No. 15-774

In the Supreme Court of the United States

SYLVIA M. BURWELL, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL., PETITIONERS

v.

DORDT COLLEGE AND CORNERSTONE UNIVERSITY

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Under federal law, health insurers and employer-sponsored group health plans generally must cover certain preventive health services, including contraceptive services prescribed for women by their doctors. Respondents object to providing contraceptive coverage on religious grounds and are eligible for a regulatory accommodation that would allow them to opt out of the contraceptive-coverage requirement. The court of appeals held, however, that the accommodation itself violates the Religious Freedom Restoration Act of 1993 (RFRA), 42 U.S.C. 2000bb *et seq.*, by requiring third parties to provide respondents' employees and their beneficiaries with separate contraceptive coverage after respondents opt out. The question presented is:

Whether RFRA entitles respondents not only to opt out of providing contraceptive coverage themselves, but also to prevent the government from arranging for third parties to provide separate coverage to the affected women.

PARTIES TO THE PROCEEDINGS

Petitioners are Sylvia M. Burwell, in her official capacity as Secretary of the United States Department of Health and Human Services; Thomas Perez, in his official capacity as Secretary of the United States Department of Labor; Jack Lew, in his official capacity as Secretary of the United States Department of the Treasury; the United States Department of Health and Human Services; the United States Department of Labor; and the United States Department of the Treasury.

Respondents are Dordt College and Cornerstone University.

TABLE OF CONTENTS

Page

Opinions below 1
Jurisdiction 1
Statutory and regulatory provisions involved 2
Statement 2
Discussion 11
Conclusion 13
Appendix A — Court of appeals opinion (Sept. 17, 2015) 1a
Appendix B — District court order (May 21, 2014) 10a
Appendix C — Statutory and regulatory provisions 20a

TABLE OF AUTHORITIES

Cases:

Burwell v. *Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751 (2014) 3, 4, 5, 6, 7, 8
Catholic Health Care Sys. v. *Burwell*, 796 F.3d 207 (2d Cir. 2015) 11
East Tex. Baptist Univ. v. *Burwell*, 793 F.3d 449 (5th Cir.), cert. granted, No. 15-35 (Nov. 6, 2015) 11
Geneva College v. *Secretary HHS*, 778 F.3d 422 (3d Cir.), cert. granted, Nos. 14-1418 and 15-191 (Nov. 6, 2015) 11
Grace Schools v. *Burwell*, 801 F.3d 788 (7th Cir. 2015) 11
King v. *Burwell*, 135 S. Ct. 2480 (2015) 2
Little Sisters of the Poor Home for the Aged v. *Burwell*, 794 F.3d 1151 (10th Cir.), cert. granted, Nos. 15-105 and 15-119 (Nov. 6, 2015) 11
Michigan Catholic Conference & Catholic Family Servs. v. *Burwell*, No. 13-2723, 2015 WL 4979692 (6th Cir. Aug. 21, 2015) 11

Cases—Continued: Page

Priests for Life v. *HHS*, 772 F.3d 229 (D.C. Cir. 2014), cert. granted, Nos. 14-1453 and 14-1505 (Nov. 6, 2015) 2, 3, 11
Sharpe Holdings, Inc. v. *HHS*, 801 F.3d 927 (8th Cir. 2015) 10, 11
University of Notre Dame v. *Burwell*, 786 F.3d 606 (7th Cir. 2015) 11
Wheaton College v. *Burwell*:
134 S. Ct. 2806 (2014) 8
791 F.3d 792 (7th Cir. 2015) 11

Statutes and regulations:

Employee Retirement Income Security Act of 1974, 29 U.S.C. 1001 *et seq.* 6
29 U.S.C. 1002(33) 6
29 U.S.C. 1003(b)(2) 6
Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 2
Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 2
42 U.S.C. 300gg-11 to 300gg-19a 2
42 U.S.C. 300gg-13 ..... 2, 20a
42 U.S.C. 300gg-13(a)(4) 3, 20a
42 U.S.C. 18011 4
Religious Freedom Restoration Act of 1993, 42 U.S.C. 2000bb *et seq.* 8, 22a
42 U.S.C. 2000bb-1 ..... 9, 23a
26 U.S.C. 6033(a)(3)(A) 4
26 C.F.R. 54.9815-2713(a)(1)(iv) 4, 26a

Regulations—Continued: Page

29 C.F.R.:
Section 2510.3-16(b) 6, 31a
Section 2590.715-2713(a)(1)(iv) 4, 34a
Section 2590.715-2713A(b)(1)(ii)(A) 8, 41a
Section 2590.715-2713A(b)(1)(ii)(B) 9, 41a
Section 2590.715-2713A(b)(2) 6, 41a
Section 2590.715-2713A(c)(1) 9, 42a
Section 2590.715-2713A(d) 7, 44a

45 C.F.R.:
Section 147.130(a)(1)(iv) 4, 47a
Section 147.131(a) 4, 52a
Section 147.131(b) 5, 53a
Section 147.131(c) 6, 53a
Section 147.131(c)(1)(i) 8, 54a
Section 147.131(c)(1)(ii) 9, 54a
Section 147.131(d) 7, 56a
Section 147.131(f) 6, 58a

Miscellaneous:

77 Fed. Reg.:
p. 8725 (Feb. 15, 2012) 4
p. 16,503 (Mar. 21, 2012) 5

78 Fed. Reg. (July 2, 2013):
p. 39,872 2
p. 39,874 7
pp. 39,875-39,880 5
pp. 39,879-39,880 6
p. 39,893 6

Miscellaneous—Continued: Page

79 Fed. Reg. (Aug. 27, 2014):
p. 51,092 9
pp. 51,094-51,095 9
p. 51,095 7
80 Fed. Reg. (July 14, 2015):
p. 41,323 6
pp. 41,324-41,330 5
p. 41,346 5
IOM, *Clinical Preventive Services for Women: Closing the Gaps* (2011) 3, 4
Kaiser Family Found. & Health Research & Educ. Trust, *Employer Health Benefits 2015 Annual Survey* (2015), http://files.kff.org/attachment/report-2015-employer-health-benefits-survey 2, 4
U.S. Dep't of Health & Human Servs., *Notice of Availability of Separate Payments for Contraceptive Services*, https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/cms-10459-enrollee-notice.pdf (last visited Dec. 14, 2015) 7

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SYLVIA M. BURWELL, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL., PETITIONERS

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DORDT COLLEGE AND CORNERSTONE UNIVERSITY

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

The Solicitor General, on behalf of the Department of Health and Human Services, *et al.*, respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Eighth Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-9a) is reported at 801 F.3d 946. The order of the district court (App., *infra*, 10a-19a) is reported at 22 F. Supp. 3d 934.

JURISDICTION

The judgment of the court of appeals was entered on September 17, 2015. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

Pertinent statutory and regulatory provisions are set forth in the appendix to this petition. App., *infra*, 20a-58a.

STATEMENT

1. The Patient Protection and Affordable Care Act (Affordable Care Act or Act), Pub. L. No. 111-148, 124 Stat. 119,[1] seeks to ensure universal access to quality, affordable health coverage. Some of the Act's provisions make insurance available to people who previously could not afford it. See *King* v. *Burwell*, 135 S. Ct. 2480, 2485-2487 (2015). Other reforms seek to improve the quality of coverage for all Americans, including the roughly 150 million people who continue to rely on employer-sponsored group health plans. See, *e.g.*, 42 U.S.C. 300gg-11 to 300gg-19a.[2]

One of the Act's reforms requires insurers and employer-sponsored group health plans to cover immunizations, screenings, and other preventive services without imposing copayments, deductibles, or other cost-sharing requirements. 42 U.S.C. 300gg-13. Congress determined that broader and more consistent use of preventive services is critical to improving public health and that people are more likely to obtain appropriate preventive care when they do not have to pay for it out of pocket. 78 Fed. Reg. 39,872 (July 2, 2013); see *Priests for Life* v. *HHS*, 772 F.3d 229, 259-

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[1] Amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029.

[2] See Kaiser Family Found. & Health Research & Educ. Trust, *Employer Health Benefits 2015 Annual Survey* 58 (2015), http://files.kff.org/attachment/report-2015-employer-health-benefits-survey (*Health Benefits Survey*).

260 (D.C. Cir. 2014) (*PFL*), cert. granted, Nos. 14-1453 and 14-1505 (Nov. 6, 2015).

The Act specifies that the preventive services to be covered without cost-sharing include "preventive care and screenings" for women "as provided for in comprehensive guidelines supported by the Health Resources and Services Administration" (HRSA), a component of the Department of Health and Human Services (HHS). 42 U.S.C. 300gg-13(a)(4); see *Burwell* v. *Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2762 (2014) (*Hobby Lobby*). Congress included a specific provision for women's health services "to remedy the problem that women were paying significantly more out of pocket for preventive care and thus often failed to seek preventive services." *PFL*, 772 F.3d at 235; see *Hobby Lobby*, 134 S. Ct. at 2785-2786 (Kennedy, J., concurring).

In identifying the women's preventive services to be covered, HRSA relied on recommendations from independent experts at the Institute of Medicine (IOM). *Hobby Lobby*, 134 S. Ct. at 2762. IOM recommended including the full range of contraceptive methods approved by the Food and Drug Administration (FDA), which IOM found can greatly decrease the risk of unintended pregnancies, adverse pregnancy outcomes, and other negative health consequences for women and children. IOM, *Clinical Preventive Services for Women: Closing the Gaps* 10, 109-110 (2011) (*IOM Report*). IOM also noted that "[c]ontraceptive coverage has become standard practice for most private insurance and federally funded insurance programs" and that "health care professional associations"—including the American Medical Association and the American Academy of Pediatrics—

"recommend the use of family planning services as part of preventive care for women." *Id.* at 104, 108.

Consistent with IOM's recommendation, the HRSA guidelines include all FDA-approved contraceptive methods, as prescribed by a doctor or other health care provider. 77 Fed. Reg. 8725 (Feb. 15, 2012); see *Hobby Lobby*, 134 S. Ct. at 2762. Accordingly, the regulations adopted by the three Departments responsible for implementing the relevant provisions of the Affordable Care Act (HHS, Labor, and the Treasury) include those contraceptive methods among the preventive services that insurers and employer-sponsored group health plans must cover without cost-sharing. 45 C.F.R. 147.130(a)(1)(iv) (HHS); 29 C.F.R. 2590.715-2713(a)(1)(iv) (Labor); 26 C.F.R. 54.9815-2713(a)(1)(iv) (Treasury).[3]

2. "'[C]hurches, their integrated auxiliaries, and conventions or associations of churches,' as well as 'the exclusively religious activities of any religious order,'" are exempt from the contraceptive-coverage requirement under a regulation that incorporates a longstanding definition from the Internal Revenue Code. *Hobby Lobby*, 134 S. Ct. at 2763 (quoting 26 U.S.C. 6033(a)(3)(A) and citing 45 C.F.R. 147.131(a)). In addition, recognizing that some other employers have religious objections to providing contraceptive coverage, the Departments developed "a system that

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[3] Under the Act's grandfathering provision, health plans that have not made specified changes since the Act's enactment are exempt from many of the Act's reforms, including the requirement to cover preventive services. *Hobby Lobby*, 134 S. Ct. at 2763-2764; see 42 U.S.C. 18011. The percentage of employees in grandfathered plans has dropped from 56% in 2011 to 25% in 2015. *Health Benefits Survey* 8, 217.

seeks to respect the religious liberty" of such employers "while ensuring that the employees of these entities have precisely the same access to all FDA-approved contraceptives" as other women. *Id.* at 2759; see 77 Fed. Reg. 16,503 (Mar. 21, 2012). That regulatory accommodation is available to any nonprofit organization that holds itself out as a religious organization and that opposes covering some or all of the required contraceptive services on religious grounds. 45 C.F.R. 147.131(b). In light of this Court's decision in *Hobby Lobby*, the Departments have also extended the same accommodation to closely held for-profit entities that object to providing contraceptive coverage based on their owners' religious beliefs. 80 Fed. Reg. 41,324-41,330, 41,346 (July 14, 2015) (to be codified at 45 C.F.R. 147.131(b)(2)(ii)).

a. The accommodation allows objecting employers to opt out of any obligation to provide contraceptive coverage and instead requires third parties to make separate payments for contraceptive services on behalf of employees (and their covered dependents) who choose to use those services. 78 Fed. Reg. at 39,875-39,880.

If the employer invoking the accommodation has an insured plan—that is, if it purchases coverage from a health insurance issuer such as BlueCross BlueShield—then the obligation to provide separate coverage falls on the insurer. The insurer must "exclude contraceptive coverage from the employer's plan and provide separate payments for contraceptive services for plan participants without imposing any cost-sharing requirements on the eligible organization, its insurance plan, or its employee beneficiaries."

Hobby Lobby, 134 S. Ct. at 2763; see 45 C.F.R. 147.131(c).[4]

Rather than purchasing coverage from an insurer, some employers "self-insure" by paying employee health claims themselves. Self-insured employers typically hire an insurance company or other outside entity to serve as a third-party administrator (TPA) responsible for processing claims and performing other administrative tasks. 78 Fed. Reg. at 39,879-39,880 & n.40. If a self-insured employer invokes the accommodation, its TPA "must 'provide or arrange payments for contraceptive services' for the organization's employees without imposing any cost-sharing requirements on the eligible organization, its insurance plan, or its employee beneficiaries." *Hobby Lobby*, 134 S. Ct. at 2763 n.8 (quoting 78 Fed. Reg. at 39,893); see 29 C.F.R. 2590.715-2713A(b)(2). The TPA may then obtain compensation for providing the required coverage through a reduction in fees paid by insurers to participate in the federally-facilitated insurance exchanges created under the Affordable Care Act. *Hobby Lobby*, 134 S. Ct. at 2763 n.8.

The accommodation operates differently if a self-insured organization has a "church plan" as defined in 29 U.S.C. 1002(33). Church plans are generally exempt from regulation under the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1001 *et seq.* See 29 U.S.C. 1003(b)(2). The government's authority to require a TPA to provide coverage under the accommodation derives from ERISA. See 29 C.F.R. 2510.3-16(b); 80 Fed. Reg. at 41,323. Accordingly, if an eligible organization with a self-insured

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[4] The same procedure applies to colleges and universities that arrange health insurance for their students. 45 C.F.R. 147.131(f).

church plan invokes the accommodation, its TPA is not legally required to provide separate contraceptive coverage to the organization's employees, but the government will reimburse the TPA if it provides coverage voluntarily. 79 Fed. Reg. 51,095 n.8 (Aug. 27, 2014).

In all cases, an employer that opts out under the accommodation has no obligation "to contract, arrange, pay, or refer for contraceptive coverage" to which it has religious objections. 78 Fed. Reg. at 39,874. The employer also need not inform plan participants of the separate coverage provided by third parties. Instead, insurers and TPAs must provide such notice themselves, must do so "separate from" materials distributed in connection with the employer's group health coverage, and must make clear that the objecting employer plays no role in covering contraceptive services. 29 C.F.R. 2590.715-2713A(d); 45 C.F.R. 147.131(d).[5] The accommodation thus "effectively exempt[s]" objecting employers from the contraceptive-coverage requirement. *Hobby Lobby*, 134 S. Ct. at 2763.

b. The original accommodation regulations provided that an eligible employer could invoke the accommodation, and thereby opt out of the contraceptive-coverage requirement, by "self-certify[ing]" its eligibility using a form provided by the Department of

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[5] A model notice informs employees that their employer "will not contract, arrange, pay, or refer for contraceptive coverage" and that the issuer or TPA "will provide separate payments for contraceptive services." HHS, *Notice of Availability of Separate Payments for Contraceptive Services*, https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/cms-10459-enrollee-notice.pdf (last visited Dec. 14, 2015).

Labor and transmitting that form to its insurer or TPA. *Hobby Lobby*, 134 S. Ct. at 2782; see 29 C.F.R. 2590.715-2713A(b)(1)(ii)(A); 45 C.F.R. 147.131(c)(1)(i). In light of this Court's interim order in *Wheaton College* v. *Burwell*, 134 S. Ct. 2806 (2014) (*Wheaton*), the Departments have also made available an alternative procedure for invoking the accommodation.

In *Wheaton*, the Court granted an injunction pending appeal to Wheaton College, which had challenged the accommodation under the Religious Freedom Restoration Act of 1993 (RFRA), 42 U.S.C. 2000bb *et seq.* As a condition for injunctive relief, the Court required Wheaton to inform HHS in writing that it satisfied the requirements for the accommodation. *Wheaton*, 134 S. Ct. at 2807. The Court provided that Wheaton "need not use the form prescribed by the Government" and "need not send copies to health insurance issuers or [TPAs]." *Ibid.* At the same time, the Court specified that "[n]othing in [its] order preclude[d] the Government from relying on" Wheaton's written notice "to facilitate the provision of full contraceptive coverage under the Act" by requiring Wheaton's insurers and TPAs to provide that coverage separately. *Ibid.* The government was able to do so because, as the Court was aware, Wheaton had identified its insurers and TPAs in the course of the litigation. *Id.* at 2815 (Sotomayor, J., dissenting).

In light of this Court's interim order in *Wheaton*, the Departments augmented the accommodation to provide all eligible employers with an option essentially equivalent to the one made available to Wheaton. The regulations allow an eligible employer to opt out by notifying HHS of its objection rather than by sending the self-certification form to its insurer or TPA.

79 Fed. Reg. at 51,092. The employer need not use any particular form and need only indicate the basis on which it qualifies for the accommodation, as well as the type of plan it offers and contact information for the plan's insurers and TPAs. *Id.* at 51,094-51,095; see 29 C.F.R. 2590.715-2713A(b)(1)(ii)(B) and (c)(1); 45 C.F.R. 147.131(c)(1)(ii). If an employer opts out using this alternative procedure, HHS or the Department of Labor will notify its issuers or TPAs of their obligation to provide separate contraceptive coverage. *Ibid.*

3. Respondents are two nonprofit religious colleges that provide or arrange health coverage for their employees and students, but that object to covering certain contraceptive services. Respondent Dordt College provides coverage for its employees through a self-insured plan and arranges coverage for its students through an insurer. Respondent Cornerstone University offers coverage to its employees through an insured plan. Respondents are eligible to opt out of the contraceptive-coverage requirement under the accommodation. App., *infra*, 2a-4a, 7a.

4. Respondents filed this suit challenging the accommodation under RFRA, which provides that the government may not "substantially burden a person's exercise of religion" unless that burden is "the least restrictive means of furthering [a] compelling governmental interest." 42 U.S.C. 2000bb-1. Respondents asserted that the accommodation substantially burdens their religious exercise because the government will arrange for their insurers and TPAs to provide employees and students with separate contraceptive coverage if respondents themselves opt out. The district court granted respondents' motion for a preliminary injunction. App., *infra*, 10a-19a.

5. The court of appeals affirmed in a brief opinion incorporating the reasoning of its decision in *Sharpe Holdings, Inc.* v. *HHS*, 801 F.3d 927 (2015), which was issued on the same day and which upheld a preliminary injunction in a parallel RFRA challenge to the accommodation. App., *infra*, 1a-9a.[6]

Sharpe Holdings acknowledged that every other court of appeals to consider RFRA challenges to the accommodation—seven courts in all—had held that the accommodation does not impose a substantial burden on the exercise of religion because it relieves objecting organizations of any involvement in the provision of contraceptive coverage and instead shifts the obligation to provide that coverage to third parties. 801 F.3d at 939-940 & n.11. But the court disagreed with those decisions, holding that it was required to "accept [respondents'] assertion that self-certification under the accommodation * * * would violate their sincerely held religious beliefs" and that nothing more was necessary to establish that the accommodation substantially burdens respondents' exercise of religion. *Id.* at 941; see *id.* at 941-943.

Sharpe Holdings further held that the accommodation is not the least restrictive means of furthering compelling government interests. 801 F.3d at 943-946. The court assumed without deciding that the contraceptive-coverage requirement advances "compelling interests in safeguarding public health and in ensuring that women have equal access to health care." *Id.* at 943. But it held that, at least on the

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[6] The government is filing a petition for a writ of certiorari seeking review of the decision in *Sharpe Holdings* concurrently with the filing of this petition. See *HHS* v. *CNS Int'l Ministries*, No. 15-___ (filed Dec. 15, 2015).

preliminary-injunction record before it, the government had not shown that the accommodation is the least-restrictive means of furthering those interests. *Id.* at 944-945.

DISCUSSION

The court of appeals held that RFRA entitles objecting employers not only to opt out of providing contraceptive coverage themselves, but also to prevent the government from eliminating the resulting harm to their female employees, students, and beneficiaries by arranging for third parties to provide those women with separate coverage under the accommodation. That conclusion was erroneous, as the other courts of appeals to consider the question have uniformly held.[7]

Parallel RFRA challenges to the accommodation are currently pending before this Court in *Zubik* v. *Burwell*, cert. granted, No. 14-1418 (Nov. 6, 2015), and six consolidated cases. See *Priests for Life* v. *HHS*, cert. granted, No. 14-1453 (Nov. 6, 2015); *Roman Catholic Archbishop of Washington* v. *Burwell*, cert.

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[7] See *Michigan Catholic Conference & Catholic Family Servs.* v. *Burwell*, No. 13-2723, 2015 WL 4979692, at *12 (6th Cir. Aug. 21, 2015); *Grace Schools* v. *Burwell*, 801 F.3d 788, 807-808 (7th Cir. 2015); *Catholic Health Care Sys.* v. *Burwell*, 796 F.3d 207, 226 (2d Cir. 2015); *Little Sisters of the Poor Home for the Aged* v. *Burwell*, 794 F.3d 1151, 1195 (10th Cir.), cert. granted, Nos. 15-105 and 15-119 (Nov. 6, 2015); *East Tex. Baptist Univ.* v. *Burwell*, 793 F.3d 449, 463 (5th Cir.), cert. granted, No. 15-35 (Nov. 6, 2015); *Wheaton College* v. *Burwell*, 791 F.3d 792, 799-801 (7th Cir. 2015); *University of Notre Dame* v. *Burwell*, 786 F.3d 606, 618-619 (7th Cir. 2015); *Geneva College* v. *Secretary HHS*, 778 F.3d 422, 439-440 (3d Cir.), cert. granted, Nos. 14-1418 and 15-191 (Nov. 6, 2015); *Priests for Life* v. *HHS*, 772 F.3d 229, 246 (D.C. Cir. 2014), cert. granted, Nos. 14-1453 and 14-1505 (Nov. 6, 2015).

granted, No. 14-1505 (Nov. 6, 2015); *East Tex. Baptist Univ.* v. *Burwell*, cert. granted, No. 15-35 (Nov. 6, 2015); *Little Sisters of the Poor Home for the Aged* v. *Burwell*, cert. granted, No. 15-105 (Nov. 6, 2015); *Southern Nazarene Univ.* v. *Burwell*, cert. granted, No. 15-119 (Nov. 6, 2015); *Geneva College* v. *Burwell*, cert. granted, No. 15-191 (Nov. 6, 2015). The government therefore respectfully requests that the Court hold this petition for a writ of certiorari pending the Court's decision in *Zubik* and the consolidated cases, and then dispose of the petition as appropriate in light of the Court's decision in those cases.

CONCLUSION

This Court should hold the petition for a writ of certiorari in this case pending the Court's decision in *Zubik* v. *Burwell*, cert. granted, No. 14-1418 (Nov. 6, 2015), and the consolidated cases, and then dispose of the petition as appropriate in light of the Court's decision in those cases.

Respectfully submitted.

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DECEMBER 2015

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

No. 14-2726

DORDT COLLEGE; CORNERSTONE UNIVERSITY,
PLAINTIFFS-APPELLEES

v.

SYLVIA M. BURWELL, IN HER OFFICIAL CAPACITY AS SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; THOMAS PEREZ, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE UNITED STATES DEPARTMENT OF LABOR; JACK LEW, IN HIS OFFICIAL CAPACITY AS SECRETARY OF THE UNITED STATES DEPARTMENT OF THE TREASURY; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; UNITED STATES DEPARTMENT OF LABOR; UNITED STATES DEPARTMENT OF THE TREASURY,
DEFENDANTS-APPELLANTS

AMERICANS UNITED FOR SEPARATION OF CHURCH AND STATE; AMERICAN CIVIL LIBERTIES UNION; AMERICAN CIVIL LIBERTIES UNION OF IOWA,
AMICI ON BEHALF OF APPELLANT(S)

ASSOCIATION OF AMERICAN PHYSICIANS & SURGEONS; AMERICAN ASSOCIATION OF PRO-LIFE OBSTETRICIANS & GYNECOLOGISTS; CHRISTIAN MEDICAL ASSOCIATION; CATHOLIC MEDICAL ASSOCIATION; THE NATIONAL CATHOLIC BIOETHICS CENTER; ALABAMA PHYSICIANS FOR LIFE; NATIONAL ASSOCIATION OF PRO LIFE NURSES; NATIONAL ASSOCIATION OF CATHOLIC NURSES, AMICI ON BEHALF OF APPELLEE(S)

Submitted: Dec. 10, 2014
Filed: Sept. 17, 2015

Appeal from the United States District Court
for the Northern District of Iowa - Sioux City

Before: WOLLMAN, COLLOTON, and BENTON, Circuit Judges.

WOLLMAN, Circuit Judge.

The Departments of Health and Human Services (HHS), Labor (DOL), and Treasury, as well as their respective Secretaries, (collectively, the government) appeal from the district court's[1] order granting a motion for a preliminary injunction that enjoins the government from enforcing certain provisions of the Patient Protection and Affordable Care Act (ACA), 42 U.S.C. § 300gg-13(a)(4), and its implementing regulations against Dordt College and Cornerstone University, each of which is a nonprofit religious educational institution that offers healthcare coverage to its employees—Dordt through a self-insured plan and Cornerstone through an insured plan.[2] The district court's order also enjoined the gov-

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[1] The Honorable Mark W. Bennett, United States District Judge for the Northern District of Iowa.

[2] A self-insured employer bears the financial risk of paying its employees' health-insurance claims and often hires a third-party administrator to manage administrative functions like processing

ernment from enforcing the challenged provisions against "any insurance provider (including insurance issuers and third-party administrators) offering health insurance to Dordt or Cornerstone." D. Ct. Order of May 21, 2014, at 8. Dordt and Cornerstone raised objections to the ACA and its implementing regulations that are substantially similar to those addressed by this court in the opinion issued today in *Sharpe Holdings, Inc. v. U.S. Department of Health and Human Services*, No. 14-1507, slip op. (8th Cir. Sept. 17, 2015). For purposes of this opinion, we provide only a brief discussion of the legislative and administrative background of the ACA and its implementing regulations, as well as an abbreviated summary of the arguments raised by the parties. For a more detailed ex amination, we direct readers to our opinion in *Sharpe Holdings*.

Dordt and Cornerstone challenged provisions of the ACA and its implementing regulations requiring them either to provide their employees with healthcare coverage for "[a]ll Food and Drug Administration [(FDA)] approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity" (the contraceptive mandate), or to apply for an accommodation excusing them from providing such coverage. 77 Fed. Reg. 8725, 8725 (Feb. 15,

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insurance claims. An insured employer, by contrast, contracts with a separate insurance company to provide healthcare coverage, bear the financial risk of insurance claims, and manage related administrative functions. *See, e.g.*, 1A Steven Plitt, et al., Couch on Insurance § 10:1 n.1 (3d ed. 2013).

2012); *see* 29 C.F.R. § 2590.715-2713(a). Although the ACA provides an exemption from the contraceptive mandate for "grandfathered" health plans, *i.e.*, those in existence at the time of the ACA's adoption, 42 U.S.C. § 18011; 29 C.F.R. § 2590.715-1251, and for health plans sponsored by "religious employers," *i.e.*, "churches, their integrated auxiliaries, and conventions or associations of churches," as well as "the exclusively religious activities of any religious order," 45 C.F.R. § 147.131(a) (citing the Internal Revenue Code, 26 U.S.C. § 6033(a)(3)(A)(i), (iii)), it does not provide a similar exemption for nonprofit religious organizations like Dordt and Cornerstone.

Instead, the ACA provides an "accommodation" for nonprofit religious organizations that have religious objections to the contraceptive mandate but do not qualify for the religious-employer exemption.[3] 78 Fed. Reg. 39,870, 39,871 (July 2, 2013); *see also* 29 C.F.R. § 2590.715-2713A. The accommodation is intended to protect religious organizations "from having to contract, arrange, pay, or refer for" contraceptive coverage. 78 Fed. Reg. at 39,872. It is available for a religious organization that (1) has religious objections to providing healthcare coverage for some or all contraceptive services, (2) "is organized and operates as a nonprofit entity,"

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[3] After the Supreme Court's decision in *Burwell v. Hobby Lobby*, 134 S. Ct. 2751 (2014), the government revised the relevant regulations effective September 14, 2015, to extend this accommodation to certain closely held for-profit entities that have a religious objection to providing coverage for some or all of the FDA-approved contraceptive methods. *See* 80 Fed. Reg. 41,318 (July 14, 2015).

(3) "holds itself out as a religious organization," and (4) complies with a self-certification process. 29 C.F.R. § 2590.715-2713A(a). A religious organization may self-certify by completing and submitting directly to its insurance issuer or third-party administrator (TPA) an EBSA Form 700—Certification (Form 700), certifying that it is a religious nonprofit entity that has religious objections to providing coverage for some or all of the contraceptives required by the mandate, 29 C.F.R. § 2590.715-2713A(a)-(b), or by providing notice to HHS stating the organization's name; the basis on which it qualifies for an accommodation; its religious objections to providing coverage for some or all contraceptives, including the specific contraceptives to which it objects; its insurance plan name and type; and its insurance issuer's or TPA's name and contact information (HHS Notice),[4]

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[4] Self-certification using HHS Notice was included in the regulations after the Supreme Court's order in *Wheaton College v. Burwell*, 134 S. Ct. 2806 (2014). Wheaton College, a religious organization, challenged the accommodation process, arguing that completing Form 700 and forwarding the Form to its insurance issuer made it complicit in the provision of contraceptive coverage in violation of its religious beliefs. The Supreme Court granted injunctive relief, enjoining the government from enforcing the contraceptive mandate while the college's challenge to the accommodation process was pending, provided that the college inform HHS "in writing that it is a nonprofit organization that holds itself out as religious and has religious objections to providing coverage for contraceptive services." 134 S. Ct. at 2807. The college was not required to self-certify using Form 700. *Id.* The Court also stated, "Nothing in this order precludes the Government from relying on this notice, to the extent it considers it necessary, to facilitate the

see 79 Fed. Reg. 51,092, 51,094-95 (Aug. 27, 2014); 80 Fed. Reg. 41,318, 41,323 (July 14, 2015); 29 C.F.R. § 2590.715-2713A(b)(1)(ii)(B). After HHS receives the Notice, it provides the information to DOL, which sends a separate notification to inform the religious organization's insurance issuer or TPA of the organization's objections to certain coverage. *See id.*

Once an insurance issuer or TPA receives Form 700 from the religious organization or the separate notification from DOL it must "provide or arrange payments for contraceptive services" for beneficiaries of the organization's group health plan either by providing those payments itself or by arranging for another party to do so. 29 C.F.R. § 2590.715-2713A(b)(2) (TPA); 45 C.F.R. § 147.131(c)(1)(i) (insurance issuer). With respect to TPAs, Form 700 or HHS notice also designates the TPA "plan administrator and claims administrator for contraceptive benefits" for the religious organization. 78 Fed. Reg. at 39,879; *see also* 29 C.F.R. § 2510.3-16(b) (providing that Form 700 becomes "an instrument under which the plan is operated [and is] treated as a designation of the [TPA] as the plan administrator under section 3(16) of ERISA[, 29 U.S.C. § 1002(33),] for any contraceptive services required to be covered"); 79 Fed. Reg. at 51,095 (providing that DOL's notification to the TPA under HHS Notice also operates to "designate" the TPA "as plan administrator" under ERISA for contraceptive benefits).

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provision of full contraceptive coverage under the" ACA to Wheaton College's employees and students. *Id.*

The insurance issuer or TPA must provide separate notice regarding contraceptive services to participants and beneficiaries enrolled in the religious organization's group health plan. 29 C.F.R. § 2590.715-2713A(b)(2).

Dordt and Cornerstone, in accordance with their sincerely held religious beliefs, oppose the use, funding, provision, or support of abortion, and they believe that certain contraceptives required under the contraceptive mandate—Plan B, ella, and copper IUDs—are functionally equivalent to abortion. *See Burwell v. Hobby Lobby*, 134 S. Ct. 2751, 2762-63 (2104) (noting that these forms of contraceptive "may have the effect of preventing an already fertilized egg from developing any further by inhibiting its attachment to the uterus"). They brought suit against the government, arguing that both the contraceptive mandate and the accommodation process impose a substantial burden on their exercise of religion in violation of the Religious Freedom Restoration Act of 1993 (RFRA), 42 U.S.C. § 2000bb-bb4. They contend that the government is coercing them to violate their religious beliefs by threatening to impose severe monetary penalties unless they either directly provide coverage for objectionable contraceptives through their group health plans or indirectly provide, trigger, and facilitate that objectionable coverage through the accommodation process.

As stated above, the district court granted their request for a preliminary injunction to enjoin enforcement of the contraceptive mandate and the accommodation regulations against them.

The government raises arguments for reversal of the district court's order that are substantially similar to those asserted by the government in *Sharpe Holdings*. Specifically, the government argues that the contraceptive mandate and accommodation process do not substantially burden Dordt and Cornerstone's exercise of religion, that it has compelling interests in safeguarding public health and ensuring equal access to health care for women, and that the contraceptive mandate and accommodation process are the least restrictive means to further those compelling interests. For the reasons set forth in *Sharpe Holdings*, we conclude that by coercing Dordt and Cornerstone to participate in the contraceptive mandate and accommodation process under threat of severe monetary penalty, the government has substantially burdened Dordt and Cornerstone's exercise of religion. Also for the reasons set forth in *Sharpe Holdings*, we conclude that, even assuming that the government's interests in safeguarding public health and ensuring equal access to health care for women are compelling, the contraceptive mandate and accommodation process likely are

not the least restrictive means of furthering those interests.[5] Thus, based on our reasoning in *Sharpe Holdings*, we affirm the order granting injunctive relief.

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[5] Dordt and Cornerstone argue that the government's asserted "compelling interests" are fatally undermined in light of the exemptions to the contraceptive mandate and accommodation process granted to grandfathered healthcare plans and religious employers —exemptions that result in thousands of women without access to contraceptive coverage through their employers' healthcare plans. Because we affirm the district court's grant of injunctive relief on the basis that the government has failed to establish that the contraceptive mandate and accommodation process are the least restrictive means to accomplish their stated compelling interests, we decline to address Dordt and Cornerstone's assertions regarding the insufficiency of the government's compelling interests. *See Hobby Lobby*, 134 S. Ct. at 2780 ("We will assume that the interest in guaranteeing cost-free access to the four challenged contraceptive methods is compelling within the meaning of RFRA . .. .").

APPENDIX B

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF IOWA
WESTERN DIVISION

No. C 13-4100-MWB

DORDT COLLEGE AND CORNERSTONE UNIVERSITY,
PLAINTIFFS

v.

KATHLEEN SEBELIUS, IN HER OFFICIAL CAPACITY AS SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL., DEFENDANTS

May 21, 2014

ORDER REGARDING PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

This case is before me on Plaintiffs Dordt College's (Dordt's) and Cornerstone University's (Cornerstone's) motion for a preliminary injunction, filed on May 6, 2014 (docket no. 44). In their motion, Plaintiffs ask that I enjoin enforcement of "the Mandate"—the provision of the Patient Protection and Affordable Care Act of 2010 (ACA) requiring that group health plans and health insurance issuers provide coverage, without cost sharing, for certain female contraceptives. *See* 42 U.S.C.

§ 300gg-13(a)(4).[1] Plaintiffs are religiously oriented colleges that must offer their employees ACA-compliant health insurance, or face severe penalties. Plaintiffs claim that the Mandate violates the Religious Freedom Restoration Act (RFRA), 42 U.S.C. §§ 2000bb to 2000bb-4. Defendants[2] resist Plaintiffs' motion (docket

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[1] Regulations implementing the Mandate provide that certain types of contraceptives—like Plan B and Ella, which Plaintiffs deem religiously objectionable—must be covered:

> The Health Resources and Services Administration has issued guidelines requiring coverage for "[a]ll Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity." *Women's Preventive Services: Required Health Plan Coverage Guidelines*, Health Resources and Services Administration, http://www.hrsa.gov/womensguidelines/ (last visited Dec. 31, 2012). The FDA has approved several contraceptive methods, including Plan B, Ella, and copper intrauterine devices (IUDs). *Birth Control Guide*, FDA Office of Women's Health, www.fda.gov/downloads/ForConsumers/ByAudience/ForWomen/FreePublications/UCM282014.pdf.
>
> The government issued a regulation (contraceptive mandate) that adopted the Health Resources and Service Administration guidelines as final. 77 Fed. Reg. 8725. Group health plans and health insurance issuers are required to provide coverage consistent with the guidelines, without cost sharing, in plan or policy years beginning on or after August 1, 2012. *Id.* at 8725-26.

Sharpe Holdings, Inc. v. U.S. Dep't of Health & Human Servs., No. 2:12 CV 92 DDN, 2013 WL 6858588, at *1 (E.D. Mo. Dec. 30, 2013) (footnote omitted).

[2] I recognize that defendant Kathleen Sebelius has resigned as Secretary of the Department of Health and Human Services. Her

no. 45). For the reasons discussed below, Plaintiffs' motion is granted.

"RFRA . . . provides that the Government cannot impose a law that substantially burdens a person's free exercise of religion unless the Government demonstrates that the law (1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest." *Harrell v. Donahue*, 638 F.3d 975, 983 (8th Cir. 2011) (quoting 42 U.S.C. § 2000bb-1(b)(1)-(2)) (internal quotation marks omitted). Plaintiffs argue that the Mandate substantially burdens their free exercise of religion by requiring Plaintiffs to offer insurance that facilitates access to contraceptives that Plaintiffs deem religiously objectionable. Plaintiffs also argue that the Mandate is not the least-restrictive means to advance any compelling governmental interest. Thus, Plaintiffs request that I enjoin enforcement of the Mandate as it applies to their employee health-insurance plans.

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successor, however, has not yet been confirmed. When the next Secretary is confirmed, I will substitute the successor as a defendant per Federal Rule of Civil Procedure 25(d), which provides:

> An action does not abate when a public officer who is a party in an official capacity dies, resigns, or otherwise ceases to hold office while the action is pending. The officer's successor is automatically substituted as a party. Later proceedings should be in the substituted party's name, but any misnomer not affecting the parties' substantial rights must be disregarded. The court may order substitution at any time, but the absence of such an order does not affect the substitution.

In support of their claims, Plaintiffs rely on their verified complaint and 26 employee declarations. I may grant a preliminary injunction based on such evidence. *See Doe v. S. Iron R-1 Sch. Dist.*, 498 F.3d 878, 880 (8th Cir. 2007) (affirming a preliminary injunction based on a verified complaint and additional documents); *Movie Sys., Inc. v. MAD Minneapolis Audio Distributors*, 717 F.2d 427, 432 (8th Cir. 1983) (holding that courts may rely solely on affidavits in granting preliminary injunctions); *see also K-2 Ski Co. v. Head Ski Co.*, 467 F.2d 1087, 1088 (9th Cir. 1972) ("A verified complaint or supporting affidavits may afford the basis for a preliminary injunction[.]" (citations omitted)).

Plaintiffs filed their motion for a preliminary injunction while their underlying suit challenging the Mandate is currently pending before me. In a recent order (docket no. 43), I informed the parties that I would wait to resolve the Plaintiffs' underlying claims until after the United States Supreme Court decided *Sebelius v. Hobby Lobby Stores, Inc.*, No. 13-354, and *Conestoga Wood Specialties Corp. v. Sebelius*, No. 13-356, because those decisions will likely impact, and may even resolve, part of this case. But, according to Plaintiffs, the Mandate will take effect against Dordt starting on June 1, 2014—before the Supreme Court will likely decide *Hobby Lobby* and *Conestoga Wood*. Thus, Plaintiffs ask that I enjoin enforcement of the Mandate until I rule on the merits of their underlying claims, which I expect to do shortly after the Supreme Court decides *Hobby Lobby* and *Conestoga Wood*. While Plaintiffs' underlying complaint comprises

multiple claims, Plaintiffs rely solely on their RFRA claim in requesting a preliminary injunction.

In deciding whether to grant a preliminary injunction, I apply

> the four factors set forth in *Dataphase Systems, Inc. v. CL Systems, Inc.*, 640 F.2d 109 (8th Cir. 1981). The *Dataphase* factors are "(1) the threat of irreparable harm to the movant; (2) the state of balance between this harm and the injury that granting the injunction will inflict on other parties litigant; (3) the probability that movant will succeed on the merits; and (4) the public interest." *Id.* at 114.

Novus Franchising, Inc. v. Dawson, 725 F.3d 885, 893 (8th Cir. 2013). Generally, the moving party need not "prove a greater than fifty per cent likelihood that [it] will prevail on the merits." *Dataphase*, 640 F.2d at 113. Rather, the movant need only show a "fair chance" of prevailing. *Heartland Acad. Cmty. Church v. Waddle*, 335 F.3d 684, 690 (8th Cir. 2003). Ultimately, "the question is whether the balance of equities so favors the movant that justice requires the court to intervene to preserve the status quo until the merits are determined." *Dataphase*, 640 F.2d at 113 (footnote omitted). Each case

> must be examined in the context of the relative injuries to the parties and the public. If the chance of irreparable injury to the movant should relief be denied is outweighed by the likely injury to other parties litigant should the injunction be granted, the

> moving party faces a heavy burden of demonstrating that he is likely to prevail on the merits. Conversely, where the movant has raised a substantial question and the equities are otherwise strongly in his favor, the showing of success on the merits can be less.

Id. Thus, "where the balance of other factors [besides probability of success] tips decidedly toward plaintiff a preliminary injunction may issue if movant has raised questions so serious and difficult as to call for more deliberate investigation." *Id.*

I recognize that "where a preliminary injunction of a duly enacted . . . statute is sought, [courts] require a more rigorous threshold showing that the movant is likely to prevail on the merits." *Planned Parenthood Minn., N.D., S.D. v. Rounds*, 530 F.3d 724, 730 (8th Cir. 2008) (en banc); *see also Johnson v. Minneapolis Park & Recreation Bd.*, 729 F.3d 1094, 1098 (8th Cir. 2013) (noting that this "more rigorous threshold" applies to injunctions of federal statutes). "[A] party seeking a preliminary injunction of the implementation of a . . . statute must demonstrate more than just a 'fair chance' that it will succeed on the merits." *Planned Parenthood*, 530 F.3d at 731-32. "We characterize this more rigorous standard . . . as requiring a showing that the movant 'is likely to prevail on the merits.'" *Id.* at 732 (citations omitted). This heightened standard for enjoining a statute "reflects the idea that governmental policies implemented through legislation or regulations developed through presumptively reasoned democratic processes are entitled to a higher degree of deference and should not be enjoined

lightly." *Id.* (citation and internal quotation marks omitted).

But this case is somewhat unique in that *both* parties claim fidelity to democratically enacted statutes. Plaintiffs seek to enforce RFRA whereas Defendants seek to enforce ACA. Whether I grant or deny injunctive relief, I risk wrongly effectuating one statute at the expense of the other. Presumably, I must be equally deferential to both statutes. Because both parties ask that I enforce a duly enacted statute, *Planned Parenthood*'s "more rigorous threshold" applies with less force to this case. But, as I note below, even if it applies with full force, the Eighth Circuit Court of Appeals has already twice concluded that plaintiffs similarly situated to Dordt and Cornerstone are likely to succeed on the merits of their cases challenging the Mandate.

Applying the *Dataphase* factors, I find that granting Plaintiffs preliminary injunctive relief is appropriate. First, Plaintiffs may suffer irreparable harm without an injunction in that they would be forced to comply with the Mandate to the detriment of their religious exercise. Even if I were to later grant Plaintiffs relief on their underlying claims, that would not remedy the harm caused by forcing the Plaintiffs to do something they deem religiously objectionable. Second, the balance of the equities favors granting a preliminary injunction. The only harm Defendants may suffer if I grant a preliminary injunction is that the Mandate may apply to Plaintiffs a few months later than expected. Third, Plaintiffs have shown that they are sufficiently likely to

succeed on the merits. I base this finding on the fact that the Eighth Circuit Court of Appeals has twice granted injunctions pending appeal to similarly situated plaintiffs challenging the Mandate under RFRA.[3] *See* Order, *O'Brien v. U.S. Dep't of Health & Human Servs.*, No. 12-3357 (8th Cir. Nov. 28, 2012) (granting similar plaintiffs an injunction pending appeal); *Annex Med., Inc. v. Sebelius*, No. 13-1118, 2013 WL 1276025, at *3 (8th Cir. Feb. 1, 2013) (noting that "the *O'Brien* panel necessarily concluded that the [similar plaintiffs] satisfied the prere-

[3] Defendants argue that these prior injunctions are inapposite because they involved differently situated, for-profit companies, rather than institutions like Dordt and Cornerstone that are eligible for religious accommodations related to the Mandate. Defendants' argument seems to be that, because accommodations are available to Dordt and Cornerstone, the Mandate does not apply to them with the same force as it would to for-profit companies and, therefore, the reasons supporting injunctions to for-profit companies do not apply here. But, in *Annex Medical, Inc. v. Sebelius*, No. 13-1118, 2013 WL 1276025, at *1, 3 (8th Cir. Feb. 1, 2013), the Eighth Circuit Court of Appeals granted an injunction in favor of a plaintiff corporation to which the Mandate does not even apply. The plaintiff in *Annex Medical* had fewer than 50 employees and, thus, was not required to provide ACA-compliant insurance to employees. *Id.* at *1 (citing 26 U.S.C. § 4980H(c)(2)(A)). The plaintiff's owner, however, claimed that it was his religious duty to provide insurance even though ACA did not require it. *Id.* On these facts, the Eighth Circuit Court of Appeals enjoined enforcement of the Mandate against the plaintiff. *Id.* at *3. The Mandate applied to the plaintiff in *Annex Medical* with even less force than it applies to Dordt or Cornerstone, yet the plaintiff in *Annex Medical* still received injunctive relief. Rather than being inapposite, this weighs in favor of granting injunctive relief here.

quisites for an injunction pending appeal, including a sufficient likelihood of success on the merits and irreparable harm"); *see also Sharpe Holdings, Inc. v. U.S. Dep't of Health & Human Servs.*, No. 2:12-CV-92-DDN, 2012 WL 6738489, at *6 (E.D. Mo. Dec. 31, 2012) (finding that similar plaintiffs demonstrated a reasonable likelihood of success). And "there is a significant interest in uniform treatment of comparable requests for interim relief within this circuit." *Annex Med.*, 2013 WL 1276025, at *3. Finally, there is no evidence here that the public interest strongly favors either side. Weighed together, these factors support Plaintiffs' request for a preliminary injunction.

The only remaining issue is bond. "The court may issue a preliminary injunction or a temporary restraining order only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained." Fed. R. Civ. P. 65(c). "The amount of the bond rests within the sound discretion of the trial court and will not be disturbed on appeal in the absence of an abuse of that discretion." *Stockslager v. Carroll Elec. Co-op. Corp.*, 528 F.2d 949, 951 (8th Cir. 1976) (citation omitted). There is no risk of monetary loss to Defendants here; the only arguable harm is that the Mandate might apply to the Plaintiffs a few months later than expected. Thus, Plaintiffs need not submit security in this case. *See Sharpe Holdings*, 2012 WL 6738489, at *7 (temporarily restraining enforcement of

the Mandate without requiring the plaintiffs to submit bond).

THEREFORE, I ORDER THE FOLLOWING:

(1) The Plaintiffs' motion for a preliminary injunction (docket no. 44) is granted.

(2) Defendants are enjoined, pending resolution of Plaintiffs' underlying claims, from enforcing the Mandate of 42 U.S.C. § 300gg-13(a)(4) and its implementing regulations against Dordt, Cornerstone, and any insurance provider (including insurance issuers and third-party administrators) offering health insurance to Dordt or Cornerstone. This injunction shall apply only with regard to health insurance offered to Dordt and Cornerstone employees. Plaintiffs need not submit bond.

IT IS SO ORDERED.

DATED this 21st day of May, 2014.

/s/ MARK W. BENNETT
MARK W. BENNETT
U.S. DISTRICT COURT JUDGE
NORTHERN DISTRICT OF IOWA

APPENDIX C

1. 42 U.S.C. 300gg-13 provides:

Coverage of preventive health services

(a) In general

A group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for—

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

(2) immunization that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved; and[1]

(3) with respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration.[2]

(4) with respect to women, such additional preventive care and screenings not described in para-

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[1] So in original. The word "and" probably should not appear.

[2] So in original. The period probably should be a semicolon.

graph (1) as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph.[2]

(5) for the purposes of this chapter, and for the purposes of any other provision of law, the current recommendations of the United States Preventive Service Task Force regarding breast cancer screening, mammography, and prevention shall be considered the most current other than those issued in or around November 2009.

Nothing in this subsection shall be construed to prohibit a plan or issuer from providing coverage for services in addition to those recommended by United States Preventive Services Task Force or to deny coverage for services that are not recommended by such Task Force.

(b) Interval

(1) In general

The Secretary shall establish a minimum interval between the date on which a recommendation described in subsection (a)(1) or (a)(2) or a guideline under subsection (a)(3) is issued and the plan year with respect to which the requirement described in subsection (a) is effective with respect to the service described in such recommendation or guideline.

(2) Minimum

The interval described in paragraph (1) shall not be less than 1 year.

(c) Value-based insurance design

The Secretary may develop guidelines to permit a group health plan and a health insurance issuer offering group or individual health insurance coverage to utilize value-based insurance designs.

2. 42 U.S.C. 2000bb provides:

Congressional findings and declaration of purposes

(a) Findings

The Congress finds that—

(1) the framers of the Constitution, recognizing free exercise of religion as an unalienable right, secured its protection in the First Amendment to the Constitution;

(2) laws "neutral" toward religion may burden religious exercise as surely as laws intended to interfere with religious exercise;

(3) governments should not substantially burden religious exercise without compelling justification;

(4) in Employment Division v. Smith, 494 U.S. 872 (1990) the Supreme Court virtually eliminated the requirement that the government justify bur-

dens on religious exercise imposed by laws neutral toward religion; and

(5) the compelling interest test as set forth in prior Federal court rulings is a workable test for striking sensible balances between religious liberty and competing prior governmental interests.

(b) Purposes

The purposes of the chapter are—

(1) to restore the compelling interest test as set forth in Sherbert v. Verner, 374 U.S. 398 (1963) and Wisconsin v. Yoder, 406 U.S. 205 (1972) and to guarantee its application in all cases where free exercise of religion is substantially burdened; and

(2) to provide a claim or defense to persons whose religious exercise is substantially burdened by the government.

3. 42 U.S.C. 2000bb-1 provides:

Free exercise of religion protected provides

(a) In general

Government shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability, except as provided in subsection (b) of this section.

(b) Exception

Government may substantially burden a person's exercise of religion only if it demonstrates that application of the burden to the person—

(1) is in furtherance of a compelling government interest; and

(2) is the least restrictive means of furthering that compelling governmental interest.

(c) Judicial relief

A person whose religious exercise has been burdened in violation of this section may assert that violation as a claim or defense in a judicial proceeding and obtain appropriate relief against a government. Standing to assert a claim or defense under this section shall be governed by the general rules of standing under article III of the Constitution.

4. 42 U.S.C. 2000bb-2 provides:

Definitions

As used in this chapter—

(1) the term "governmental" includes a branch, department, agency, instrumentality, and official (or other person acting under color of law) of the United States, or of a covered entity;

(2) the term "covered entity" means the District of Columbia, the Commonwealth of Puerto Rico, and each territory and possession of the United States;

(3) the term "demonstrates" means meets the burdens of going forward with the evidence and of persuasion; and

(4) the term "exercise of religion" means religious exercise, as defined in section 2000cc-5 of this title.

5. 42 U.S.C. 2000bb-3 provides:

Applicability

(a) In general

This chapter applies to all Federal law, and the implementation of that law, whether statutory or otherwise, and whether adopted before or after November 16, 1993.

(b) Rule of construction

Federal statutory law adopted after November 16, 1993, is subject to this chapter unless such law explicitly excludes such application by reference to this chapter.

(c) Religious belief unaffected

Nothing in this chapter shall be construed to authorize any government to burden any religious belief.

6. 42 U.S.C. 2000bb-4 provides:

Establishment clause unaffected

Nothing in this chapter shall be construed to affect, interpret, or in any way address that portion of the First Amendment prohibiting laws respecting the establishment of religion (referred to in this section as the "Establishment Clause"). Granting government funding, benefits, or exemptions, to the extent permissible under the Establishment Clause, shall not constitute a violation of this chapter. As used in this section, the term "granting", used with respect to government funding, benefits, or exemptions, does not include the denial of government funding, benefits or exemptions.

7. 26 C.F.R. 54.9815-2713 provides:

Coverage of preventive health services

(a) *Services*—(1) *In general.* Beginning at the time described in paragraph (b) of this section and subject to §54.9815-2713A, a group health plan, or a health insurance issuer offering group health insurance coverage, must provide coverage for all of the following items and services, and may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) with respect to those items and services;

(i)-(iii) [Reserved]

(iv) With respect to women, to the extent not described in paragraph (a)(1)(i) of this section,

evidence-in-formed preventive care and screenings provided for in binding comprehensive health plan coverage guidelines supported by the Health Resources and Services Administration, in accordance with 45 CFR 147.131(a).

(2) *Office visits.* [Reserved]

(3) *Out-of-network providers.* [Reserved]

(4) *Reasonable medical management.* [Reserved]

(5) *Services not described.* [Reserved]

(b) *Timing.* [Reserved]

(c) *Recommendations not current.* [Reserved]

(d) *Effective/applicability date.* April 16, 2012.

8. 26 C.F.R. 54.9815-2713A provides:

Accommodations in connection with coverage of preventive health services

(a) *Eligible organizations.* An eligible organization is an organization that satisfies all of the following requirements:

(1) The organization opposes providing coverage for some or all of any contraceptive services required to be covered under § 54.9815-2713(a)(1)(iv) on account of religious objections.

(2) The organization is organized and operates as a nonprofit entity.

(3) The organization holds itself out as a religious organization.

(4) The organization self-certifies, in a form and manner specified by the Secretaries of Health and Human Services and Labor, that it satisfies the criteria in paragraphs (a)(1) through (3) of this section, and makes such self-certification available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (b) or (c) of this section applies. The self-certification must be executed by a person authorized to make the certification on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(b) [Reserved]. For further guidance, see § 54.9815-2713AT(b).

(c) *Contraceptive coverage—insured group health plans.* (1) [Reserved]. For further guidance, see § 54.9815-2713AT(c)(1).

(2) *Payments for contraceptive services.* (i) [Reserved]. For further guidance, see § 54.9815-2713AT(c)(2)(i) introductory text.

(A) Expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan; and

(B) Provide separate payments for any contraceptive services required to be covered under § 54.9815-2713(a)(1)(iv) for plan participants and beneficiaries for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or impose any premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contraceptive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act, as incorporated into section 9815. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 54.9815-2713(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group health plan does not provide payments for all contraceptive services, at the issuer's option.

(d) *Notice of availability of separate payments for contraceptive services—self-insured and insured group health plans.* For each plan year to which the accommodation in paragraph (b) or (c) of this section is to apply, a third party administrator required to pro-

vide or arrange payments for contraceptive services pursuant to paragraph (b) of this section, and an issuer required to provide payments for contraceptive services pursuant to paragraph (c) of this section, must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application with enrollment (or re-enrollment) in group health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the third party administrator or issuer, as applicable, provides separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (d): "Your employer has certified that your group health plan qualifies for an accommodation with respect to the federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your employer will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of third party administrator/health insurance issuer] will provide or arrange separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your group health

plan. Your employer will not administer or fund these payments. If you have any questions about this notice, contact [contact information for third party administrator/health insurance issuer]."

(e) *Reliance—insured group health plans.* (1) If an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation in paragraph (c) of this section, and the representation is later determined to be incorrect, the issuer is considered to comply with any requirement under § 54.9815-2713(a)(1)(iv) to provide contraceptive coverage if the issuer complies with the obligations under this section applicable to such issuer.

(2) A group health plan is considered to comply with any requirement under § 54.9815-2713(a)(1)(iv) to provide contraceptive coverage if the plan complies with its obligations under paragraph (c) of this section, without regard to whether the issuer complies with the obligations under this section applicable to such issuer.

(f) [Reserved]. For further guidance, see § 54.9815-2713AT(f).

9. 29 C.F.R. 2510.3-16 provides:

Definition of "plan administrator"

(a) *In general.* The term "plan administrator" or "administrator" means the person specifically so designated by the terms of the instrument under which

the plan is operated. If an administrator is not so designated, the plan administrator is the plan sponser, as defined in section 3(16)(B) of ERISA.

(b) In the case of a self-insured group health plan established or maintained by an eligible organization, as defined in § 2590.715-2713A(a) of this chapter, the copy of the self-certification provided by the eligible organization to a third party administrator (including notice of the eligible organization's refusal to administer or fund contraceptive benefits) in accordance with § 2590.715-2713A(b)(1)(ii) of this chapter shall be an instrument under which the plan is operated, shall be treated as a designation of the third party administrator as the plan administrator under section 3(16) of ERISA of any contraceptive services required to be covered under § 2590.715-2713(a)(1)(iv) of this chapter to which the eligible organization objects on religious grounds, and shall supersede any earlier designation. A third party administrator that becomes a plan administrator pursuant to this section shall be responsible for—

(1) The plan's compliance with section 2713 of the Public Health Service Act (42 U.S.C. 300gg-13) (as incorporated into section 715 of ERISA) and § 2590.715-2713 of this chapter with respect to coverage of contraceptive services. To the extent that the plan contracts with different third party administrators for different classifications of benefits (such as prescription drug benefits versus inpatient and outpatient benefits), each third party administrator is responsible for

providing contraceptive coverage that complies with section 2713 of the Public Health Service Act (as incorporated into section 715 of ERISA) and § 2590.715-2713 of this chapter with respect to the classification or classifications of benefits subject to its contract.

(2) Establishing and operating a procedure for determining such claims for contraceptive services in accordance with § 2560.503-1 of this chapter.

(3) Complying with disclosure and other requirements applicable to group health plans under Title I of ERISA with respect to such benefits.

10. 29 C.F.R. 2590.715-2713 provides:

Coverage of preventive health services.

(a) *Services*—(1) *In general.* Beginning at the time described in paragraph (b) of this section and subject to § 2590.715-2713A, a group health plan, or a health insurance issuer offering group health insurance coverage, must provide coverage for all of the following items and services, and may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) with respect to those items and services:

(i) Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual involved (except as otherwise provided in paragraph (c) of this section);

(ii) Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved (for this purpose, a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention, and a recommendation is considered to be for routine use if it is listed on the Immunization Schedules of the Centers for Disease Control and Prevention);

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

(iv) With respect to women, to the extent not described in paragraph (a)(1)(i) of this section, evidence-informed preventive care and screenings Employee Benefits Security Admin., Labor provided for in binding comprehensive health plan coverage guidelines supported by the Health Resources and Services Administration, in accordance with 45 CFR 147.131(a).

(2) *Office visits*—(i) If an item or service described in paragraph (a)(1) of this section is billed separately (or is tracked as individual encounter data separately) from an office visit, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

(ii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is the delivery of such an item or service, then a plan or issuer may not impose cost-sharing requirements with respect to the office visit.

(iii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is not the delivery of such an item or service, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

(iv) The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* An individual covered by a group health plan visits an in-network health care provider. While visiting the provider, the individual is screened for cholesterol abnormalities, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit and for the laboratory work of the cholesterol screening test.

(ii) *Conclusion.* In this *Example 1,* the plan may not impose any cost-sharing requirements with respect to the separately-billed laboratory work of the cholesterol screening test. Because the office visit is billed sepa-

rately from the cholesterol screening test, the plan may impose cost-sharing requirements for the office visit.

Example 2. (i) *Facts.* Same facts as *Example 1.* As the result of the screening, the individual is diagnosed with hyperlipidemia and is prescribed a course of treatment that is not included in the recommendations under paragraph (a)(1) of this section.

(ii) *Conclusion.* In this *Example 2,* because the treatment is not included in the recommendations under paragraph (a)(1) of this section, the plan is not prohibited from imposing cost-sharing requirements with respect to the treatment.

Example 3. (i) *Facts.* An individual covered by a group health plan visits an in-network health care provider to discuss recurring abdominal pain. During the visit, the individual has a blood pressure screening, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit.

(ii) *Conclusion.* In this *Example 3,* the blood pressure screening is provided as part of an office visit for which the primary purpose was not to deliver items or services described in paragraph (a)(1) of this section. Therefore, the plan may impose a cost-sharing requirement for the office visit charge.

Example 4. (i) *Facts.* A child covered by a group health plan visits an in-network pediatrician to receive an annual physical exam described as part of the compre-

hensive guidelines supported by the Health Resources and Services Administration. During the office visit, the child receives additional items and services that are not described in the comprehensive guidelines supported by the Health Resources and Services Administration, nor otherwise described in paragraph (a)(1) of this section. The provider bills the plan for an office visit.

(ii) *Conclusion.* In this *Example 4,* the service was not billed as a separate charge and was billed as part of an office visit. Moreover, the primary purpose for the visit was to deliver items and services described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. Therefore, the plan may not impose a cost-sharing requirement with respect to the office visit.

(3) *Out-of-network providers.* Nothing in this section requires a plan or issuer that has a network of providers to provide benefits for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider. Moreover, nothing in this section precludes a plan or issuer that has a network of providers from imposing cost-sharing requirements for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider.

(4) *Reasonable medical management.* Nothing prevents a plan or issuer from using reasonable medical management techniques to determine the frequency, method, treatment, or setting for an item or service described in paragraph (a)(1) of this section to the extent not specified in the recommendation or guideline.

(5) *Services not described.* Nothing in this section prohibits a plan or issuer from providing coverage for items and services in addition to those recommended by the United States Preventive Services Task Force or the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, or provided for by guidelines supported by the Health Resources and Services Administration, or from denying coverage for items and services that are not recommended by that task force or that advisory committee, or under those guidelines. A plan or issuer may impose cost-sharing requirements for a treatment not described in paragraph (a)(1) of this section, even if the treatment results from an item or service described in paragraph (a)(1) of this section.

(b) *Timing*—(1) *In general.* A plan or issuer must provide coverage pursuant to paragraph (a)(1) of this section for plan years that begin on or after September 23, 2010, or, if later, for plan years that begin on or after the date that is one year after the date the recommendation or guideline is issued.

(2) *Changes in recommendations or guidelines.* A plan or issuer is not required under this section to provide coverage for any items and services specified in any recommendation or guideline described in paragraph (a)(1) of this section after the recommendation or guideline is no longer described in paragraph (a)(1) of this section. Other requirements of Federal or State law may apply in connection with a plan or issuer ceasing to provide coverage for any such items or services, including PHS Act section 2715(d)(4), which requires a plan or issuer to give

60 days advance notice to an enrollee before any material modification will become effective.

(c) *Recommendations not current.* For purposes of paragraph (a)(1)(i) of this section, and for purposes of any other provision of law, recommendations of the United States Preventive Services Task Force regarding breast cancer screening, mammography, and prevention issued in or around November 2009 are not considered to be current.

(d) *Applicability date.* The provisions of this section apply for plan years beginning on or after September 23, 2010. *See* § 2590.715-1251 of this Part for determining the application of this section to grandfathered health plans (providing that these rules regarding coverage of preventive health services do not apply to grandfathered health plans).

11. 29 C.F.R. 2590.715-2713A provide:

Accommodations in connection with coverage of preventive health services.

(a) *Eligible organizations.* An eligible organization is an organization that satisfies all of the following requirements:

(1) The organization opposes providing coverage for some or all of any contraceptive services required to be covered under § 2590.715-2713(a)(1)(iv) on account of religious objections.

(2) The organization is organized and operates as a nonprofit entity.

(3) The organization holds itself out as a religious organization.

(4) The organization self-certifies, in a form and manner specified by the Secretary, that it satisfies the criteria in paragraphs (a)(1) through (3) of this section, and makes such self-certification available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (b) or (c) of this section applies. The self-certification must be executed by a person authorized to make the certification on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of ERISA.

(b) *Contraceptive coverage—self-insured group health plans*—(1) A group health plan established or maintained by an eligible organization that provides benefits on a self-insured basis complies for one or more plan years with any requirement under § 2590.715-2713(a)(1)(iv) to provide contraceptive coverage if all of the requirements of this paragraph (b)(1) are satisfied:

(i) The eligible organization or its plan contracts with one or more third party administrators.

(ii) The eligible organization provides each third party administrator that will process claims for any contraceptive services required to be covered under § 2590.715-2713(a)(1)(iv) with a copy of the self-

certification described in paragraph (a)(4) of this section, which shall include notice that—

(A) The eligible organization 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

(B) Obligations of the third party administrator are set forth in § 2510.3-16 of this chapter and § 2590.715-2713A.

(iii) The eligible organization must not, directly or indirectly, seek to interfere with a third party administrator's arrangements to provide or arrange separate payments for contraceptive services for participants or beneficiaries, and must not, directly or indirectly, seek to influence the third party administrator's decision to make any such arrangements.

(2) If a third party administrator receives a copy of the self-certification described in paragraph (a)(4) of this section, and agrees to enter into or remain in a contractual relationship with the eligible organization or its plan to provide administrative services for the plan, the third party administrator shall provide or arrange payments for contraceptive services using one of the following methods

(i) Provide payments for contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or imposing a premium, fee, or other charge, or any portion thereof, directly or indirectly,

on the eligible organization, the group health plan, or plan participants or beneficiaries; or

(ii) Arrange for an issuer or other entity to provide payments for contraceptive services for plan participants and beneficiaries without imposing any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or imposing a premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries.

(3) If a third party administrator provides or arranges payments for contraceptive services in accordance with either paragraph (b)(2)(i) or (ii) of this section, the costs of providing or arranging such payments may be reimbursed through an adjustment to the Federally-facilitated Exchange user fee for a participating issuer pursuant to 45 CFR 156.50(d).

(4) A third party administrator may not require any documentation other than the copy of the self-certification from the eligible organization regarding its status as such.

(c) *Contraceptive coverage—insured group health plans*—(1) *General rule.* A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers complies for one or more plan years with any requirement under § 2590.715-2713(a)(1)(iv) to provide contraceptive coverage if the eligible organization or group health plan furnishes a copy of the self-certification described in paragraph (a)(4) of this section

to each issuer that would otherwise provide such coverage in connection with the group health plan. An issuer may not require any documentation other than the copy of the self-certification from the eligible organization regarding its status as such.

(2) *Payments for contraceptive services*—(i) A group health insurance issuer that receives a copy of the self-certification described in paragraph (a)(4) of this section with respect to a group health plan established or maintained by an eligible organization in connection with which the issuer would otherwise provide contraceptive coverage under § 2590.715-2713(a)(1)(iv) must—

(A) Expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan; and

(B) Provide separate payments for any contraceptive services required to be covered under § 2590.715-2713(a)(1)(iv) for plan participants and beneficiaries for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or impose any premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contracep-

tive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act, as incorporated into section 715 of ERISA. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 2590.715-2713(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(d) *Notice of availability of separate payments for contraceptive services—self-insured and insured group health plans.* For each plan year to which the accommodation in paragraph (b) or (c) of this section is to apply, a third party administrator required to provide or arrange payments for contraceptive services pursuant to paragraph (b) of this section, and an issuer required to provide payments for contraceptive services pursuant to paragraph (c) of this section, must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the third party administrator or issuer, as applicable, provides separate payments for

contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (d): "Your employer has certified that your group health plan qualifies for an accommodation with respect to the federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your employer will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of third party administrator/health insurance issuer] will provide or arrange separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your group health plan. Your employer will not administer or fund these payments. If you have any questions about this notice, contact [contact information for third party administrator/health insurance issuer]."

(e) *Reliance—insured group health plans*—(1) If an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation in paragraph (c) of this section, and the representation is later determined to be incorrect, the issuer is considered to comply with any requirement under § 2590.715-2713(a)(1)(iv) to provide contraceptive coverage if the issuer complies with the obligations under this section applicable to such issuer.

(2) A group health plan is considered to comply with any requirement under § 2590.715-2713(a)(1)(iv) to pro-

vide contraceptive coverage if the plan complies with its obligations under paragraph (c) of this section, without regard to whether the issuer complies with the obligations under this section applicable to such issuer.

12. 45 C.F.R. 147.130 provides:

Coverage of preventive health services.

(a) *Services*—(1) *In general.* Beginning at the time described in paragraph (b) of this section and subject to § 147.131, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide coverage for all of the following items and services, and may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) with respect to those items and services:

(i) Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual involved (except as otherwise provided in paragraph (c) of this section);

(ii) Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved (for this purpose, a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been

adopted by the Director of the Centers for Disease Control and Prevention, and a recommendation is considered to be for routine use if it is listed on the Immunization Schedules of the Centers for Disease Control and Prevention);

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

(iv) With respect to women, to the extent not described in paragraph (a)(1)(i) of this section, evidence-informed preventive care and screenings provided for in binding comprehensive health plan coverage guidelines supported by the Health Resources and Services Administration.

(2) *Office visits*—(i) If an item or service described in paragraph (a)(1) of this section is billed separately (or is tracked as individual encounter data separately) from an office visit, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

(ii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is the delivery of such an item or service, then a plan or issuer may not impose cost-sharing requirements with respect to the office visit.

(iii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as

individual encounter data separately) from an office visit and the primary purpose of the office visit is not the delivery of such an item or service, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

(iv) The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* An individual covered by a group health plan visits an in-network health care provider. While visiting the provider, the individual is screened for cholesterol abnormalities, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit and for the laboratory work of the cholesterol screening test.

(ii) *Conclusion.* In this *Example 1,* the plan may not impose any cost-sharing requirements with respect to the separately-billed laboratory work of the cholesterol screening test. Because the office visit is billed separately from the cholesterol screening test, the plan may impose cost-sharing requirements for the office visit.

Example 2. (i) *Facts.* Same facts as *Example 1.* As the result of the screening, the individual is diagnosed with hyperlipidemia and is prescribed a course of treatment that is not included in the recommendations under paragraph (a)(1) of this section.

(ii) *Conclusion.* In this *Example 2,* because the treatment is not included in the recommendations under

paragraph (a)(1) of this section, the plan is not prohibited from imposing cost-sharing requirements with respect to the treatment.

Example 3. (i) *Facts.* An individual covered by a group health plan visits an in-network health care provider to discuss recurring abdominal pain. During the visit, the individual has a blood pressure screening, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit.

(ii) *Conclusion.* In this *Example 3,* the blood pressure screening is provided as part of an office visit for which the primary purpose was not to deliver items or services described in paragraph (a)(1) of this section. Therefore, the plan may impose a cost-sharing requirement for the office visit charge.

Example 4. (i) *Facts.* A child covered by a group health plan visits an in-network pediatrician to receive an annual physical exam described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. During the office visit, the child receives additional items and services that are not described in the comprehensive guidelines supported by the Health Resources and Services Administration, nor otherwise described in paragraph (a)(1) of this section. The provider bills the plan for an office visit.

(ii) *Conclusion.* In this *Example 4,* the service was not billed as a separate charge and was billed as part of an

office visit. Moreover, the primary purpose for the visit was to deliver items and services described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. Therefore, the plan may not impose a cost-sharing requirement for the office visit charge.

(3) *Out-of-network providers.* Nothing in this section requires a plan or issuer that has a network of providers to provide benefits for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider. Moreover, nothing in this section precludes a plan or issuer that has a network of providers from imposing cost-sharing requirements for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider.

(4) *Reasonable medical management.* Nothing prevents a plan or issuer from using reasonable medical management techniques to determine the frequency, method, treatment, or setting for an item or service described in paragraph (a)(1) of this section to the extent not specified in the recommendation or guideline.

(5) *Services not described.* Nothing in this section prohibits a plan or issuer from providing coverage for items and services in addition to those recommended by the United States Preventive Services Task Force or the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, or provided for by guidelines supported by the Health Resources and Services Administration, or from denying coverage for items and services that are not recommended by that task

force or that advisory committee, or under those guidelines. A plan or issuer may impose cost-sharing requirements for a treatment not described in paragraph (a)(1) of this section, even if the treatment results from an item or service described in paragraph (a)(1) of this section.

(b) *Timing*—(1) *In general.* A plan or issuer must provide coverage pursuant to paragraph (a)(1) of this section for plan years (in the individual market, policy years) that begin on or after September 23, 2010, or, if later, for plan years (in the individual market, policy years) that begin on or after the date that is one year after the date the recommendation or guideline is issued.

(2) *Changes in recommendations or guidelines.* A plan or issuer is not required under this section to provide coverage for any items and services specified in any recommendation or guideline described in paragraph (a)(1) of this section after the recommendation or guideline is no longer described in paragraph (a)(1) of this section. Other requirements of Federal or State law may apply in connection with a plan or issuer ceasing to provide coverage for any such items or services, including PHS Act section 2715(d)(4), which requires a plan or issuer to give 60 days advance notice to an enrollee before any material modification will become effective.

(c) *Recommendations not current.* For purposes of paragraph (a)(1)(i) of this section, and for purposes of any other provision of law, recommendations of the United States Preventive Services Task Force regarding breast cancer screening, mammography, and prevention issued

in or around November 2009 are not considered to be current.

(d) *Applicability date.* The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. *See* § 147.140 of this part for determining the application of this section to grandfathered health plans (providing that these rules regarding coverage of preventive health services do not apply to grandfathered health plans).

13. 45 C.F.R. 147.131 provides:

Exemption and accommodations in connection with coverage of preventive health services.

(a) *Religious employers.* In issuing guidelines under § 147.130(a)(1)(iv), the Health Resources and Services Administration may establish an exemption from such guidelines with respect to a group health plan established or maintained by a religious employer (and health insurance coverage provided in connection with a group health plan established or maintained by a religious employer) with respect to any requirement to cover contraceptive services under such guidelines. For purposes of this paragraph (a), a "religious employer" is 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.

(b) *Eligible organizations.* An eligible organization is an organization that satisfies all of the following requirements:

(1) The organization opposes providing coverage for some or all of any contraceptive services required to be covered under § 147.130(a)(1)(iv) on account of religious objections.

(2) The organization is organized and operates as a nonprofit entity.

(3) The organization holds itself out as a religious organization.

(4) The organization self-certifies, in a form and manner specified by the Secretary, that it satisfies the criteria in paragraphs (b)(1) through (3) of this section, and makes such self-certification available for examination upon request by the first day of the first plan year to which the accommodation in paragraph (c) of this section applies. The self-certification must be executed by a person authorized to make the certification on behalf of the organization, and must be maintained in a manner consistent with the record retention requirements under section 107 of the Employee Retirement Income Security Act of 1974.

(c) *Contraceptive coverage—insured group health plans*—(1) *General rule.* A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers complies for one or more plan years with any requirement under § 147.130(a)(1)(iv) to provide

contraceptive coverage if the eligible organization or group health plan provides either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of Health and Human Services that it is an eligible organization and of its religious objection to coverage for all or a subset of contraceptive services.

(i) When a self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 147.130. An issuer may not require any further documentation from the eligible organization regarding its status as such.

(ii) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization and the basis on which it qualifies for an accommodation; its objection based on its sincerely held religious beliefs to coverage of some or all contraceptive services, as applicable (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable); the plan name and type *(i.e.,* whether it is a student health insurance plan within the meaning of § 147.145(a) or a church plan within the meaning of ERISA section 3(33)); and the name and contact information for any of the plan's third party administrators and health insurance issuers. If there is a change in any of the information required to be included in the notice, the organization must provide updated information to the Secretary of Health and Human Services. The Department of Health and Human Services will send a separate notification to each of

the plan's health insurance issuers informing the issuer that the Secretary of Health and Human Services has received a notice under paragraph (c)(1) of this section and describing the obligations of the issuer under this section.

(2) *Payments for contraceptive services*—(i) A group health insurance issuer that receives a copy of the self-certification or notification described in paragraph (c)(1)(ii) of this section with respect to a group health plan established or maintained by an eligible organization in connection with which the issuer would otherwise provide contraceptive coverage under § 147.130(a)(1)(iv) must—

(A) Expressly exclude contraceptive coverage from the group health insurance coverage provided in connection with the group health plan; and

(B) Provide separate payments for any contraceptive services required to be covered under § 147.130(a)(1)(iv) for plan participants and beneficiaries for so long as they remain enrolled in the plan.

(ii) With respect to payments for contraceptive services, the issuer may not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible), or impose any premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, the group health plan, or plan participants or beneficiaries. The issuer must segregate premium revenue collected from the eligible organization from the monies used to provide payments for contraceptive services. The issuer must provide payments for contracep-

tive services in a manner that is consistent with the requirements under sections 2706, 2709, 2711, 2713, 2719, and 2719A of the PHS Act. If the group health plan of the eligible organization provides coverage for some but not all of any contraceptive services required to be covered under § 147.130(a)(1)(iv), the issuer is required to provide payments only for those contraceptive services for which the group health plan does not provide coverage. However, the issuer may provide payments for all contraceptive services, at the issuer's option.

(d) *Notice of availability of separate payments for contraceptive services—insured group health plans and student health insurance coverage.* For each plan year to which the accommodation in paragraph (c) of this section is to apply, an issuer required to provide payments for contraceptive services pursuant to paragraph (c) of this section must provide to plan participants and beneficiaries written notice of the availability of separate payments for contraceptive services contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in group health coverage that is effective beginning on the first day of each applicable plan year. The notice must specify that the eligible organization does not administer or fund contraceptive benefits, but that the issuer provides separate payments for contraceptive services, and must provide contact information for questions and complaints. The following model language, or substantially similar language, may be used to satisfy the notice requirement of this paragraph (d):

"Your [employer/institution of higher education] has certified that your [group health plan/student health insurance coverage] qualifies for an accommodation with respect to the federal requirement to cover all Food and Drug Administration-approved contraceptive services for women, as prescribed by a health care provider, without cost sharing. This means that your [employer/institution of higher education] will not contract, arrange, pay, or refer for contraceptive coverage. Instead, [name of health insurance issuer] will provide separate payments for contraceptive services that you use, without cost sharing and at no other cost, for so long as you are enrolled in your [group health plan/student health insurance coverage]. Your [employer/institution of higher education] will not administer or fund these payments. If you have any questions about this notice, contact [contact information for health insurance issuer]."

(e) *Reliance*—(1) If an issuer relies reasonably and in good faith on a representation by the eligible organization as to its eligibility for the accommodation in paragraph (c) of this section, and the representation is later determined to be incorrect, the issuer is considered to comply with any requirement under § 147.130(a)(1)(iv) to provide contraceptive coverage if the issuer complies with the obligations under this section applicable to such issuer.

(2) A group health plan is considered to comply with any requirement under § 147.130(a)(1)(iv) to provide contraceptive coverage if the plan complies with its obligations under paragraph (c) of this section, without regard

to whether the issuer complies with the obligations under this section applicable to such issuer.

(f) *Application to student health insurance coverage*. The provisions of this section apply to student health insurance coverage arranged by an eligible organization that is an institution of higher education in a manner comparable to that in which they apply to group health insurance coverage provided in connection with a group health plan established or maintained by an eligible organization that is an employer. In applying this section in the case of student health insurance coverage, a reference to "plan participants and beneficiaries" is a reference to student enrollees and their covered dependents.