the ACA provision that refers specifically to preventive care for women and pursuant to which HRSA included contraceptive coverage.[117]

On October 6, 2017, the Departments reversed their position on the legality of the accommodation process and issued two interim final rules (IFRs)[118] that made that process "optional."[119] The first rule (the Religious Exemption IFR) expanded the HRSA exemption formerly available only to houses of worship and related entities[120] to include any nongovernmental organization that objected to providing or arranging coverage for some or all contraceptives based on "sincerely held religious beliefs."[121] The second rule (the Moral Exemption IFR) extended the same exemption to certain nongovernmental organizations whose objections were based on "sincerely held moral convictions," rather than religious beliefs.[122] Pursuant to these rules, "an eligible organization [that] pursue[d] the optional accommodation process through the EBSA Form 700 or other specified notice to HHS" would "voluntarily shift[] an obligation to provide separate but seamless contraceptive coverage to its issuer or [TPA]."[123] However, if an employer or institution chose to rely on the exemption rather than the accommodation, neither the objecting entity *nor its insurer or TPA* would need to provide coverage for the objected-to contraceptive methods.[124] The Departments also added an "individual exemption" that allowed willing employers and issuers, both governmental and

[117] Exec. Order No. 13,798, Promoting Free Speech and Religious Liberty, 82 Fed. Reg. 21,675, 21,675 (May 4, 2017).

[118] The Administrative Procedure Act (APA) generally requires agencies to seek comments from the public on proposed rules before finalizing a new regulation. *See* 5 U.S.C. § 553. However, if an agency determines that it has good cause to bypass the notice and comment requirements, it may choose to issue an interim final rule that takes effect immediately, sometimes soliciting comments through that rule and modifying the final rule based on those comments. OFF. OF FED. REGISTER, A GUIDE TO THE RULEMAKING PROCESS 9 (2011).

[119] Religious Exemption IFR, *supra* note 9, at 47,799. *But cf. id.* at 47,808–09 (noting that employers that sponsor plans governed by ERISA would still have to notify participants and beneficiaries of the excluded coverage in their plan documents as a result of "existing [ERISA] disclosure requirements"). HHS explained that after reevaluating its position, the agency had concluded that "requiring certain objecting entities or individuals to choose between the [contraceptive coverage] Mandate, the accommodation, or penalties for noncompliance violates their rights under RFRA." *Id.* at 47,800, *see also id.* at 47,806 ("We recognize that this is a change of position on this issue . . . .").

[120] 45 C.F.R. § 147.131(a) (2017).

[121] Religious Exemption IFR, *supra* note 9, at 47,806–11 (explaining that the exemption would be available to houses of worship and other nonprofit organizations, to closely held and non-closely held for-profit companies, to institutions of higher education, and to insurance issuers and non-employer plan sponsors (e.g., unions) with their own religious objections).

[122] Moral Exemption IFR, *supra* note 9, at 47,862 (quoting language to be codified at 45 C.F.R. § 147.133(a)(2)); *see also id.* at 47844 (explaining the exemption). In contrast to the Religious Exemption IFR, the Moral Exemption IFR did not extend the exemption to *all* for-profit companies. Instead, it excluded companies with a publicly traded ownership interest. *Id.* at 47851. Before the Moral Exemption IFR, at least one federal court, in a case involving a "non-profit, non-religious pro-life organization," had held that the contraceptive coverage requirement violated equal protection principles under the Fifth Amendment because its regulations exempted religious employers, but not employers with similar moral or ethical objections to contraception. *See* March for Life v. Burwell, 128 F. Supp. 3d 116, 122, 125–28 (D.D.C. 2015).

[123] Religious Exemption IFR, *supra* note 9, at 47,813; Moral Exemption IFR, *supra* note 9, at 47,854 (noting that "the accommodation process works the same as it does for entities with objections based on sincerely held religious beliefs as described in the [Religious Exemption IFR]").

[124] Religious Exemption IFR, *supra* note 9, at 47,808–09; Moral Exemption IFR, *supra* note 9, at 47,850. In its final rule, the Departments clarified that a group health plan would still be responsible for providing coverage if the *issuer* holds the objection, unless the plan also has a religious or moral objection. 83 Fed. Reg. 57,536, 57,565 (Nov. 15, 2018).

nongovernmental, to provide alternative policies or contracts that did not offer contraceptive coverage to individual enrollees who objected to such coverage based on sincerely held religious beliefs or moral convictions.[125]

The Departments estimated that the Religious Exemption IFR "would affect the contraceptive costs of approximately 31,700 women" based on information derived from the litigating positions of various objecting entities and notices the agency received pursuant to the previous accommodation process.[126] They further estimated that the total costs potentially transferred to those affected women would amount to "approximately $18.5 million."[127] However, in order to "account for uncertainty" in its estimate, the agencies also examined the "possible upper bound economic impact" of the Religious Exemption IFR.[128] Applying a different methodology, the Departments arrived at a figure of approximately 120,000 women, with potential transfer costs totaling $63.8 million.[129] The Departments projected a smaller effect with respect to the Moral Exemption IFR, estimating that it could affect the contraceptive costs of 15 women, an aggregate effect of approximately $8,760.[130]

The Departments finalized the Religious and Moral Exemption IFRs on November 15, 2018, with effective dates of January 14, 2019 (collectively, the 2019 Final Rules).[131] The 2019 Final Rules amended the regulatory text "to clarify the intended scope of the language" but retained the substance of the interim final rules.[132] The Departments increased their upper-bound estimate of

[125] Religious Exemption IFR, *supra* note 9, at 47,807, 47,812; Moral Exemption IFR, *supra* note 9, at 47,853.

[126] Religious Exemption IFR, *supra* note 9, at 47,821.

[127] *See id.* (estimating "the cost of contraception to women" based on the approximate per-person cost of providing contraceptive coverage for a subset of issuers in 2015).

[128] *Id.*

[129] *Id.* at 47,823–24. For their upper-bound estimate, the Departments considered the number of women of childbearing age who (1) used contraceptives covered by the HRSA guidelines; and (2) were employed by "private, non-publicly traded employers that did not cover contraception pre-Affordable Care Act" and that were not previously exempt. *Id.* at 47,823. The Departments estimated this number to be "362,100" such women. *Id.* However, given that only a subset of these employers would have a sincere religious exemption making them eligible for the expanded exemption, the Departments concluded that a "reasonable estimate" of the number of women "likely" to be affected by the Religious Exemption IFR was closer to 120,000. *Id.* In calculating transfer costs, the Departments accounted for the possibility of partial offsets due to adjustments to premiums. *Id.* at 47,824.

[130] Moral Exemption IFR, *supra* note 9, at 47,857–58 (attributing such projected costs to the potential for for-profit entities with moral objections to use the expanded exemption but concluding that the expanded exemption for nonprofit entities and institutions of higher education would not likely reduce coverage for employees who want it).

[131] Religious Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,536 (Nov. 15, 2018) (effective Jan. 14, 2019) [hereinafter Religious Exemption]; Moral Exemptions and Accommodations for Coverage of Certain Preventive Services Under the Affordable Care Act, 83 Fed. Reg. 57,592 (Nov. 15, 2018) (effective Jan. 14, 2019) [hereinafter Moral Exemption].

[132] Religious Exemption, *supra* note 131, at 57,537; Moral Exemption, *supra* note 131, at 57,593; *see also* California v. HHS, 351 F. Supp. 3d 1267, 1279 (N.D. Cal. 2019) (describing the 2019 Final Rules as "nearly identical" in substance to the interim rules). For example, the Departments amended the Religious Exemption IFR to bring the "operative language" describing the scope of the exemption more in line with the Moral Exemption IFR. Religious Exemption, *supra* note 131, at 57,567. Accordingly, in the final Religious Exemption, the exemption applies if an entity has sincere religious objections to providing or arranging for *either* "[c]overage or payments for some or all contraceptive services" *or* a "plan, issuer, or third party administrator that provides or arranges such coverage or payments." *Id.* at 57,590. The purpose of amending the language, the Departments said, was to clarify that "an entity would be exempt from the Mandate if it objected to complying with the Mandate, or if it objected to complying with the accommodation." *Id.* at 57,567. The Departments also clarified that if an insurance issuer objected to providing coverage on religious or moral grounds, the plan would still be responsible for providing that coverage unless it also qualified for an exemption. *Id.* at 57,565–66.

the number of women that the expanded Religious Exemption could affect from 120,000 women to 126,400 women, yielding potential transfer costs of $67.3 million.[133]

Post-2017 Legal Developments

The expanded exemptions generated a new set of legal challenges from states concerned with the fiscal burdens of the revised rules and the Departments' authority to promulgate them.[134] In addition, some private parties (including a nationwide class of employers) successfully obtained injunctions against enforcement of the prior accommodation process after the government stopped defending the process on RFRA grounds.[135] This section discusses some of the key decisions among the pending cases concerning the contraceptive coverage requirement.

Pennsylvania v. Trump

In late 2018, Pennsylvania and New Jersey asked a federal court to block the 2019 Final Rules, alleging, among other claims, that the rules (1) "failed to comply with the notice-and-comment procedures" required by the Administrative Procedure Act (APA) and (2) were "'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law' in violation of the substantive provisions of the APA."[136] After concluding that the states had standing to bring these claims,[137] the U.S. District Court for the Eastern District of Pennsylvania examined whether the states were "likely to succeed" on their APA challenges—a key consideration in determining whether to issue a preliminary injunction.[138] The court first considered the states' procedural APA claim that the 2019 Final Rules were invalid because the Departments failed to provide for notice and comment before issuing the interim rules. The APA's notice-and-comment requirement, the court explained, means that an agency must:

> issue a general notice of proposed rulemaking; "give interested persons an opportunity to participate in the rule making through submission of written data, views or arguments . . ."; and, "[a]fter consideration of the relevant matter presented, . . . incorporate in the rules adopted a concise general statement of their basis and purpose."[139]

The district court reasoned that even though the Departments solicited comments before ultimately finalizing the interim rules, such "post-promulgation" efforts did not cure the procedural defect because the interim rules "fundamentally changed the 'question to be decided

[133] Religious Exemption, *supra* note 131, at 57,551, 57,581. The Departments did not change their numerical estimates with respect to the Moral Exemption. *See* Moral Exemption, *supra* note 131, at 57,627–28.

[134] *E.g.*, Pennsylvania v. Trump, 351 F. Supp. 3d 791 (E.D. Pa. 2019), *aff'd sub nom.* Pennsylvania v. President United States, 930 F.3d 543 (3d Cir. 2019).

[135] *See, e.g.*, DeOtte v. Azar, No. 4:18-cv-00825-O, 2019 U.S. Dist. LEXIS 137849, at *16 (N.D. Tex. June 5, 2019); Order Granting Permanent Injunction & Declaratory Relief, Geneva Coll. v. Azar, No. 2:12-cv-00207 (W.D. Pa. July 5, 2018), ECF No. 153; Order Reopening Case and Granting Permanent Injunction, Little Sisters of the Poor Home for the Aged v. Azar, No. 1:13-cv-02611 (D. Colo. May 29, 2018), ECF No. 82.

[136] *Pennsylvania*, 351 F. Supp. 3d at 803–04. The district court had previously granted Pennsylvania's motion for a preliminary injunction against enforcement of the *interim* rules, a decision that was on appeal when the Departments issued the 2019 Final Rules. *Id.* at 802–03.

[137] *Id.* at 804–08 (reasoning, *inter alia*, that "the Final Rules inflict a direct injury upon the States by imposing substantial financial burdens on their coffers").

[138] *Id.* at 810.

[139] *Id.* (internal citations omitted) (citing and quoting 5 U.S.C. § 553(b)–(c)).

in the [subsequent] rulemaking.'"[140] The court observed that "instead of asking whether substantial expansions to the exemption and accommodation should be made *at all*," the Departments "solicited comments on whether those changes should be *finalized*."[141] For these reasons, the court concluded that the 2019 Final Rules likely violated the APA's procedural requirements.[142]

The court next considered whether the 2019 Final Rules were "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right"—grounds for a reviewing court to "set aside" the rules under the APA.[143] The Departments argued that (1) the ACA "include[d] a broad delegation of authority" that encompassed this rulemaking; and (2) RFRA required the Departments to issue the Religious Exemption.[144]

The court first concluded that the ACA did not authorize the Departments to create what the court viewed as "blanket" exceptions to the preventive services requirement.[145] Reciting the statutory language, the court observed that group health plans and issuers of group or individual coverage "shall" cover "such additional preventive care . . . as provided for in comprehensive guidelines supported by [HRSA]."[146] The court disagreed with the Departments' contention that HRSA's authority to define "*what* preventive care [would] be covered" necessarily included the authority to decide "*who* must provide preventive coverage."[147] The court also rejected the Departments' view that such a delegation was implicit in the language "as provided for in comprehensive guidelines supported by [HRSA]," stating that it "strains credulity to say that by granting HRSA the authority to 'support' guidelines on 'preventive care,' Congress necessarily delegated to HRSA the authority to subvert the 'preventive care' coverage mandate through the blanket exemptions set out in the Final Rules."[148] The court concluded that the 2019 Final Rules exceeded the Departments' authority under the ACA and thus violated the APA.[149]

The court also disagreed with the Departments' argument that the Religious Exemption was necessary to bring the contraceptive coverage requirement into compliance with RFRA.[150] As a threshold matter, the court reasoned that whether a law's application complies with RFRA—a statute authorizing "[j]udicial [r]elief" for aggrieved persons—is primarily a judicial determination.[151] The court then concluded that the Religious Exemption far exceeded what

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[140] *Id.* at 814 (quoting Nat. Res. Def. Council v. EPA, 683 F.2d 752, 768 (3d Cir. 1982)).

[141] *Id.*

[142] *Id.* at 816.

[143] *Id.* at 816–17 (internal quotation marks omitted) (quoting 5 U.S.C. § 706(2)(A), (C)).

[144] *Id.* at 817. The court observed that unlike the Religious Exemption, the government did not argue that RFRA required the Moral Exemption and reasoned that such an argument would fail because "RFRA protects a person's 'exercise of religion,' and does not speak to broader moral convictions." *Id.* at 821 n.22.

[145] *Id.* at 819.

[146] *Id.* at 817 (quoting 42 U.S.C. § 300gg-13(a)).

[147] *Id.*

[148] *Id.* at 819; *see also id.* at 820 (concluding, in addition, that "Congress used 'as' [in the phrase] to indicate that the HRSA guidelines would be forthcoming, *i.e.* in anticipation of HRSA issuing guidelines—not to the conclusion that the ACA implicitly provides the Agencies with the authority to create exemptions" (emphasis removed)).

[149] *Id.* at 817, 821.

[150] *Id.* at 822–23.

[151] *See id.* at 822 (quoting 42 U.S.C. § 2000bb-1(c)); *id.* at 823 (stating that unlike policy decisions within their purview, "administrative agencies may not simply formulate a view of a law outside their particular area of expertise, issue regulations pursuant to that view, claim that the law requires those regulations, then seek to insulate their legal

RFRA required because it provided a "blanket exemption" for religious objectors rather than one that left room for the balancing contemplated by RFRA (i.e., allowing the government to achieve its compelling interest through a least restrictive means).[152]

Finally, the court rejected the Departments' argument that the prior accommodation process substantially burdened the religious exercise of objecting organizations, noting that the Third Circuit already held to the contrary in *Geneva College v. Secretary of HHS* (one of the cases consolidated and later vacated in the *Zubik* litigation).[153] In *Geneva* and a subsequent decision, the Third Circuit held that "an independent obligation on a third party"—whether the insurer providing coverage instead of the objecting employer or an employer providing coverage to its employees over the objections of some employees—"can[not] impose a substantial burden on the exercise of religion in violation of RFRA."[154] For these reasons, the district court concluded that the Departments lacked the substantive authority to promulgate the 2019 Final Rules under the APA.[155]

Having decided that the states met the other requirements for a preliminary injunction, the court concluded that enjoining the rules on a "nationwide" basis was the appropriate remedy to afford "complete relief" to the states.[156] Among other reasons, the court noted that an "injunction limited to Pennsylvania and New Jersey would, by its terms, not reach Pennsylvania and New Jersey citizens who work for out-of-state employers."[157] In the court's view, a preliminary injunction would "maintain the status quo."[158] The court reasoned that organizations that were eligible for an exemption or accommodation under the previous regulatory regime (i.e., before the Religious or Moral IFRs) would "maintain their status" and challengers could continue to pursue judicial relief or rely on injunctions that they previously obtained against enforcement of the contraceptive coverage requirement.[159]

On appeal, the Third Circuit agreed with much of the district court's reasoning and affirmed its central conclusions.[160] It ruled that "the state plaintiffs are likely to succeed in proving that the [Departments] did not follow the APA and that the regulations are not authorized under the ACA or required by [RFRA]."[161] The circuit court also upheld the district court's decision to issue a

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determination from judicial scrutiny").

[152] *See id.* at 824–25 (observing that in the *Hobby Lobby* decision, the Supreme Court noted that in passing the ACA, Congress considered and rejected a proposal to include a general "conscience amendment" allowing employers to deny coverage on religious grounds, and that the Court commented that Congress might have done so because such a "blanket exemption" would have "extended more broadly than the . . . protections of RFRA" (quoting Burwell v. Hobby Lobby Stores, Inc., 573 U.S. 682, 719 n.30 (2014))).

[153] *Id.* at 825 (citing Geneva Coll. v. Sec'y of HHS, 778 F.3d 422, 442 (3d Cir. 2015), *vacated and remanded sub nom.* Zubik v. Burwell, 136 S. Ct. 1557 (2016) (per curiam)).

[154] Real Alternatives, Inc. v. Sec'y of HHS, 867 F.3d 338, 364 (3d Cir. 2017) (quoting *Geneva*, 778 F.3d at 440–41)).

[155] *Pennsylvania*, 351 F. Supp. 3d at 827.

[156] *Id.* at 835. The court expressed concern that the loss of coverage for "numerous citizens" would result in "'significant, direct and proprietary harm' to the States in the form of increased use of state-funded contraceptive services, as well as increased costs associated with unintended pregnancies." *Id.* (quoting from the plaintiff-states' allegations).

[157] *Id.* at 833.

[158] *Id.* at 829.

[159] *Id.* at 829–30.

[160] Pennsylvania v. President United States, 930 F.3d 543, 563–64, 569, 572, 575 (3d Cir. 2019).

[161] *Id.* at 556.

nationwide preliminary injunction.[162] The government and an objecting entity that the district court allowed to intervene as a defendant in the case have indicated their intent to appeal the Third Circuit's ruling.[163]

California v. HHS

Proceeding alongside the Pennsylvania litigation was an action in the U.S. District Court for the Northern District of California. In 2018, 14 states moved to enjoin enforcement preliminarily of the 2019 Final Rules.[164] A subset of these states had already obtained a nationwide injunction against enforcement of the interim rules, which the Ninth Circuit then modified to apply only in the states that were plaintiffs in the action.[165] In renewing their challenge to the 2019 Final Rules, the states advanced APA, Establishment Clause, and Equal Protection Clause claims.[166] As with its first ruling on the interim rules,[167] the district court decided the motion for injunctive relief on statutory grounds.[168]

After concluding that the plaintiff-states had standing, the court examined the Departments' authority to institute the expanded exemptions.[169] Like the district court in the Pennsylvania action, the court reasoned that agency authority to create exemptions was "inconsistent" with Congress's directive in the ACA that nongrandfathered plans and insurers "shall" provide preventive services without cost sharing.[170]

The court also concluded that RFRA neither required nor authorized the Religious Exemption.[171] It emphasized that a threshold question under RFRA is whether the law "substantially burdens" a person's exercise of religion.[172] Under the Ninth Circuit's RFRA precedent, the court explained, "a 'substantial burden' is imposed only when individuals are forced to choose between following the tenets of their religion and receiving a governmental benefit . . . or coerced to act contrary to their religious beliefs by the threat of civil or criminal sanctions."[173] The district court observed that of the nine circuits to have considered the question, all but one (the Eighth Circuit) concluded that the prior accommodation process did *not* impose a substantial burden on objectors' exercise of religion.[174] Unlike the Eighth Circuit, the district court reasoned that whether a burden is

[162] *Id.* at 575–76.

[163] *See* Order at 4–5, Pennsylvania v. Trump, 351 F. Supp. 3d 791 (2019) (No. 17-454), ECF No. 232 (stating that during a July 23, 2019, conference call with the parties, "Defendants and Defendant-Intervenor represented that they intend to seek further appellate review of the Third Circuit's decision"; staying further proceedings; and requiring the parties to submit a joint status report to the court on October 25, 2019).

[164] California v. HHS, 351 F. Supp. 3d 1267, 1279–80 (N.D. Cal. 2019), *appeal filed and argued sub nom.* California v. Azar, Nos. 19-15150 et al. (9th Cir. 2019).

[165] *Id.* at 1278–79; *see* California v. Azar, 911 F.3d 558, 566, 585 (9th Cir. 2018), *cert. denied sub nom.* Little Sisters of the Poor Jeanne Jugan Residence v. California, No. 18-1192, 2019 U.S. LEXIS 4042 (U.S. June 17, 2019).

[166] *California*, 351 F. Supp. 3d at 1279.

[167] *See* California v. HHS, 281 F. Supp. 3d 806, 813, 824 (N.D. Cal. 2017) (concluding that "at a minimum," the IFRs likely violated the APA's procedural requirements).

[168] *California*, 351 F. Supp. at 1284.

[169] *Id.*

[170] *Id.* at 1286.

[171] *Id.* at 1286–96.

[172] *Id.* at 1287.

[173] *Id.* (quoting Navajo Nation v. U.S. Forest Serv., 535 F.3d 1058, 1070 (9th Cir. 2008)).

[174] *Id.* at 1287–88.

"substantial" is an "objective legal matter," not to be determined by deferring to the objectors' claims.[175] The district court agreed with the analysis of the Eleventh Circuit and other courts that "under the accommodation 'the only action required of the eligible organization is opting out: literally, the organization's notification of its objection,' at which point all responsibilities related to contraceptive coverage fall upon its insurer or TPA."[176] The district court concurred with these courts, too, that providing notice did not substantially burden an objector's religious exercise by making it "complicit" in the provision of contraception because "it is the ACA and the guidelines that entitle plan participants and beneficiaries to contraceptive coverage, not any action taken by the objector."[177]

The district court further concluded that there were "serious questions going to the merits" of the case as to whether the Religious Exemption was even permissible, let alone required.[178] First, it questioned whether the expanded exemption violated the Establishment Clause in light of the Supreme Court's proviso that "[a]t some point, accommodation may devolve into an unlawful fostering of religion."[179] Second, the court observed that while the Supreme Court has mandated that courts "take adequate account of the burdens a requested accommodation may impose on nonbeneficiaries,"[180] there is "substantial debate among commentators as to how to assess the legality of accommodations not mandated by RFRA when those accommodations impose harms on third parties"—women who would otherwise receive contraceptive coverage under the law.[181]

Ultimately, the district court issued a preliminary injunction against enforcement in the plaintiff states based on the likelihood that the 2019 Final Rules violated the APA.[182] The court reserved for the merits stage of the litigation the possibility of additional rulings on the underlying legal disputes regarding the scope of RFRA and the rules' compliance with the Establishment Clause.[183] The district court anticipated that its preliminary injunction would preserve the "status quo" of the exemptions and the accommodation process that existed before the Departments

[175] *Id.* at 1288 (quoting Catholic Health Care Sys. v. Burwell, 796 F.3d 207, 217 (2d Cir. 2015)). The court distinguished between the deference to be afforded a party's claim that a particular practice violates its religious beliefs (a question of fact) and the determination as to whether the infringement is "substantial" under the law. *Id.*

[176] *Id.* at 1289 (quoting Eternal Word TV Network, Inc. v. Sec'y of HHS, 818 F.3d 1122, 1149 (11th Cir. 2016)). The Eleventh Circuit later vacated its RFRA decision in the consolidated cases in *Eternal Word TV Network, Inc.* without expressing its views "on the merits of the cases" to give the parties "an opportunity to address the issues raised in *Zubik*." Eternal Word TV Network, Inc. v. Sec'y of HHS, Nos. 14-12696-CC et al., 2016 U.S. App. LEXIS 24382, at *11 (11th Cir. May 31, 2016).

[177] *California*, 351 F. Supp. at 1287–89.

[178] *Id.* at 1291.

[179] *Id.* at 1294 (internal quotation marks omitted) (quoting Corp. of Presiding Bishop of Church of Jesus Christ of Latter-Day Saints v. Amos, 483 U.S. 327, 334–35 (1987)).

[180] *Id.* at 1294 (internal quotation marks omitted) (quoting Burwell v. Hobby Lobby Stores, Inc., 573 U.S. 682, 729 n.37 (2014)).

[181] *Id.* at 1295. In the district court's view, the expanded exemption in effect "depriv[ed] female employees, students and other beneficiaries connected to exempted religious objectors of their statutory right under the ACA to seamlessly-provided contraceptive coverage at no cost," apparently "without even requiring any direct notice to the [affected] women." *Id.* at 1294.

[182] *Id.* at 1301. The court later extended the scope of the preliminary injunction to include an additional state, Oregon. *See* California v. HHS, No. 17-cv-05783-HSG, 2019 U.S. Dist. LEXIS 110818, at *5 (N.D. Cal. July 2, 2019).

[183] *California*, 351 F. Supp. 3d at 1296.

issued the Religious and Moral IFRs.[184] The Ninth Circuit is currently reviewing the district court's decision.[185]

Massachusetts v. HHS

A lawsuit by the Commonwealth of Massachusetts to block the enforcement of the interim rules—and later the final rules—instituting the expanded exemptions was initially barred on standing grounds.[186] The district court rejected the Commonwealth's primary standing argument that the expanded exemptions threatened fiscal injury to the state.[187] In essence, the Commonwealth had alleged that as more employers availed themselves of the exemptions, Massachusetts would need to assume the costs of contraceptive coverage for qualifying residents as well as prenatal and postnatal care resulting from unintended pregnancies.[188] The district court found this argument too speculative.[189]

On May 2, 2019, the U.S. Court of Appeals for the First Circuit reversed the district court's ruling,[190] holding that Massachusetts had shown an "imminent" harm "fairly traceable" to the expanded exemptions, sufficient to confer standing.[191] The court determined that the Commonwealth had demonstrated through the Departments' own regulatory impact estimates and data that there was a "substantial risk" that "*some* women in Massachusetts" would lose coverage and that it was "highly likely" that three Massachusetts employers with health plans exempt from state regulation (one of which was Hobby Lobby) would utilize the expanded exemptions.[192] Even though the Commonwealth's argument "proceed[ed] in steps,"[193] the "causal chain" from

[184] *Id.* at 1298–99. The court noted that its preliminary injunction did not affect other judicial orders enjoining the Departments from either enforcing the contraceptive coverage requirement against specific plaintiffs or requiring those plaintiffs to comply with the prior accommodation process. *Id.* at 1299 n.16.

[185] *See* California v. Azar, Nos. 19-15150 et al. (9th Cir. 2019).

[186] Massachusetts v. HHS, 301 F. Supp. 3d 248 (D. Mass. 2018), *vacated and remanded*, 923 F.3d 209 (1st Cir. 2019). Massachusetts had alleged that the interim rules violated the APA, the First Amendment's Establishment Clause, and the "equal protection guarantee" of the Fifth Amendment's Due Process Clause. *Id.* at 250.

[187] *Id.* at 258; *see also* Massachusetts v. HHS, 923 F.3d 209, 222 (1st Cir. 2019) ("The Commonwealth's primary argument for standing is based on a fiscal injury to itself.").

[188] *Massachusetts*, 301 F. Supp. 3d at 258–64. Massachusetts alleged that some residents whose employers or colleges could rely on the expanded exemption would qualify for "wrap around" (i.e., supplemental) coverage under the state's Medicaid program, MassHealth, which was required by federal law to cover contraception. *Id.* at 255–56. In addition, the state posited that some low-income residents would enroll in plans offering contraceptive coverage funded by the state's Sexual and Reproductive Health Program (SRHP), three-fourths of which was funded through state appropriations. *Id.* at 256.

[189] The court found it significant that Massachusetts had not identified particular employees who would lose coverage and rely on state-funded services. *Id.* at 263. And the court doubted that Massachusetts would be "proportionally affected by the IFRs" because the Commonwealth had enacted a law "requir[ing] essentially the same coverage as the ACA mandate." *Id.* at 259–60.

[190] *Massachusetts*, 923 F.3d at 213. When the First Circuit rendered its decision, the 2019 Final Rules already were enjoined nationwide as a result of the district court decisions in the *Pennsylvania* and *California* actions. *See id.* at 220.

[191] *Id.* at 222. The court noted that the Departments did not contest that an imminent fiscal injury would be "concrete and particularized" or "redressable" by an injunction against the rules' enforcement—the other two elements necessary to support standing—but concluded that these elements were satisfied as well. *Id.* at 221–22, 227–28.

[192] *Id.* at 224. The appellate court further reasoned that the Commonwealth did not need to identify particular women who would lose coverage to establish standing. *Id.* at 225. The court also cited Massachusetts's estimates regarding the number of women who would likely turn to state-funded services upon losing coverage, noting that the Commonwealth did not need to be "exactly correct" in its calculations to show an imminent fiscal injury. *Id.* at 225–27.

[193] *Id.* at 223.

loss of coverage to use of state-funded services at the Commonwealth's expense was not too "attenuated" and relied on "probable market behavior."[194] The appellate court remanded the case to the district court to consider the parties' substantive arguments.[195] The parties' motions for summary judgment—asking the court for a ruling on the legal issues prior to (and ultimately in lieu of) a trial—are pending before the district court.[196]

DeOtte v. Azar

While the *Pennsylvania* and *California* actions resulted in preliminary injunctions against the 2019 Final Rules, the Departments are also enjoined from enforcing the prior accommodation process in key respects as a result of a nationwide injunction issued by the U.S. District Court for the Northern District of Texas.[197] In *DeOtte v. Azar*, the court certified two classes of objectors to the contraceptive coverage requirements.[198] The "Employer Class" consisted of:

> Every current and future employer in the United States that objects, based on its sincerely held religious beliefs, to establishing, maintaining, providing, offering, or arranging for: (i) coverage or payments for some or all contraceptive services; or (ii) a plan, issuer, or third-party administrator that provides or arranges for such coverage or payments.[199]

The "Individual Class" consisted of:

> All current and future individuals in the United States who: (1) object to coverage or payments for some or all contraceptive services based on sincerely held religious beliefs; and (2) would be willing to purchase or obtain health insurance that excludes coverage or payments for some or all contraceptive services from a health insurance issuer, or from a plan sponsor of a group plan, who is willing to offer a separate benefit package option, or a separate policy, certificate, or contract of insurance that excludes coverage or payments for some or all contraceptive services.[200]

The court granted these classes summary judgment on their RFRA claims.[201] Similar to the Eighth Circuit's reasoning, the district court concluded with respect to the Employer Class that the court could not question the lead plaintiff's position "that the act of executing the accommodation forms is itself immoral."[202] As for the Individual Class, the court accepted the plaintiffs' argument

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[194] *Id.* at 227 (internal quotation marks omitted).

[195] *Id.* at 228.

[196] *See* Motion to Dismiss and for Summary Judgment, No. 17-cv-11930-NMG (D. Mass. Aug. 30, 2019), ECF No. 121; Commonwealth of Massachusetts' Motion for Summary Judgment, No. 17-cv-11930-NMG (D. Mass. July 31, 2019), ECF No. 115. During the summary judgment phase of litigation, the "court considers the contents of the pleadings, the motions, and additional evidence adduced by the parties to determine whether there is a genuine issue of material fact rather than one of law." *Summary Judgment*, BLACK'S LAW DICTIONARY (11th ed. 2019). In the absence of a material factual dispute, the court may grant the moving party's motion if that party is "entitled to prevail as a matter of law." *Id.*

[197] *See* Katie Keith, *ACA Litigation Round-Up: Contraceptive Mandate, Section 1557, and More*, HEALTHAFFAIRS (Aug. 6, 2019), https://www.healthaffairs.org/do/10.1377/hblog20190806.847241/full/ (noting that "[o]ther courts have enjoined the federal government from enforcing the contraceptive mandate against religious plaintiffs," but "the employer and individual class allowed by [the Northern District of Texas] are far broader").

[198] DeOtte v. Azar, No. 4:18-cv-00825-O, 2019 U.S. Dist. LEXIS 137849, at *16 (N.D. Tex. June 5, 2019).

[199] *Id.*

[200] *Id.*

[201] *Id.* at *36, *41–42.

[202] *Id.* at *29. The district court acknowledged that the Fifth Circuit had held that the Departments' prior accommodation process (requiring objecting employers to notify HHS or their insurers of their objections to providing coverage) did not violate RFRA. *Id.* at 22 (reasoning that the appellate court's decision did not bind the district court

that purchasing plans that cover certain forms of contraception substantially burdens their religious exercise because it makes them "complicit" in the provision of contraception to which they object.[203] Having found that the requirement imposed a substantial burden on these groups, the court then concluded that the requirement was insufficiently tailored.[204] It reasoned that "[i]f the Government has a compelling interest in ensuring access to free contraception, it has ample options at its disposal that do not involve conscripting religious employers" or requiring the participation of objecting employees.[205]

The district court permanently enjoined the government from enforcing the contraceptive coverage requirement against any member of the Employer Class to the extent of its objection.[206] It further enjoined the government from preventing a "willing" employer or insurer from offering Individual Class members plans that do not include contraceptive coverage.[207] In its final order specifying the terms of its nationwide, permanent injunction, the court included a "safe harbor" allowing the Departments to (1) ask employers or individuals whether they are sincere religious objectors; (2) enforce the contraceptive coverage requirement with respect to employers or individuals who "admit" they are not sincere religious objectors; and (3) seek a declaration from the court that an employer or individual falls outside the certified classes if the government "reasonably and in good faith doubt[s] the sincerity of that employer or individual's asserted religious objections."[208]

Before entering final judgment, the district court denied the State of Nevada's motion to intervene (supported by 22 additional states) in the litigation.[209] Nevada has appealed that denial and the court's injunction to the Fifth Circuit.[210]

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because it had been vacated and remanded by the Supreme Court in the *Zubik* litigation). However, the court reasoned that two "material development[s]" warranted a different conclusion. *Id.* at 24. First, the court observed that the Departments subsequently clarified the effect of the accommodation process on a subset of employer-sponsored plans—"self-insured plans governed by ERISA." *Id.* at *23 (emphasis removed). For such plans, the court reasoned, notifying the TPA of the employer's objection would likely result in the provision of contraceptive coverage through the same employer-sponsored plan rather than a separate plan, supporting the argument that the accommodation made those employers' plans a "vehicle" for coverage to which they objected. *Id.* at *23–24. Second, the court observed that following the Supreme Court's remand in *Zubik*, the Departments concluded that they were, in the district court's words, "unable to adequately protect religious employers' civil rights through the accommodation process." *Id.* at *24.

[203] *Id.* at *36–37 (observing that, in the plaintiffs' view, their premiums subsidize other people's access to contraception). *But see* Real Alternatives, Inc. v. Sec'y of HHS, 867 F.3d 338, 362 (3d Cir. 2017) (denying employees' RFRA claim, reasoning that "[t]here is a material difference between employers arranging or providing an insurance plan that includes contraception coverage . . . and becoming eligible to apply for reimbursement for a service of one's choosing").

[204] *DeOtte*, 2019 U.S. Dist. LEXIS 137849, at *32, *41.

[205] *Id.* at *34, *41.

[206] *Id.* at *50–52 (permitting the government to require coverage of those contraceptives to which the sponsoring Employer Class member does not have religious objections).

[207] *Id.* at *51–52.

[208] *Id.* at *48, *52–54; *see also* DeOtte v. Azar, No. 4:18-CV-00825-O, 2019 U.S. Dist. LEXIS 137519, at *39–40 (N.D. Tex. July 29, 2019) (entering final judgment and issuing permanent injunction).

[209] *See* Order, *DeOtte*, No. 4:18-cv-00825-O (N.D. Tex. July 29, 2019), ECF No. 97 (denying Nevada's motion to intervene); Brief of Amici Curiae Opposing Plaintiffs' Motion for Summary Judgment and Permanent Injunction and Supporting Nevada's Motion to Intervene, *DeOtte*, No. 4:18-cv-00825-O (N.D. Tex. July 9, 2019), ECF No. 93.

[210] Amended Notice of Appeal, DeOtte v. Azar, No. 19-10754 (5th Cir. Aug. 30, 2019) (appealing, *inter alia*, the district court's judgment and its denial of Nevada's motion to intervene); Protective Notice of Appeal, *DeOtte*, No. 19-10754 (5th Cir. July 5, 2019) (stating Nevada's intent to appeal the court's June 5, 2019, order granting the plaintiffs a permanent injunction if intervention is granted). Against this backdrop, the same district court ordered in a separate case that a central provision of the ACA, the "Individual Mandate," exceeded Congress's authority and could not be

Considerations for Congress

Although the contraceptive coverage requirement remains in effect,[211] the injunctions discussed above leave its implementation and enforcement in an uncertain posture. In combination, these rulings affect the regulatory frameworks that existed both before and after the promulgation of the expanded exemptions. The injunctions entered in the *Pennsylvania* and *California* actions do not bar entities that qualified for an exemption or an accommodation before the Religious or Moral Exemption IFRs from availing themselves of those options.[212] Accordingly, it appears that (1) qualifying institutions (e.g., houses of worship) can still invoke the exemption for religious employers; and (2) "eligible organizations"—including closely held corporations as defined in the 2015 rule—can still use the accommodation process.[213]

However, as a result of the injunctions entered in *DeOtte* and other cases concerning the accommodation, the government is more limited in its ability to enforce the requirement against entities that choose *not* to notify their insurers or HHS of their objections. For example, regardless of an entity's compliance with the accommodation process, the government may not enforce the requirement against employers within the Employer Class (i.e., those that object to providing or arranging for contraceptive coverage based on sincerely held religious beliefs), at least to the extent of those employers' objections.[214] And the government may not prevent employers or insurers from offering plans without contraceptive coverage to individuals who oppose that coverage based on sincere religious beliefs.[215] The *DeOtte* injunction does not bar the government from (1) enforcing the contraceptive coverage requirement against employers "who admit that they are not sincere religious objectors"; (2) asking employers who fail to comply with the coverage requirement whether they are sincere religious objectors; or (3) challenging an

"severed" from the rest of that law, invalidating the ACA in its entirety. Texas v. United States, 340 F. Supp. 3d 579, 586, 619 (N.D. Tex. 2018) (noting that "the ACA established a '[r]equirement to maintain minimum essential coverage'—commonly known as the 'Individual Mandate'" (quoting 26 U.S.C. § 5000A(a))). However, the court stayed its ruling during the pendency of the government's appeal to the Fifth Circuit. *See* Texas v. United States, No. 4:18-cv-00167-O, 2018 U.S. Dist. LEXIS 222345, at *41–42 (N.D. Tex. Dec. 30, 2018).

[211] HRSA has thus far maintained its guidelines requiring contraceptive coverage. However, HRSA could elect not to support including contraceptives among women's preventive services, in which case the ACA would not mandate such coverage unless amended by Congress. *See* 42 U.S.C. § 300gg-13(a)(4) (linking coverage for preventive services "with respect to women" to "such additional preventive care and screenings . . . as provided for in comprehensive guidelines supported by [HRSA] for purposes of this paragraph").

[212] *See* Pennsylvania v. Trump, 351 F. Supp. 3d 791, 829–30 (E.D. Pa. 2019) (stating that under the court's nationwide injunction, "those eligible for exemptions or accommodations prior to October 6, 2017 will maintain their status"), *aff'd sub nom.* Pennsylvania v. President United States, 930 F.3d 543, 575 (3d Cir. 2019) (stating that "the public interest favors minimizing harm to third-parties by ensuring that women who may lose ACA guaranteed contraceptive coverage are able to maintain access to [that coverage] . . . while final adjudication of the Rules is pending" because, among other reasons, "the current Accommodation does not substantially burden employers' religious exercise"); California v. HHS, 351 F. Supp. 3d 1267, 1298–99 (N.D. Cal. 2019) (discussing reasons for preserving the "status quo" that "preceded the Final Rules and the 2017 IFRs—in which eligible entities still would be permitted to avail themselves of the exemption or the accommodation").

[213] *See, e.g.*, 45 C.F.R. § 147.131 (2017).

[214] *See* DeOtte v. Azar, No. 4:18-cv-00825-O, 2019 U.S. Dist. LEXIS 137519, at *37–38 (N.D. Tex. July 29, 2019); DeOtte v. Azar, No. 4:18-cv-00825-O, 2019 U.S. Dist. LEXIS 137849, at *15 (N.D. Tex. June 5, 2019) (describing the Employer Class as "consisting of employers who object to the Contraceptive Mandate's accommodation process for religious reasons"); *see also id.* at *47 (responding to the government's concerns about discerning class members for enforcement purposes by stating that "class members should be able to simply decline the offending coverage with the comfort that, like other exempt entities and individuals, they will not be subjected to a religious test").

[215] *See DeOtte*, 2019 U.S. Dist. LEXIS 137519, at *38–39.

employer's claim to have a sincere religious objection in federal court.[216] In addition, because the Third Circuit has preliminarily blocked enforcement of the Moral Exemption nationwide, and because the *DeOtte* injunction extends only to employers with *religious* objections, it appears that, as a general matter, the government is not barred from enforcing the requirement against entities with ethical or moral, but not religious, objections to contraception.[217] However, injunctions entered in other cases may preclude enforcement against particular parties.[218] Further direction from the Departments or the courts following review on the merits may clarify the scope of the coverage requirement.[219]

Beyond the effects of the recent injunctions, the ongoing litigation reflects a broader public policy debate over the extent to which the government should accommodate entities with religious or moral objections to contraception, particularly when those accommodations may compromise their employees' or students' access to the full range of contraceptive services covered for other women. The complex legal questions stemming from this public policy debate remain largely unresolved five years after *Hobby Lobby*. Over the years, individual Members of Congress have weighed in on this topic,[220] and Congress, if interested, could do so as a whole to clarify the legal landscape. A number of approaches have been proposed that would recalibrate the legal framework for contraceptive coverage, including those that would have the government take a more active role in facilitating access to contraception and others that would attempt to clarify the responsibilities of the government in accommodating those with genuine religious objections to a coverage requirement.

Some lawmakers have proposed amendments to the ACA's preventive services coverage requirements "with respect to women"[221] to explicitly require coverage of contraception. For example, a bill introduced in the last Congress would have amended subsection (a)(4) to include "contraceptive care," including "the full range of [FDA-approved] female-controlled contraceptive methods" and "instruction in fertility awareness-based methods . . . for women

[216] *See id.* at *39–40.

[217] *See id.* at *35–36 (defining the Employer Class); *see also* Pennsylvania v. President United States, 930 F.3d 543, 575–76 (3d Cir. 2019) (upholding the nationwide preliminary injunction against both final rules).

[218] *See, e.g.*, March for Life v. Burwell, 128 F. Supp. 3d 116, 134 (D.D.C. 2015) (permanently enjoining the government from enforcing the contraceptive coverage requirement against "March for Life, its health insurance issuer, and the insurance issuer(s) of [certain] employee plaintiffs").

[219] On September 18, 2019, Attorneys General from the 15 states that are parties to the *California* action sent a letter to the Departments expressing concern that the Departments' websites do not reflect the preliminary injunctions currently in force and "may lead the public to incorrectly believe that employers can opt out of providing contraceptive coverage, in violation of the court's orders." Letter to Sec. Alex M. Azar II, HHS, Acting Sec. Patrick Pizzella, DOL, and Sec. Steven T. Mnuchin, U.S. Dep't of the Treasury 3 (Sept. 18, 2019), http://illinoisattorneygeneral.gov/pressroom/2019_09/09-18-19_California_v_Azar-USDeptofHHS_Labor_n_Treasury.pdf.

[220] *E.g.*, Brief of 123 Members of the United States Congress as Amici Curiae in Support of Respondents, Zubik v. Burwell, 136 S. Ct. 1557 (2016) (Nos. 14-1418 et al.); Brief of Amici Curiae 207 Members of Congress in Support of Petitioners, *Zubik*, 136 S. Ct. 1557 (Nos. 14-1418 et al.); Brief of 91 Members of the United States House of Representatives as Amici Curiae in Support of the Government, Burwell v. Hobby Lobby Stores, Inc., 573 U.S. 682 (2014) (Nos. 13-354, 13-356); Brief of Amici Curiae Members of Congress in Support of Respondents, *Hobby Lobby*, 573 U.S. 682 (No. 13-354).

[221] 42 U.S.C. § 300gg-13(a)(4).

desiring an alternative method."[222] Other proposals, including a bill introduced this Congress, would direct the Departments to include certain forms of contraception at the regulatory level.[223]

In general, legislation specifying that contraception is among the required preventive health services may help tip the scales on the government interest prong of the RFRA analysis toward a compelling interest in providing cost-free coverage for contraception through employer-sponsored health plans. In *Hobby Lobby*, the Supreme Court assumed that the government had a compelling interest in "guaranteeing cost-free access" to the objected-to contraceptive methods.[224] However, the majority noted that "there are features of ACA that support" the opposing view, in particular, the inapplicability of the requirement to grandfathered plans.[225] The Departments went a step further in the 2019 Final Rules, suggesting that the government did not have a compelling interest in contraceptive coverage because Congress left the decision of whether to include it to the agencies.[226] Codifying the requirement may respond to arguments of this nature. However, proposals to expand contraceptive coverage, standing alone, could still be susceptible to challenge by religious objectors who might still assert that laws mandating coverage—even if they include some exemptions—impose a substantial burden on their religious exercise and are not narrowly tailored under RFRA.[227]

RFRA applies by default to all federal statutes adopted after its enactment (November 16, 1993) "unless such law explicitly excludes such application by reference to this Act."[228] Some legislation concerning contraception includes language excepting those provisions from RFRA or excluding RFRA claims.[229] A pair of bills introduced in the wake of *Hobby Lobby* would have

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[222] Save Women's Preventive Care Act, S. 1045, 115th Cong. § 4(a) (as introduced May 4, 2017), https://www.congress.gov/bill/115th-congress/senate-bill/1045; *see also* Women's Preventive Health Awareness Campaign, H.R. 2355, 114th Cong. § 4 (as introduced May 15, 2015), https://www.congress.gov/bill/114th-congress/house-bill/2355 (stating that in applying the ACA's preventive services coverage requirements "with respect to women," the "guidelines supported under subsection (a)(4) shall be treated as including the recommendation of one form of contraception in each of the methods identified by the [FDA] in its current Birth Control Guide as well as clinical services needed for provision of such contraceptive method, including patient education and counseling").

[223] *See* Affordability Is Access Act, H.R. 3296, 116th Cong. § 5 (as introduced June 14, 2019), https://www.congress.gov/bill/116th-congress/house-bill/3296/ (directing the Departments to "clarify that coverage of contraceptives pursuant to section 2713(a)(4) of the Public Health Service Act (42 U.S.C. 300gg–13(a)(4)) includes coverage of over-the-counter contraceptive methods approved by the [FDA], even if the enrollee does not have a prescription for the contraceptive"); S. 1847, 116th Cong. § 5 (as introduced June 13, 2019), https://www.congress.gov/bill/116th-congress/senate-bill/1847/ (same).

[224] Burwell v. Hobby Lobby Stores, Inc., 573 U.S. 682, 728 (2014).

[225] *Id.* at 727.

[226] In the 2019 Final Rules, the Departments indicated that they no longer believed that applying the contraceptive coverage requirement to objecting entities served a compelling governmental interest. They posited that "the structure of section 2713(a)(4) [(pertaining to preventive services for women)] and the ACA evince a desire by Congress to grant a great amount of discretion on the issue of whether, and to what extent, to require contraceptive coverage in health plans," which "inform[ed] the Departments' assessment of whether the interest in mandating the coverage constitutes a compelling [one]." Religious Exemption, *supra* note 131, at 57,546–47.

[227] *See* Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal, 546 U.S. 418, 434 (2006) ("The Government argues that the existence of a *congressional* exemption for peyote does not indicate that the Controlled Substances Act is amenable to *judicially crafted* exceptions. RFRA, however, plainly contemplates that *courts* would recognize exceptions—that is how the law works.").

[228] 42 U.S.C. § 2000bb-3(b).

[229] *See, e.g.*, Access to Birth Control Act, H.R. 2182, 116th Cong. § 3 (as introduced Apr. 9, 2019), https://www.congress.gov/bill/116th-congress/house-bill/2182 ("The Religious Freedom Restoration Act of 1993 (42 U.S.C. 2000bb et seq.) shall not provide a claim concerning, or a defense to a claim under, a covered title, or provide a basis for challenging the application or enforcement of a covered title.").

prohibited an "employer that establishes or maintains a group health plan for its employees" from "deny[ing] coverage of a specific health care item or service . . . where the coverage of such item or service is required under any provision of Federal law or the regulations promulgated thereunder," notwithstanding RFRA.[230] Lawmakers have also proposed amendments to RFRA itself. Similar bills introduced in both chambers this Congress would provide that RFRA's strict scrutiny standard does not apply to certain types of laws, including "any provision of law or its implementation that provides for or requires . . . access to, . . . referrals for, provision of, or coverage for, any health care item or service."[231]

Laws that make RFRA inapplicable to the contraceptive coverage requirement would not foreclose challenges based on the Free Exercise Clause.[232] However, as previously noted, Free Exercise claims are potentially subject to a less stringent standard of review than RFRA-based objections because of the Supreme Court's holding in *Employment Division v. Smith* that the Free Exercise Clause typically does not require the government to provide religious-based exemptions to generally applicable laws.[233]

Other approaches to contraceptive coverage have focused on accommodating the interests of religious objectors. Some courts and objecting employers have suggested that Congress could avoid or minimize burdens on religious objectors by funding separate contraceptive coverage or expanding access to programs that provide free contraception instead of requiring employers to provide this coverage.[234] Along these lines, the Departments have separately issued a rule to give the directors of federally funded family planning projects the authority to extend contraceptive services to some women whose employers do not provide coverage for such services because of a

[230] Protect Women's Health From Corporate Interference Act of 2014, S. 2578, 113th Cong. § 4(a)–(b) (as introduced July 9, 2014), https://www.congress.gov/bill/113th-congress/senate-bill/2578; H.R. 5051, 113th Cong. § 4(a)–(b) (as introduced July 9, 2014), https://www.congress.gov/bill/113th-congress/house-bill/5051. The "Findings" section of the Senate version stated that the bill was "intended to be consistent with the Congressional intent in enacting [RFRA], and with the exemption for houses of worship, and an accommodation for religiously-affiliated nonprofit organizations with objections to contraceptive coverage." S. 2578, § 3(19). Both bills stated that the Departments' regulations concerning the religious employer exemption and the accommodation process for eligible organizations were to apply. S. 2578, § 4(c); H.R. 5051, § 4(c).

[231] Do No Harm Act, H.R. 1450, 116th Cong. § 3 (as introduced Feb. 28, 2019), https://www.congress.gov/bill/116th-congress/house-bill/1450; S. 593, 116th Cong. § 3 (as introduced Feb. 28, 2019), https://www.congress.gov/bill/116th-congress/senate-bill/593.

[232] *See generally* City of Boerne v. Flores, 521 U.S. 507, 519 (1997) (stating that Congress does not have the "power to determine what constitutes a constitutional violation").

[233] By way of illustration, prior to the federal contraceptive coverage requirement, the highest courts in California and New York rejected Free Exercise challenges to state law contraceptive coverage requirements in those jurisdictions based on the Supreme Court's decision in *Employment Division v. Smith*. *See* Catholic Charities of Sacramento, Inc. v. Superior Court, 85 P.3d 67, 94 (Cal. 2004) (reasoning, in a challenge brought by a nonprofit corporation affiliated with the Catholic Church, that the plaintiff's free exercise claim would fail under the *Smith* standard and concluding that the California law survived even strict scrutiny); Catholic Charities of Diocese of Albany v. Serio, 859 N.E.2d 459, 465 (N.Y. 2006) (reasoning that *Smith* posed "an insuperable obstacle to plaintiffs' federal free exercise claim").

[234] *See, e.g.*, Burwell v. Hobby Lobby Stores, Inc., 573 U.S. 682, 728–30 (2014) ("The most straightforward way of doing this would be for the Government to assume the cost of providing the four contraceptives at issue to any women who are unable to obtain them under their health-insurance policies due to their employers' religious objections."); Sharpe Holdings, Inc. v. HHS, 801 F.3d 927, 945 (8th Cir. 2015) (reasoning that on the limited record before it, the government had not shown the infeasibility of the alternatives proposed by the plaintiffs: government "subsidies, reimbursements, tax credits, or tax deductions to employees" or funding "for the distribution of contraceptives at community health centers, public clinics, and hospitals with income-based support").

religious or moral exemption.[235] (This rule is also the subject of pending litigation.[236]) While the efficacy of such proposals in maintaining or increasing access to contraception is beyond the scope of this report, alternatives that do not involve requiring private parties to provide contraceptive coverage or otherwise take an action that results in the provision of coverage by a third party could reduce the potential for both RFRA and Free Exercise challenges.[237]

Other proposals seek to codify exemptions to the contraceptive coverage requirement for entities with religious or moral objections. For example, the Religious Liberty Protection Act of 2014 would have prohibited HHS from "implement[ing] or enforc[ing]" any rule that "relates to requiring any individual or entity to provide coverage of sterilization or contraceptive services to which the individual or entity is opposed on the basis of religious belief."[238] That bill also would have included a "special rule" in the ACA stating that a "health plan shall not be considered to have failed to provide" the required preventive health services "on the basis that the plan does not provide (or pay for) coverage of sterilization or contraceptive services because—(A) providing (or paying for) such coverage is contrary to the religious or moral beliefs of the sponsor, issuer, or other entity offering the plan; or (B) such coverage, in the case of individual coverage, is contrary to the religious or moral beliefs of the purchaser or beneficiary of the coverage."[239] Enacting statutory exemptions to the contraceptive coverage requirement might avoid future litigation over the Departments' authority under the ACA to create categorical exemptions.[240] In addition, broader exemptions could reduce the potential for RFRA or Free Exercise challenges. At the same time, they could increase the prospect of Establishment Clause challenges like those brought in response to the expanded exemptions in the 2019 Final Rules.[241] While the Supreme Court has said that "there is room for play in the joints" between the Free Exercise Clause and the

[235] Compliance With Statutory Program Integrity Requirements, 84 Fed. Reg. 7,714, 7,734, 7,787 (Mar. 4, 2019); *see also* CRS In Focus IF11142, *Title X Family Planning Program: 2019 Final Rule*, by Angela Napili and Victoria L. Elliott.

[236] *See, e.g.*, California v. Azar, 927 F.3d 1068, 1073 (9th Cir. 2019) (per curiam) (staying three district courts' preliminary injunctions blocking the rule's implementation upon concluding that the government was likely to succeed in showing that the rule was valid), *reh'g en banc granted*, 927 F.3d 1045, 1046 (9th Cir. 2019).

[237] *Cf. Sharpe Holdings, Inc.*, 801 F.3d at 941 ("Even if the ACA requires that insurance issuers and group health plans include contraceptive coverage regardless of whether [the plaintiffs] self-certify, it also compels [the plaintiffs] 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. . . . [I]f one sincerely believes that completing Form 700 or HHS Notice will result in conscience-violating consequences, what some might consider an otherwise neutral act is a burden too heavy to bear."), *vacated and remanded sub nom.* HHS v. CNS Int'l Ministries, 136 S. Ct. 2006 (2016).

[238] H.R. 4396, 113th Cong. § 3(a) (as introduced Apr. 3, 2014), https://www.congress.gov/bill/113th-congress/house-bill/4396.

[239] *Id.* § 3(b); *see also* Health Care Conscience Rights Act, H.R. 940, 113th Cong. (as introduced Mar. 4, 2013), https://www.congress.gov/bill/113th-congress/house-bill/940 (amending the ACA title that includes the preventive health services coverage requirements to state that "no provision of this title . . . shall . . . require an issuer of health insurance coverage or the sponsor of a group health plan to include, in any such coverage or plan, coverage of an abortion or other item or service to which such issuer or sponsor has a moral or religious objection" and stating that any regulation that violates that restriction must not be "given legal effect").

[240] *See* Pennsylvania v. President United States, 930 F.3d 543, 570 (3d Cir. 2019) ("Nothing from § 300gg-13(a) gives HRSA the discretion to wholly exempt actors of its choosing from providing the guidelines services.").

[241] *See, e.g.*, First Amended Complaint for Declaratory and Injunctive Relief ¶ 129, California v. HHS, 351 F. Supp. 3d 1267 (N.D. Cal. 2019) (No. 17-cv-05783) ("By promulgating the new IFRs, Defendants have violated the Establishment Clause because the IFRs do not have a secular legislative purpose, the primary effect advances religion, especially in that they place an undue burden on third parties—the women who seek birth control, and the IFRs foster excessive government entanglement with religion.").

Establishment Clause,[242] it remains to be seen whether broad accommodations like the Religious Exemption and the Moral Exemption fit comfortably in that space.[243]

In the five years since the *Hobby Lobby* decision, the Departments promulgated six different rules concerning the contraceptive coverage requirement, a change in presidential administration marked a turning point in the Departments' RFRA calculus, and the Supreme Court underwent its own changes with the appointment of two new Justices. As lower courts continue to adjudicate challenges to the requirement in its most recent iterations, Congress, the Executive, and the Judiciary may all have a role to play in defining the interests at stake and the balance to be achieved in the years ahead.

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[242] Locke v. Davey, 540 U.S. 712, 718–19 (2004) (internal quotation marks and citation omitted) ("In other words, there are some state actions permitted by the Establishment Clause but not required by the Free Exercise Clause.").

[243] *See* California v. HHS, 351 F. Supp. 3d 1267, 1291–92 (N.D. Cal. 2019) (observing that whether "RFRA operates as a floor on religious accommodation" or "a ceiling" in terms of what it authorizes or requires agencies to do raises "what appears to be a complex issue at the intersection of RFRA, Free Exercise, and Establishment Clause jurisprudence" (internal quotation marks and citation omitted)).