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DEPARTMENT OF LABOR**Employee Benefits Security Administration****29 CFR Parts 2510 and 2590**

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Coverage of Certain Preventive Services Under the Affordable Care Act

AGENCIES: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Centers for Medicare & Medicaid Services, Department of Health and Human Services.

ACTION: Final rules.

SUMMARY: This document contains final regulations regarding coverage of certain preventive services under section 2713 of the Public Health Service Act (PHS Act), added by the Patient Protection and Affordable Care Act, as amended, and incorporated into the Employee Retirement Income Security Act of 1974 and the Internal Revenue Code. Section 2713 of the PHS Act requires coverage without cost sharing of certain preventive health services by non-grandfathered group health plans and health insurance coverage. Among these services are women's preventive health services, as specified in guidelines supported by the Health Resources and Services Administration (HRSA). As authorized by the current regulations, and consistent with the HRSA guidelines, group health plans established or maintained by certain religious employers (and group health insurance coverage provided in connection with such plans) are exempt from the otherwise applicable requirement to cover certain contraceptive services. These final regulations simplify and clarify the religious employer exemption. These final regulations also establish

accommodations with respect to the contraceptive coverage requirement for group health plans established or maintained by eligible organizations (and group health insurance coverage provided in connection with such plans), as well as student health insurance coverage arranged by eligible organizations that are institutions of higher education. These regulations also finalize related amendments to regulations concerning Affordable Insurance Exchanges.

DATES: *Effective date:* These final regulations are effective on August 1, 2013. *Applicability date:* With the exception of the amendments to the religious employer exemption, which apply to group health plans and health insurance issuers for plan years beginning on or after August 1, 2013, these final regulations apply to group health plans and health insurance issuers for plan years beginning on or after January 1, 2014.

FOR FURTHER INFORMATION CONTACT: For inquiries related to the religious employer exemption and eligible organization accommodations: Jacob Ackerman, Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS), at (410) 786-1565; Amy Turner or Beth Baum, Employee Benefits Security Administration (EBSA), Department of Labor, at (202) 693-8335; Karen Levin, Internal Revenue Service (IRS), Department of the Treasury, at (202) 927-9639.

For matters related to the Federally-facilitated Exchange user fee adjustment: Ariel Novick, CMS, HHS, at (301) 492-4309.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1-866-444-EBSA (3272) or visit the Department of Labor's Web site (www.dol.gov/ebsa). Information from HHS on private health insurance coverage can be found on CMS's Web site (www.cms.gov/ccio), and information on health care reform can be found at www.HealthCare.gov.

SUPPLEMENTARY INFORMATION:**I. Background**

The Patient Protection and Affordable Care Act (Pub. L. 111-148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) was enacted on March 30, 2010. These statutes are collectively known as the Affordable Care Act. The Affordable Care Act reorganizes, amends, and adds to the provisions of

part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The Affordable Care Act adds section 715(a)(1) to the Employee Retirement Income Security Act of 1974 (ERISA) and section 9815(a)(1) to the Internal Revenue Code (Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and to make them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans. The sections of the PHS Act incorporated into ERISA and the Code are sections 2701 through 2728.

Section 2713(a)(4) of the PHS Act, as added by the Affordable Care Act and incorporated into ERISA and the Code, requires that non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage provide benefits for certain women's preventive health services without cost sharing, as provided for in comprehensive guidelines supported by the Health Resources and Services Administration (HRSA). On August 1, 2011, HRSA adopted and released guidelines for women's preventive health services (HRSA Guidelines) based on recommendations of the independent Institute of Medicine. As relevant here, the HRSA Guidelines include all Food and Drug Administration (FDA)-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity, as prescribed by a health care provider (collectively, contraceptive services).¹ Except as discussed later in this section, non-grandfathered group health plans and health insurance coverage are required to provide coverage consistent with the HRSA Guidelines without cost sharing for plan years (in the individual market, policy years) beginning on or after August 1, 2012.²

Interim final regulations implementing section 2713 of the PHS Act were published on July 19, 2010 (75 FR 41726) (2010 interim final

¹ The HRSA Guidelines exclude services relating to a man's reproductive capacity, such as vasectomies and condoms.

² Interim final regulations published by the Departments on July 19, 2010, generally provide that plans and issuers must cover a newly recommended preventive service starting with the first plan year (in the individual market, policy year) that begins on or after the date that is one year after the date on which the new recommendation is issued. 26 CFR 54.9815-2713T(b)(1); 29 CFR 2590.715-2713(b)(1); 45 CFR 147.130(b)(1).

regulations). On August 1, 2011, the Departments of Health and Human Services (HHS), Labor, and the Treasury (collectively, the Departments) amended the 2010 interim final regulations to provide HRSA with authority that would effectively exempt group health plans established or maintained by certain religious employers (and group health insurance coverage provided in connection with such plans) from the requirement to cover contraceptive services consistent with the HRSA Guidelines (76 FR 46621) (2011 amended interim final regulations), and, on the same date, HRSA exercised this authority in the HRSA Guidelines such that group health plans established or maintained by these religious employers (and group health insurance coverage provided in connection with such plans) are exempt from the requirement to cover contraceptive services.³ The 2011 amended interim final regulations specified that, for purposes of this exemption, a religious employer is one that: (1) Has the inculcation of religious values as its purpose; (2) primarily employs persons who share its religious tenets; (3) primarily serves persons who share its religious tenets; and (4) is a nonprofit organization described in section 6033(a)(1) and (a)(3)(A)(i) or (iii) of the Code. Section 6033(a)(3)(A)(i) and (iii) of the Code refers to churches, their integrated auxiliaries, and conventions or associations of churches, as well as to the exclusively religious activities of any religious order. Final regulations issued on February 10, 2012, adopted the definition of religious employer in the 2011 amended interim final regulations without modification (2012 final regulations).⁴

Contemporaneous with the issuance of the 2012 final regulations, HHS, with the agreement of the Departments of Labor and the Treasury, issued guidance establishing a temporary safe harbor from enforcement of the contraceptive coverage requirement by the Departments for group health plans established or maintained by certain nonprofit organizations with religious objections to contraceptive coverage (and group health insurance coverage provided in connection with such plans).⁵ The guidance provided that the

temporary enforcement safe harbor would remain in effect until the first plan year beginning on or after August 1, 2013. The Departments committed to rulemaking during the 1-year safe harbor period to ensure more women broad access to recommended preventive services, including contraceptive services, without cost sharing, while simultaneously protecting certain additional nonprofit religious organizations with religious objections to contraceptive coverage from having to contract, arrange, pay, or refer for such coverage.

On March 21, 2012, the Departments published an advance notice of proposed rulemaking (ANPRM) that described and solicited comments on possible approaches to achieve these goals (77 FR 16501).

On February 6, 2013, following review of the comments on the ANPRM, the Departments published proposed regulations at 78 FR 8456 (proposed regulations). The regulations proposed to simplify and clarify the definition of religious employer for purposes of the religious employer exemption. The regulations also proposed accommodations for health coverage established or maintained or arranged by certain nonprofit religious organizations with religious objections to contraceptive coverage. These organizations were referred to as eligible organizations.

The regulations proposed that, in the case of an insured group health plan established or maintained by an eligible organization, the health insurance issuer providing group health insurance coverage in connection with the plan would be required to assume sole responsibility, independent of the eligible organization and its plan, for providing contraceptive coverage to plan participants and beneficiaries without cost sharing, premium, fee, or other charge to plan participants or beneficiaries or to the eligible organization or its plan. The Departments proposed a comparable accommodation with respect to insured

Section 9815(a)(1) of the Internal Revenue Code, issued on February 10, 2012, and reissued on August 15, 2012. Available at: <http://www.cms.gov/CCIIO/Resources/Files/Downloads/prev-services-guidance-08152012.pdf>. The guidance, as reissued on August 15, 2012, clarifies, among other things, that plans that took some action before February 10, 2012, to try, without success, to exclude or limit contraceptive coverage are not precluded from eligibility for the safe harbor. The temporary enforcement safe harbor is also available to insured student health insurance coverage arranged by nonprofit institutions of higher education with religious objections to contraceptive coverage that meet the conditions set forth in the guidance. See final rule entitled "Student Health Insurance Coverage" published March 21, 2012 (77 FR 16457).

student health insurance coverage arranged by eligible organizations that are institutions of higher education.

In the case of a self-insured group health plan established or maintained by an eligible organization, the proposed regulations presented potential approaches under which the third party administrator of the plan would arrange for a health insurance issuer to provide contraceptive coverage to plan participants and beneficiaries without cost sharing, premium, fee, or other charge to plan participants or beneficiaries or to the eligible organization or its plan. An issuer (or its affiliate) would be able to offset the costs incurred by the third party administrator and the issuer in the course of arranging and providing such coverage by claiming an adjustment in the Federally-facilitated Exchange (FFE) user fee.

The Departments received over 400,000 comments (many of them standardized form letters) in response to the proposed regulations. After consideration of the comments, the Departments are publishing these final regulations. With the exception of the amendments to the religious employer exemption, which apply to group health plans and group health insurance issuers for plan years beginning on or after August 1, 2013, these final regulations apply to group health plans and health insurance issuers for plan years beginning on or after January 1, 2014, which is when the majority of plan years begin.^{6,7} Contemporaneously issued amendments to the HRSA Guidelines implementing the simplified and clarified religious employer exemption authorized by 45 CFR 147.131(a) of these final regulations will be effective on August 1, 2013.

⁶ Section 2713(b) of the PHS Act and the companion provisions of ERISA and the Code provide that the Secretary shall establish an interval of not less than one year between when new recommendations or guidelines under PHS Act section 2713(a) are issued and the first plan year (in the individual market, policy year) for which coverage of services addressed in such recommendations or guidelines must be in effect. Under the 2010 interim final regulations, the requirement on a non-exempt, non-grandfathered group health plan or group or individual health insurance policy to cover a newly recommended preventive service without cost sharing takes effect starting with the first plan year (in the individual market, policy year) that begins on or after the date that is one year after the new recommendation is issued. 26 CFR 54.9815-2713T(b)(1); 29 CFR 2590.715-2713(b)(1); 45 CFR 147.130(b)(1). In the case of contraceptive services, this 1-year period ended on August 1, 2012, because the HRSA Guidelines including such services were issued on August 1, 2011. These final regulations do not alter this effective date.

⁷ This estimate is based on the Department of Labor's analysis of Form 5500 data.

³ The 2011 amended interim final regulations were issued and effective on August 1, 2011, and published on August 3, 2011 (76 FR 46621).

⁴ The 2012 final regulations were published on February 15, 2012 (77 FR 8725).

⁵ Guidance on the Temporary Enforcement Safe Harbor for Certain Employers, Group Health Plans, and Group Health Insurance Issuers with Respect to the Requirement to Cover Contraceptive Services Without Cost Sharing Under Section 2713 of the Public Health Service Act, Section 715(a)(1) of the Employee Retirement Income Security Act, and

Two additional guidance documents are being issued contemporaneously with these final regulations. First, HHS is issuing guidance extending the temporary safe harbor from enforcement of the contraceptive coverage requirement by the Departments to encompass plan years beginning on or after August 1, 2013, and before January 1, 2014. This guidance continues to include a form to be used by an organization during this temporary period to self-certify that its plan qualifies for the temporary enforcement safe harbor. Second, as described in more detail later in this preamble, HHS and DOL are also issuing a self-certification form to be executed by an organization seeking to be treated as an eligible organization for purposes of an accommodation under these final regulations. This self-certification form is applicable in conjunction with the accommodations under these final regulations (that is, for plan years beginning on or after January 1, 2014), after the expiration of the temporary enforcement safe harbor.

II. Overview of the Final Regulations

These final regulations promote two important policy goals. First, the regulations provide women with access to contraceptive coverage without cost sharing, thereby advancing the compelling government interests in safeguarding public health and ensuring that women have equal access to health care. Second, the regulations advance these interests in a narrowly tailored fashion that protects certain nonprofit religious organizations with religious objections to providing contraceptive coverage from having to contract, arrange, pay, or refer for such coverage. The regulations finalize the general approach described in the proposed regulations, with modifications in response to comments that are intended primarily to simplify administration of the policy.

Section 2713 of the PHS Act reflects a determination by Congress that coverage of recommended preventive services without cost sharing by non-grandfathered group health plans and health insurance coverage is necessary to achieve access to basic health care for more Americans. Individuals are more likely to use preventive services if they do not have to satisfy cost-sharing requirements (such as a copayment, coinsurance, or a deductible). Use of preventive services results in a healthier population and reduces health care costs by helping individuals avoid preventable conditions and receive

treatment earlier.⁸ Further, Congress, by amending the Affordable Care Act during Senate consideration of the bill to ensure that recommended preventive services for women would be covered adequately by non-grandfathered group health plans and health insurance coverage, recognized that women have unique health care needs.⁹ Such needs include contraceptive services.¹⁰

Some commenters asserted that contraceptive services should not be considered preventive health services, arguing that they do not prevent disease and have been shown by some studies to be harmful to women's health. The HRSA Guidelines are based on recommendations of the independent Institute of Medicine (IOM), which undertook a review of the scientific and medical evidence on women's preventive services. As documented in the IOM report, "Clinical Preventive Services for Women: Closing the Gaps," women experiencing an unintended pregnancy may not immediately be aware that they are pregnant, and thus delay prenatal care. They also may be less motivated to cease behaviors during pregnancy, such as smoking and consumption of alcohol, that pose pregnancy-related risks. Studies show a greater risk of preterm birth and low birth weight among unintended pregnancies.¹¹ In addition, contraceptive use helps women improve birth spacing and therefore avoid the increased risk of adverse pregnancy outcomes that comes with pregnancies that are too closely spaced. Short interpregnancy intervals in particular have been associated with low birth weight, prematurity, and small-for-gestational age births.¹² Contraceptives

also have medical benefits for women who are contraindicated for pregnancy, and there are demonstrated preventive health benefits from contraceptives relating to conditions other than pregnancy (for example, prevention of certain cancers, menstrual disorders, and acne).¹³ In addition, by reducing the number of unintended pregnancies, contraceptives reduce the number of women seeking abortions.¹⁴ It is for a woman and her health care provider in each particular case to weigh any risks against the benefits in deciding whether to use contraceptive services in general or any particular contraceptive service.

Covering contraceptives also yields significant cost savings. A 2000 study estimated that it would cost 15 to 17 percent more not to provide contraceptive coverage in employee health plans than to provide such coverage, after accounting for both the direct medical costs of pregnancy and the indirect costs, such as employee absence.¹⁵ Consistent with this finding, when contraceptive coverage was added to the Federal Employees Health Benefits Program, premiums did not increase because there was no resulting net health care cost increase.¹⁶ Specific to public financing of contraceptive services, a 2010 analysis projected that expanding access to family planning services under Medicaid saves \$4.26 for every \$1 spent.¹⁷ Additional research

89:S25–S33 (2005); Fuentes-Afflick, E., & Hessel, N., Interpregnancy Interval and the Risk of Premature Infants, *Obstetrics & Gynecology*, 95(3):383–390 (2000).

¹³ Institute of Medicine, *Clinical Preventive Services for Women: Closing the Gaps*, Washington, DC: National Academy Press, 2011, at p. 107.

¹⁴ Institute of Medicine, *Clinical Preventive Services for Women: Closing the Gaps*, Washington, DC: National Academy Press, 2011, at p. 105. See also, Peipert, J., et al., Preventing Unintended Pregnancies by Providing No-Cost Contraception, *Obstetrics & Gynecology*, 120(6): 1291–1297 (2012); see also Bongaarts, J., & Westoff, C., The Potential Role of Contraception in Reducing Abortion, *Studies in Family Planning*, 31(3): 193–202 (2000).

¹⁵ Testimony of Guttmacher Inst., submitted to the Comm. on Preventive Servs. for Women, Institute of Medicine, January 12, 2012, p. 11, citing Bonoan, R. & Gonen, J.S., Promoting Healthy Pregnancies: Counseling and Contraception as the First Step, Washington Business Group on Health, Family Health in Brief, Issue No. 3. August 2000; see also Sonfield, A., The Case for Insurance Coverage of Contraceptive Services and Supplies Without Cost Sharing, 14 *Guttmacher Pol'y Rev.* 10 (2011); Mavranzeouli, I., Health Economics of Contraception, 23 *Best Practice & Res. Clinical Obstetrics & Gynecology* 187–198 (2009); Trussell, J., et al., Cost Effectiveness of Contraceptives in the United States, 79 *Contraception* 5–14 (2009); Trussell, J., The Cost of Unintended Pregnancy in the United States, 75 *Contraception* 168–170 (2007).

¹⁶ Dailard, C., Special Analysis: The Cost of Contraceptive Insurance Coverage, *Guttmacher Rep. on Public Policy* (March 2003).

¹⁷ Sawhill, R., et al., An Ounce of Prevention: Policy Prescriptions to Reduce the Prevalence of Fragile Families, *Future of Children*, 20(2):133–155.

⁸ Institute of Medicine, *Clinical Preventive Services for Women: Closing the Gaps*, Washington, DC: National Academy Press, 2011, at p. 16.

⁹ S.Amdt. 2791 to S.Amdt. 2786 to H.R. 3590 (Service Members Home Ownership Tax Act of 2009), December 3, 2009.

¹⁰ Institute of Medicine, *Clinical Preventive Services for Women: Closing the Gaps*, Washington, DC: National Academy Press, 2011, at p. 9; see also Sonfield, A., The Case for Insurance Coverage of Contraceptive Services and Supplies Without Cost Sharing, 14 *Guttmacher Policy Review*. 10 (2011), available at www.guttmacher.org/pubs/gpr/14/1/gpr140107.html. See also *Congressional Record*, S12025 (Dec. 1, 2009), S12114, S12271, S12277 (December 3, 2009) (statements of Senators B. Boxer, D. Feinstein, A. Franken, and B. Nelson, respectively).

¹¹ Gipson, J.D., et al., The Effects of Unintended Pregnancy on Infant, Child and Parental Health: A Review of the Literature, *Studies on Family Planning*, 2008, 39(1):18–38.

¹² Conde-Aguledo, A., et al., Birth Spacing and Risk of Adverse Perinatal Outcomes—A Meta-Analysis, *Journal of the American Medical Association*, 295(15):1809–1823 (2006); see also Zhu, B., Effect of Interpregnancy Interval on Birth Outcomes: Findings from Recent U.S. Studies, *International Journal of Gynecology & Obstetrics*,

arrived at a similar conclusion and found that, in total, services provided at publicly funded family planning centers saved \$5.1 billion in 2008.¹⁸

Further, the importance of covering contraceptive services has been recognized by many states, issuers, and employers. Twenty-eight states now have laws requiring health insurance issuers to cover contraceptives.¹⁹ A 2002 study found that more than 89 percent of insured plans covered contraceptives.²⁰ And a 2010 survey of employers revealed that 85 percent of large employers and 62 percent of small employers offered coverage of FDA-approved contraceptives, with another 32 percent of small employers reporting that they did not know whether they did so.²¹

Furthermore, in directing non-grandfathered group health plans and health insurance coverage to cover preventive services and screenings for women described in HRSA Guidelines without cost sharing, the statute acknowledges that both existing health coverage and existing preventive services recommendations often did not adequately serve the unique health needs of women. This disparity placed women in the workforce at a disadvantage compared to their male coworkers. Research shows that access to contraception improves the social and economic status of women.²²

¹⁸ Frost, J., et al., *Contraceptive Needs and Services, National and State Data, 2008 Update*, New York: Guttmacher Institute (2010).

¹⁹ Sonfield, A., et al., U.S. Insurance Coverage of Contraceptives and the Impact of Contraceptive Coverage Mandates, *Perspectives on Sexual and Reproductive Health* 36(2):72–79, 2002.

²⁰ Sonfield, A., et al., U.S. Insurance Coverage of Contraceptives and the Impact of Contraceptive Coverage Mandates, *Perspectives on Sexual and Reproductive Health* 36(2):72–79, 2002.

²¹ Claxton, G., et al., *Employer Health Benefits: 2010 Annual Survey*, Menlo Park, Cal.: Kaiser Family Found. & Chicago, Illinois: Health Research & Education Trust, 2010. While many employers included contraceptive coverage in their group health plans prior to the Affordable Care Act, the Departments note that the contraceptive coverage requirement promotes the government's interests with respect to even these plans' participants and beneficiaries by ensuring that these plans cover contraceptive services without cost sharing, a significant financial barrier to such services that was prevalent before the contraceptive coverage requirement. Institute of Medicine, *Clinical Preventive Services for Women: Closing the Gaps*, Washington, DC: National Academy Press, 2011, at p. 107. See also Postlethwaite, D., et al., A Comparison of Contraceptive Procurement Pre- and Post-Benefit Change, *76 Contraception* 360 (2007).

²² Testimony of Guttmacher Institute, submitted to the Comm. on Preventive Services for Women, Institute of Medicine, January 12, 2012, p. 6, citing Goldin, C. & Katz, L., Career and Marriage in the Age of the Pill, *American Economic Review*, 2000, 90(2):461–465; Goldin, C. & Katz, L.F., The Power of the Pill: Oral Contraceptives and Women's Career and Marriage Decisions, *Journal of Political Economy*, 2002, 110(4):730–770; Bailey, M.J., More

Research also shows that cost sharing can be a significant barrier to access to contraception.²³ As IOM noted, women use preventive services more than men, generating significant out-of-pocket expenses for women.²⁴ Thus, eliminating cost sharing is particularly critical to addressing the gender disparity of concern here.

The Departments aim to advance these compelling public health and gender equity interests by providing more women broad access to recommended preventive services, including contraceptive services, without cost sharing, while simultaneously protecting certain nonprofit religious organizations with religious objections to contraceptive coverage from having to contract, arrange, pay, or refer for such coverage, as described in these final regulations. Moreover, through these final regulations, the Departments seek to achieve these goals in ways that take into account the responsibilities imposed on health insurance issuers and third party administrators.

A. Amendments to Coverage of Recommended Preventive Health Services—26 CFR 54.9815–2713, 29 CFR 2590.715–2713, 45 CFR 147.130

These sections of the final regulations finalize technical amendments to the existing preventive services coverage regulations as proposed. The final regulations amend paragraph (a) of the existing regulations so that the general requirement to provide coverage for recommended preventive services without cost sharing is subject to the religious employer exemption and eligible organization accommodations discussed later in this section.

The regulations also finalize proposed amendments to paragraph (a)(1)(iv) of the existing regulations. As amended, the authorization for HRSA to exempt religious employers from the contraceptive coverage requirement and the definition of religious employer are now located in new 45 CFR 147.131(a) of the HHS regulation and incorporated by reference in the regulations of the Departments of Labor and the Treasury.

There are no other changes to the provisions of the 2010 interim final regulations related to providing

Power to the Pill: The Impact of Contraceptive Freedom on Women's Life Cycle Labor Supply, *Quarterly Journal of Economics*, 2006, 121(1):289–320.

²³ Postlethwaite, D., et al., A Comparison of Contraceptive Procurement Pre- and Post-Benefit Change, *76 Contraception* 360 (2007).

²⁴ Institute of Medicine, *Clinical Preventive Services for Women: Closing the Gaps*, Washington, DC: National Academy Press, 2011, p. 19.

coverage for recommended preventive services without cost sharing. Accordingly, consistent with the general rules for the provision of coverage for recommended preventive services without cost sharing set forth in the 2010 interim final regulations, 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 to the extent not specified in a recommendation or guideline and nothing requires a plan or issuer that has a network of health care providers to provide benefits or eliminate cost sharing for items or services that are delivered out-of-network.²⁵

B. Religious Employer Exemption and Accommodations for Health Coverage Established or Maintained or Arranged by Eligible Organizations—26 CFR 54.9815–2713A, 29 CFR 2590.715–2713A, 45 CFR 147.131

These sections of the final regulations simplify and clarify the criteria for the religious employer exemption from the contraceptive coverage requirement. These sections also establish accommodations with respect to the contraceptive coverage requirement for group health plans established or maintained by eligible organizations (and group health insurance coverage provided in connection with such plans), as well as student health insurance coverage arranged by eligible organizations that are institutions of higher education.

1. Religious Employer Exemption

Under the 2012 final regulations, HRSA has the authority to issue guidelines in a manner that exempts group health plans established or maintained by religious employers (and group health insurance coverage provided in connection with such plans) from any requirement to cover contraceptive services consistent with the HRSA Guidelines that would otherwise apply. A religious employer was defined for this purpose as one that: (1) Has the inculcation of religious values as its purpose; (2) primarily employs persons who share its religious tenets; (3) primarily serves persons who

²⁵ See 26 CFR 54.9815–2713T(a)(3) and (4); 29 CFR 2590.715–2713(a)(3) and (4); 45 CFR 147.130(a)(3) and (4). Note, however, if a plan or issuer does not have in its network a provider who can provide the particular service, then the plan or issuer must cover the item or service when performed by an out-of-network provider and not impose cost sharing with respect to the item or service. See FAQs About Affordable Care Act Implementation (Part XII), Q3 (February 20, 2013), available at: <http://www.dol.gov/ebsa/faqs/faq-aca12.html>.

share its religious tenets; and (4) is a nonprofit organization described in section 6033(a)(1) and 6033(a)(3)(A)(i) or (iii) of the Code. Section 6033(a)(3)(A)(i) and (iii) of the Code refers to churches, their integrated auxiliaries, and conventions or associations of churches, as well as to the exclusively religious activities of any religious order.

The Departments proposed to simplify and clarify the definition of religious employer by eliminating the first three prongs and clarifying the fourth prong of the definition. Under this proposal, an employer that is organized and operates as a nonprofit entity and is referred to in section 6033(a)(3)(A)(i) or (iii) of the Code would be considered a religious employer for purposes of the religious employer exemption. These proposed amendments were intended to eliminate any question as to whether group health plans of houses of worship that provide educational, charitable, or social services to their communities qualify for the exemption. Specifically, they were intended to ensure that an otherwise exempt plan is not disqualified because the employer's purposes extend beyond the inculcation of religious values or because the employer hires or serves people of different religious faiths. The Departments also proposed to clarify that, for purposes of the religious employer exemption, an employer that is organized and operates as a nonprofit entity is not limited to any particular form of entity under state law. The Departments reiterate that, under this standard, it is not necessary to determine the federal tax-exempt status of the nonprofit entity in determining whether the religious employer exemption applies.²⁶

The Departments received numerous comments addressing the definition of religious employer. Some commenters stated that the proposed definition of religious employer was too narrow and should be broadened to include all employers, both nonprofit and for-profit, that have a religious objection to providing contraceptive coverage in their group health plan. Some commenters requested that the definition of religious employer be expanded to exempt not only churches and other houses of worship, but also religiously affiliated hospitals and other health care organizations and other religiously affiliated ministries using the concepts of Code section 414(e). Other

commenters recommended that the requirement to cover contraceptive services be rescinded altogether.

Some commenters stated that the exemption for religious employers should be eliminated and that religious employers should instead be subject to the accommodations for eligible organizations so that their employees may also receive alternative contraceptive coverage without cost sharing. Other commenters opposed eliminating the first three prongs of the definition of religious employer, stating that only churches and other houses of worship that meet the criteria of all of the prongs should be subject to the exemption. Many commenters agreed with the Departments that the proposed definition of religious employer would not materially expand the universe of religious employers, but others felt that the proposed definition would unduly broaden it.

Based on their review of these comments, the Departments are finalizing without change the definition of religious employer in the proposed regulations. As indicated in the preamble to the proposed regulations (78 FR 8461), the simplified and clarified definition of religious employer does not expand the universe of religious employers that qualify for the exemption beyond that which was intended in the 2012 final regulations, but only eliminates any perceived potential disincentive for religious employers to provide educational, charitable, and social services to their communities. The Departments believe that the simplified and clarified definition of religious employer continues to respect the religious interests of houses of worship and their integrated auxiliaries in a way that does not undermine the governmental interests furthered by the contraceptive coverage requirement. Houses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are more likely than other employers to employ people of the same faith who share the same objection, and who would therefore be less likely than other people to use contraceptive services even if such services were covered under their plan.

Contemporaneous with the issuance of these final regulations, HRSA is issuing amended guidelines implementing the simplified and clarified religious employer exemption authorized by 45 CFR 147.131(a) of these final regulations (and incorporated by reference in 26 CFR 54.9815–2713(a)(1)(iv) and 29 CFR 2590.715–2713(a)(1)(iv)). The amendments to the

guidelines will become effective beginning August 1, 2013.

2. Accommodations for Health Coverage Established or Maintained or Arranged by Eligible Organizations

In addition to simplifying and clarifying the definition of religious employer, these final regulations establish accommodations with respect to the contraceptive coverage requirement for health coverage established or maintained or arranged by eligible organizations, as defined in these final regulations. After meeting a self-certification standard, as described in more detail in this preamble, nonprofit religious organizations that qualify for these accommodations are not required to contract, arrange, pay, or refer for contraceptive coverage; however, plan participants and beneficiaries (or student enrollees and their covered dependents) will still benefit from separate payments for contraceptive services without cost sharing or other charge in accordance with section 2713 of the PHS Act and the companion provisions of ERISA and the Code. As discussed later in this section, the accommodations established under these final regulations do not require the issuance of a separate excepted benefits individual health insurance policy covering contraceptive services, as set forth in the proposed regulations, but instead require a simpler method of providing direct payments for contraceptive services.

a. Definition of Eligible Organization

The final regulations retain the definition of eligible organization set forth in the proposed regulations. Accordingly, under these final regulations, an eligible organization is an organization that: (1) Opposes providing coverage for some or all of the contraceptive services required to be covered under section 2713 of the PHS Act and the companion provisions of ERISA and the Code on account of religious objections; (2) is organized and operates as a nonprofit entity; (3) holds itself out as a religious organization; and (4) self-certifies that it satisfies the first three criteria (as discussed in more detail later in this section).

Some commenters requested that the definition of eligible organization be broadened to include nonprofit secular employers and for-profit employers with religious objections to contraceptive coverage. Other commenters urged that the definition not be extended to for-profit employers, arguing that for-profit employers should not be accommodated because their purposes are commercial, not religious. Additionally, several

²⁶ Similarly, whether a nonprofit entity is a religious employer is determined under this definition without regard to whether the entity files Form 990 with the IRS.

commenters recommended clarifying how an eligible organization would show that it holds itself out as a religious organization. Specifically, commenters suggested clarifying that only organizations that prominently and consistently hold themselves out to the public as religious organizations may qualify for an accommodation.

The Departments decline to adopt these suggestions. The definition of eligible organization in these final regulations is the same as that in the proposed regulations, and is intended to allow health coverage established or maintained or arranged by various types of nonprofit religious organizations with religious objections to contraceptive coverage to qualify for an accommodation. Consistent with religious accommodations in related areas of federal law, such as the exemption for religious organizations under Title VII of the Civil Rights Act of 1964, the definition of eligible organization in these final regulations does not extend to for-profit organizations. The Departments are unaware of any court granting a religious exemption to a for-profit organization, and decline to expand the definition of eligible organization to include for-profit organizations.

b. Self-Certification

Each organization seeking to be treated as an eligible organization under the final regulations, to avoid contracting, arranging, paying, or referring for contraceptive coverage, is required to self-certify, prior to the beginning of the first plan year to which an accommodation is to apply, that it meets the definition of an eligible organization.²⁷ The self-certification (as described in these final regulations) needs to be executed once. A copy of the self-certification needs to be provided to a new health insurance issuer or a new third party administrator if the eligible organization changes issuers or third party administrators. Comments addressing this topic generally approved of the approach proposed by the Departments, but some commenters suggested that stronger protections were needed to promote oversight, enforcement, and transparency and to prevent abuse. For example, some commenters recommended requiring eligible organizations to file their self-certifications with the Departments and

making such records available to the public. Other commenters argued that the act of self-certification would infringe on the First Amendment right of free speech.

The final regulations do not require the self-certification to be submitted to any of the Departments. An eligible organization must simply maintain the self-certification (executed by an authorized representative of the organization) in its records, in a manner consistent with the record retention requirements under section 107 of ERISA, and make the self-certification available for examination upon request. The Departments believe that the requirement to make the self-certification available for examination upon request appropriately balances regulators', issuers', third party administrators', and plan participants and beneficiaries' (and student enrollees and their covered dependents') interest in verifying compliance and eligible organizations' interest in avoiding undue inquiry into their character, mission, or practices. Further, the Departments do not believe that the self-certification standard infringes on freedom of speech.

The proposed regulations provided that the self-certification would specify the contraceptive services for which the organization will not establish, maintain, administer, or fund coverage. The final regulations eliminate this requirement, pursuant to the standard exclusion policy discussed later in this section. Further, the final regulations provide that, if an organization seeks to be treated as an eligible organization under the final regulations, an issuer or third party administrator may not require any documentation from the organization beyond its self-certification as to its status as an eligible organization. The form to be used for the self-certification is being finalized contemporaneous with the issuance of these final regulations through the process provided for under the Paperwork Reduction Act of 1995.

As discussed previously, the self-certification form is applicable in conjunction with the accommodations under these final regulations (that is, for plan years beginning on or after January 1, 2014), after the expiration of the temporary enforcement safe harbor. The self-certification standard referenced in these final regulations (and the form to be executed by an eligible organization to make such self-certification, which is being issued contemporaneously with these final regulations) are different from the standard (and the form) associated with the guidance regarding the extension of the temporary

enforcement safe harbor, which is also being issued contemporaneously with these final regulations.

c. Separate Payments for Contraceptive Services for Participants and Beneficiaries in Insured Group Health Plans

The proposed regulations provided, in the case of an insured group health plan established or maintained by an eligible organization, that the health insurance issuer providing group coverage in connection with the plan be required to assume sole responsibility, independent of the eligible organization and its plan, for providing separate individual health insurance policies covering contraceptive services for plan participants and beneficiaries without cost sharing, premium, fee, or other charge to plan participants or beneficiaries or to the eligible organization or its plan. Under this proposal, an organization seeking to be treated as an eligible organization would need only to meet the self-certification standard. The issuer, in turn, would automatically enroll plan participants and beneficiaries in separate individual health insurance policies that cover contraceptive services (and notify them of such enrollment) without the imposition of any cost-sharing requirement (such as a copayment, coinsurance, or a deductible), premium, fee, or other charge on plan participants or beneficiaries or on the eligible organization or its plan.

Some commenters stated that the Departments should not provide a tailored accommodation for an eligible organization that objects to only some types of contraceptive services. These commenters said that customizing individual contraceptive policies for participants and beneficiaries (or students enrollees and their covered dependents) in plans of eligible organizations based on the differing religious objections to contraceptive coverage of each eligible organization would create an administrative burden for issuers and confuse plan participants and beneficiaries (or student enrollees and their covered dependents). Some commenters also noted that requiring coordination of benefits might not be feasible, because many states prohibit coordination between individual and group health insurance coverage.

In response to these comments, the final regulations provide that an issuer providing payments for contraceptive services in accordance with these final regulations may use a standard exclusion from a group health insurance policy that encompasses all recommended contraceptive services

²⁷ Although not required to do so by these final regulations, nothing in these final regulations prevents a religious employer from drafting and executing a self-certification regarding its status as a religious employer and sharing the self-certification with issuers, plan service providers, plan participants or beneficiaries, or others.

and not violate PHS Act section 2713 and the companion provisions of ERISA and the Code with respect to the requirement to cover contraceptive services. While issuers may, at their option, choose to offer customized exclusions from group health insurance policies based on the differing religious objections to contraceptive coverage of each eligible organization (or offer several different but standardized exclusions from group health insurance policies from which eligible organizations may choose), they are not required to do so under these final regulations. Regardless of whether an issuer uses a standard or customized exclusion from a group health insurance policy, plan participants and beneficiaries (and student enrollees and their covered dependents) are assured that the issuer will make payments for any recommended contraceptive services excluded from the group health insurance policy (or student health insurance coverage).

Some commenters noted that the proposed individual health insurance policies covering contraceptive services might not be viewed as enforceable contracts under state contract law because there would be no premium associated with the coverage and no ability for an individual to decline coverage. Commenters suggested that states would need to develop new regulatory processes for reviewing forms and rates for such policies, and noted that the inability to charge a premium for such policies could raise actuarial soundness and financial reserve concerns. Commenters also noted that state laws would prevent issuers licensed to issue group health insurance policies in one state from issuing individual health insurance policies to employees of an eligible organization residing in other states, and expressed concern about the cost and administrative complexity of issuing and administering individual contraceptive coverage policies.

These final regulations achieve the same end by requiring that a health insurance issuer providing group health insurance coverage in connection with a group health plan established or maintained by an eligible organization assume sole responsibility for providing separate payments for contraceptive services directly for plan participants and beneficiaries, without cost sharing, premium, fee, or other charge to plan participants or beneficiaries or to the eligible organization or its plan. The requirement that, for plan participants and beneficiaries, issuers provide payments for contraceptive services, in lieu of individual health insurance

policies that cover contraceptive services, represents a simpler approach and responds to concerns raised by commenters, while still ensuring that eligible organizations and their plans do not contract, arrange, pay, or refer for such coverage, and that contraceptive coverage is expressly excluded from the group health insurance coverage.

Under these final regulations, as under the proposed regulations, the eligible organization need only meet the self-certification standard and provide to the issuer a copy of its self-certification. The issuer that receives the copy of the self-certification from the eligible organization must expressly exclude contraceptive coverage—either all contraceptive coverage or coverage of specific contraceptive services if the issuer chooses to customize the exclusion—from the group health insurance coverage of the eligible organization. The issuer must also notify plan participants and beneficiaries, 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, that the issuer provides payments for contraceptive services at no cost separate from the group health plan for so long as the participant or beneficiary remains enrolled in the plan, as discussed later in this section. Unlike under the proposed regulations, the issuer is not required to issue to plan participants and beneficiaries individual health insurance policies covering contraceptive services, and, thus, there is no need to consider such coverage excepted benefits, as proposed. Instead, under these final regulations, the issuer must, as a federal regulatory requirement, provide payments for contraceptive services for plan participants and beneficiaries, separate from the group health plan, without the imposition of cost sharing, premium, fee, or other charge on plan participants or beneficiaries or on the eligible organization or its plan. Under this simplified approach, issuers will not incur the associated administrative costs of issuing individual contraceptive coverage policies.

This simpler approach to the accommodation for insured coverage does not trigger certain aspects of state insurance law. As the payments at issue derive solely from a federal regulatory requirement, not a health insurance policy, they do not implicate issues such as issuer licensing and product approval requirements under state law, and they minimize cost and

administrative complexity for issuers. At the same time, because the payments for contraceptive services are not a group health plan benefit under this approach, this policy ensures that eligible organizations and their plans do not contract, arrange, pay, or refer for contraceptive coverage, and that such coverage is expressly excluded from their group health insurance policies. This approach also minimizes barriers in access to care because plan participants and beneficiaries (and their health care providers) do not have to have two separate health insurance policies (that is, the group health insurance policy and the individual contraceptive coverage policy). Furthermore, Small Business Health Insurance Options Programs (SHOPs) (the small group market Exchanges) do not need to make operational changes as a result of the accommodation. Small employers that are eligible organizations purchasing coverage through a SHOP can simply provide a copy of their self-certification to the issuer (rather than provide it to the SHOP) to ensure that their small group market policy is provided in a manner consistent with these final regulations.

Although these payments for contraceptive services are not benefits under a health insurance policy, to fulfill an issuer's responsibilities under section 2713 of the PHS Act and the companion provisions of ERISA and the Code and consistent with the proposed regulations, an issuer must make them available in a way that meets minimum standards for consumer protection, which would ordinarily accompany coverage of recommended preventive health services without cost sharing under section 2713 of the PHS Act and the companion provisions of ERISA and the Code. Thus, issuers, in order to satisfy their regulatory obligations under these final regulations, must make these payments for contraceptive services in a manner consistent with the requirements under the following provisions of the PHS Act and the companion provisions of ERISA and the Code (and their implementing regulations): PHS Act sections 2706 (non-discrimination in health care), 2709 (coverage for individuals participating in approved clinical trials), 2711 (no lifetime or annual limits), 2713 (coverage of preventive health services), 2719 (appeals process), and 2719A (patient protections), as incorporated by reference into ERISA section 715 and Code section 9815.²⁸ Consistent with

²⁸ With respect to the accommodation for self-insured coverage of eligible organizations under these final regulations, a comparable requirement to

these standards and as described in the 2010 interim final regulations, an issuer may apply reasonable medical management techniques and may require that contraceptive services be obtained in-network (if an issuer has a network of providers) in order for plan participants and beneficiaries to obtain such services without cost sharing.²⁹

Issuers are prohibited from charging any premium, fee, or other charge to eligible organizations or their plans, or to plan participants or beneficiaries, for making payments for contraceptive services, and must segregate the premium revenue collected from eligible organizations from the monies they use to make such payments. In making such payments, the issuer must ensure that it does not use any premiums collected from eligible organizations. Issuers have flexibility in how to structure these payments, provided that the payments in no way involve the eligible organization, and provided that issuers are able to account for this segregation of funds in accordance with applicable, generally accepted accounting and auditing standards.

The Departments stated in the preamble of the proposed regulations that issuers would find that providing contraceptive coverage is at least cost neutral because they would be insuring the same set of individuals under both the group health insurance policies and the separate individual contraceptive coverage policies and, as a result, would experience lower costs from improvements in women's health, healthier timing and spacing of pregnancies, and fewer unplanned pregnancies. The Departments continue to believe, and have evidence to support, that, with respect to the accommodation for insured coverage established under these final regulations, providing payments for contraceptive services is cost neutral for issuers. Several studies have estimated that the costs of providing contraceptive coverage are balanced by cost savings from lower pregnancy-related costs and from improvements in women's

provide separate payments for contraceptive services consistent with these consumer protections is not explicitly placed on the third party administrator. This is because, as the plan administrator for contraceptive coverage, the third party administrator is already required to comply with these consumer protections, as well as all other provisions of ERISA that are applicable to group health plans, including ERISA sections 104 and 503, and the requirements of Part 7 of ERISA.

²⁹ See 26 CFR 54.9815-2713T(a)(3) and (4); 29 CFR 2590.715-2713(a)(3) and (4); 45 CFR 147.130(a)(3) and (4).

health.^{30 31} The Departments are unaware of any studies to the contrary.³²

Some commenters raised specific premium rating and accounting issues related to the proposed regulations' approach to the cost neutrality of issuers providing contraceptive coverage. These commenters generally asserted that the cost savings due to lower pregnancy-related costs and improvements in women's health would flow to employers through reduced premiums, thereby leaving issuers uncompensated for the cost of providing contraceptive coverage. Further, commenters stated that, in the case of a group health insurance policy in the small group market, the small employer's reduced claims experience attributable to contraceptive coverage (not including the issuer's direct costs of contraceptive coverage) would be spread across the issuer's single risk pool for the entire small group market in a state and result in a lower index rate for pricing all of the issuer's small group market products. Thus, according to these commenters, in both the large and small group markets, issuers would not reap the cost savings attributable to contraceptive coverage, and would need to fund the costs of a free-standing contraceptive coverage policy from some other source.

³⁰ Bertko, J., Glied, S., *et al.* The Cost of Covering Contraceptives Through Health Insurance (February 9, 2012), <http://aspe.hhs.gov/health/reports/2012/contraceptives/ib.shtml>; Washington Business Group on Health, Promoting Healthy Pregnancies: Counseling and Contraception as the First Step, Report of a Consultation with Business and Health Leader (September 20, 2000), <http://www.businessgrouphealth.org/pdfs/healthypregnancy.pdf>; Campbell, K.P., Investing in Maternal and Child Health: An Employer's Toolkit, National Business Group on Health http://www.businessgrouphealth.org/healthtopics/maternalchild/investing/docs/mch_toolkit.pdf; Trussell, J., *et al.* The Economic Value of Contraception: A Comparison of 15 Methods, *American Journal Public Health*, 1995; 85(4):494-503, Revenues of H.R. 3162, the Children's Health and Medicare Protection Act, for the Rules Committee (August 1, 2007) <http://www.cbo.gov/ftpdocs/85xx/doc8519/HR3162.pdf>.

³¹ The Departments believe that these same cost savings found by issuers of group health insurance would also be found by issuers of student health insurance coverage.

³² One commenter cited two studies disputing the cost effectiveness of preventive health services, but these studies are not specific to contraceptive services. Further, these studies find that preventive care is not cost effective when a large population receives the preventive service but only a small fraction of that population would have developed the condition being prevented, a circumstance not presented here. See Cohen, J., *et al.*, *New England Journal of Medicine*. 2008, 358:661-663 (February 14, 2008) <http://www.nejm.org/toc/nejm/358/7>; CBO Letter to Congressman Nathan Deal, (August 7, 2009). <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/104xx/doc10492/08-07-prevention.pdf>.

One commenter suggested that it would be possible to view the provision of contraceptive coverage as cost neutral if an issuer were to set the premium otherwise charged to an eligible organization as though plan participants and beneficiaries did not have separate contraceptive coverage. Other commenters argued that the rationale for providing Federally-facilitated Exchange (FFE) user fee adjustments in connection with the accommodation for self-insured group health plans of eligible organizations was equally applicable in the context of insured group health plans of eligible organizations and recommended that issuers be permitted to charge a premium or otherwise be compensated for providing contraceptive coverage.

In response to these comments, the Departments continue to believe that issuers have various options for achieving cost neutrality, notwithstanding that they must make payments for contraceptive services without cost sharing, premium, fee, or other charge to the eligible organization, the group health plan, or plan participants or beneficiaries.

Issuers of large group insured products have an option by which they can ensure that they accrue the cost savings from reduced pregnancy-related expenses and other health care costs. For large group market products, issuers base premiums on an employer's prior year claims cost (that is, experience rating) and other factors.³³ Some commenters asserted that this rating practice means that any cost savings from fewer pregnancies and childbirths and improvements in women's health will be passed to the employer in the large group insured market. Given that there appears to be no legal requirement that issuers use this particular rating practice, and that this practice often entails adding costs to premiums that are not based solely on the experience of the employer's group,³⁴ issuers reasonably could set the premium for an eligible organization's large group policy as if no payments for contraceptive services had been provided to plan participants and beneficiaries—reflecting the actual terms of the group policy, which expressly excludes contraceptive coverage. This approach would be consistent with pricing methodologies currently used in the health insurance industry.

³³ http://www.nahu.org/consumer/Group_Insurance.cfm.

³⁴ http://www.actuary.org/files/Draft_Large_Group_Medical_Business_Practice_Note_Jan_2013.pdf.

Another option is to treat the cost of payments for contraceptive services for women enrolled in insured group health plans established or maintained by eligible organizations as an administrative cost that is spread across the issuer's entire risk pool, excluding plans established or maintained by eligible organizations given that issuers are prohibited from charging any premium, fee, or other charge to eligible organizations or their plans for providing payments for contraceptive services. In the small group market, issuers are required beginning in 2014 to treat all of their non-grandfathered business within a state as a single risk pool, and administrative costs may be spread evenly across all plans in the single risk pool (although issuers are permitted to apply them on a plan basis). In the large group market, while there is no single risk pool requirement, issuers generally spread administrative costs across their entire book of business.³⁵ In 2011, health insurance issuers earned approximately \$290 billion in premiums in the insured small and large group markets.³⁶ If the cost of providing payments for contraceptive services for participants and beneficiaries in insured group health plans established or maintained by eligible organizations were treated as an administrative cost spread across an issuer's entire book of business (excluding plans established or maintained by eligible organizations), the cost of providing such payments would result in an imperceptible increase in administrative load.³⁷ These changes in premiums would be negligible and effectively cost neutral to issuers, even before considering any reductions in claims costs that accrue to the issuer.

Under either option, after meeting the self-certification standard, the eligible organization would not contract, arrange, pay, or refer for contraceptive coverage.

HHS intends to clarify in guidance that an issuer of group health insurance coverage that makes payments for contraceptive services under these final regulations may treat those payments as an adjustment to claims costs for purposes of medical loss ratio and risk

corridor program calculations.³⁸ This adjustment compensates for any increase in incurred claims associated with making payments for contraceptive services.

Several commenters expressed concern that participants and beneficiaries in plans of eligible organizations would be automatically enrolled in individual contraceptive coverage policies and recommended providing an opt-out for plan participants and beneficiaries who object to contraceptive coverage on religious grounds. Other commenters stated that allowing participants and beneficiaries to opt out of such contraceptive coverage would create an administrative burden on issuers and privacy concerns for individuals because the issuers would know which individuals opted in or opted out of such coverage. The simplified approach described in these final regulations eliminates this issue altogether, because issuers are not required to issue individual contraceptive coverage policies at all.³⁹ Rather, they are required only to provide payments for contraceptive services for those plan participants and beneficiaries who opt to use such services. Nothing in these final regulations compels any plan participant or beneficiary to use such services, and nothing causes participants or beneficiaries to be automatically enrolled in contraceptive coverage; therefore, these concerns are addressed without the need for an opt-out mechanism. Moreover, nothing in these final regulations precludes employers or others from expressing any opposition to the use of contraceptives or requires health care providers to prescribe or provide contraceptives, if doing so is against their religious beliefs.

The Departments explained in the preamble of the proposed regulations that a health insurance issuer providing group health insurance coverage in connection with a group health plan established or maintained by an eligible organization would be held harmless if the issuer relied in good faith on a representation by the organization as to its eligibility for the accommodation and such representation was later determined to be incorrect. The Departments also explained that an

eligible organization and its plan would be held harmless if the issuer were to fail to comply with the requirement to provide separate payments for contraceptive services for plan participants and beneficiaries at no cost. Some commenters requested that the Departments codify this policy in regulation text. Accordingly, this policy is now codified in paragraph (e) of 26 CFR 54.9815-2713A, 29 CFR 2590.715-2713A, and 45 CFR 147.131 of these final regulations.

To summarize, the following are the key elements of the accommodation that is being made for eligible organizations with insured group health plans:

- An organization seeking to be treated as an eligible organization needs only to self-certify that it is an eligible organization, provide the issuer with a copy of the self-certification, and satisfy the recordkeeping and inspection requirements of the self-certification standard.

- The issuer that receives a self-certification must then expressly exclude contraceptive coverage from the eligible organization's group health insurance coverage.

- The issuer must, 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, notify plan participants and beneficiaries that the issuer provides separate payments for contraceptive services at no cost for so long as the participant or beneficiary remains enrolled in the plan.

- The issuer must segregate premium revenue collected from the eligible organization from the monies used to make payments for contraceptive services. When it makes payments for contraceptive services used by plan participants and beneficiaries, the issuer must do so without imposing any premium, fee, or other charge, or any portion thereof, directly or indirectly, on the eligible organization, its group health plan, or its plan participants or beneficiaries. In making such payments, the issuer must ensure that it does not use any premiums collected from eligible organizations. Issuers have flexibility in how to structure these payments, but must be able to account for this segregation of funds, subject to applicable, generally accepted accounting and auditing standards. Thus, an eligible organization need not contract, arrange, pay or refer for contraceptive coverage.

³⁵ Bluhm, W., ed., *Group Insurance*, 5th Ed. 2007), 459-460.

³⁶ 2011 MLR-A data, submitted to CMS in July 2012.

³⁷ Office of Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, "Cost-Neutrality of Contraceptive Coverage."

³⁸ See 45 CFR Part 158 for standards related to the medical loss ratio and 45 CFR Part 153 Subpart F for standards related to the risk corridor program.

³⁹ The same is true with respect to the accommodation for self-insured coverage of eligible organizations under these final regulations, given that third party administrators similarly are not required to arrange for individual contraceptive coverage policies at all.

- Plan participants and beneficiaries may refuse to use contraceptive services.
- An eligible organization and its group health plan are considered to comply with the contraceptive coverage requirement even if the issuer fails to comply with the requirement to provide separate payments for contraceptive services for plan participants and beneficiaries at no cost.

d. Separate Payments for Contraceptive Services for Participants and Beneficiaries in Self-Insured Group Health Plans

Comments varied as to which of the three proposed approaches to providing separate contraceptive coverage without cost sharing for participants and beneficiaries in self-insured plans of eligible organizations should be finalized. Some commenters suggested that none of the proposed approaches would enable objecting employers to separate themselves completely from the administration of contraceptive coverage. These commenters requested an unqualified exemption from the contraceptive coverage requirement for such employers. Other commenters stated that none of the proposed approaches would sufficiently ensure that participants and beneficiaries in self-insured plans of eligible organizations would receive separate contraceptive coverage without cost sharing. These commenters requested that the final regulations require that objecting employers retain legal responsibility for any failure on the part of issuers or third party administrators to provide such coverage.

A number of commenters expressed concern about the responsibilities that one or more of the proposed approaches would impose on third party administrators. Some of these commenters suggested that the proposed requirement that third party administrators arrange for separate contraceptive-only coverage through an issuer would convert third party administrators into health insurance brokers. Others suggested that third party administrators would not be willing to assume the responsibility of arranging for separate contraceptive-only coverage. These commenters also suggested that, even if a third party administrator were willing to assume such responsibility, it would pass along the resultant increase in its administrative costs to the employer.

Other commenters expressed concern about an approach that would require third party administrators to become plan administrators and fiduciaries under section 3(16) of ERISA for the

sole purpose of arranging contraceptive coverage. These commenters suggested that requiring third party administrators to serve as fiduciaries would increase their exposure to legal liability and also create conflicts of interest with their plan sponsor clients given that many agreements between third party administrators and plan sponsors prohibit third party administrators from serving as fiduciaries.

A number of commenters questioned the Department of Labor's legal authority to designate a third party administrator as the plan administrator for contraceptive coverage by virtue of the eligible organization providing a copy of its self-certification to the third party administrator. These commenters suggested that the self-certification of the eligibility of the organization for the accommodation would be insufficient to act as a designation under ERISA section 3(16)(A)(i), and questioned whether the self-certification could be defined as an instrument under which the plan is operated.

After reviewing the comments on the three proposed approaches, the Departments are finalizing the third approach under which the third party administrator becomes an ERISA section 3(16) plan administrator and claims administrator solely for the purpose of providing payments for contraceptive services for participants and beneficiaries in a self-insured plan of an eligible organization at no cost to plan participants or beneficiaries or to the eligible organization. The Departments have determined that the ERISA section 3(16) approach most effectively enables eligible organizations to avoid contracting, arranging, paying, or referring for contraceptive coverage after meeting the self-certification standard, while also creating the fewest barriers to or delays in plan participants and beneficiaries obtaining contraceptive services without cost sharing.

Under this approach, as set forth in these final regulations, with respect to the contraceptive coverage requirement, an eligible organization is considered to comply with section 2713 of the PHS Act and the companion provisions in ERISA and the Code if it provides to all third party administrators with which it or its plan has contracted a copy of its self-certification, consistent with the requirements of these final regulations.⁴⁰ The self-certification

⁴⁰ Third party administrators are hired by plan sponsors to process claims and administer other administrative aspects of employee benefit plans. In some cases, a plan hires different third party administrator to administer claims for different classifications of benefits. (For example, one plan may contract with a pharmacy benefit manager

must: (1) State that the eligible organization will not act as the plan administrator or claims administrator with respect to contraceptive services or contribute to the funding of contraceptive services; and (2) cite 29 CFR 2510.3-16 and 26 CFR 54.9815-2713A and 29 CFR 2590.715-2713A, which explain the obligations of the third party administrator. Upon receipt of the copy of the self-certification, the third party administrator may decide not to enter into, or remain in, a contractual relationship with the eligible organization to provide administrative services for the plan.

As relevant here, a plan administrator is defined in ERISA section 3(16)(A)(i) as "the person specifically so designated by the terms of the instrument under which the plan is operated." As a document notifying the third party administrator(s) that the eligible organization will not provide, fund, or administer payments for contraceptive services, the self-certification is one of the instruments under which the employer's plan is operated under ERISA section 3(16)(A)(i). The self-certification will afford the third party administrator notice of obligations set forth in these final regulations, and will be treated as a designation of the third party administrator(s) as plan administrator and claims administrator for contraceptive benefits pursuant to section 3(16) of ERISA. Additional conditions the eligible organization must meet in order to be considered to comply with PHS Act section 2713 and the companion provisions in ERISA and the Code include prohibitions on: (1) Directly or indirectly interfering with a third party administrator's efforts to provide or arrange separate payments for contraceptive services for participants or beneficiaries in the plan and (2) directly or indirectly seeking to influence a third party administrator's

(PBM) to handle claims administration for prescription drugs and another third party administrator to handle claims for inpatient and outpatient medical/surgical benefits.) To the extent the plan hires more than one third party administrator, each third party administrator would become the section 3(16) plan administrator with respect to the types of claims it normally processes (that is, the PBM would continue to handle claims for prescription drugs and the other third party administrator would continue to handle claims for inpatient and outpatient medical/surgical benefits); each would do so in accordance with section 2713 of the PHS Act and the companion provisions of ERISA and the Code (even if plan terms might otherwise provide differently) as plan administration that may be funded in accordance with 45 CFR 156.50(d).

decision to provide or arrange such payments.⁴¹

A third party administrator that receives a copy of the self-certification and that agrees to enter into or remain in a contractual relationship with the eligible organization to provide administrative services for the plan must provide or arrange separate payments for contraceptive services for participants and beneficiaries in the plan without cost sharing, premium, fee, or other charge to plan participants or beneficiaries, or to the eligible organization or its plan. The third party administrator can provide such payments on its own, or it can arrange for an issuer or other entity to provide such payments. In either case, like the payments for contraceptive services under the accommodation for insured plans of eligible organizations discussed previously, the payments are not health insurance policies. Moreover, in either case, the third party administrator can make arrangements with an issuer offering coverage through an FFE to obtain reimbursement for its costs (including an allowance for administrative costs and margin). As discussed later in this section, the issuer offering coverage through the FFE can receive an adjustment to the FFE user fee, and the issuer is required to pass on a portion of that adjustment to the third party administrator to account for the costs of providing or arranging payments for contraceptive services. A third party administrator that provides or arranges the payments is entitled to retain reimbursement for its costs for the period during which it reasonably and in good faith relied on a representation by the eligible organization that it was eligible for the accommodation. This is so even if the organization's representation was later determined to be incorrect.

The third party administrator must provide plan participants and beneficiaries with notice of the availability of the 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 coverage that is effective beginning on the first day of each applicable plan year (as discussed in more detail later in this section). Third party administrators must also take on the statutory responsibilities of a plan administrator under ERISA, including setting up and operating a claims procedure under

ERISA section 503, providing plan participants and beneficiaries with disclosures required under ERISA section 104, and complying with the requirements of Part 7 of ERISA. The Departments note that there is no obligation for a third party administrator to enter into or remain in a contract with the eligible organization if it objects to any of these responsibilities.

The Departments believe that this approach most successfully addresses both the desire of some commenters for plan participants and beneficiaries to receive contraceptive coverage without cost sharing without delays or other barriers, and the desire of other commenters for objecting employers to be separated from contracting, arranging, paying, or referring for contraceptive coverage. The third party administrator serving as the plan administrator for contraceptive benefits ensures that there is a party with legal authority to arrange for payments for contraceptive services and administer claims in accordance with ERISA's protections for plan participants and beneficiaries. At the same time, the approach enables objecting employers, after providing third party administrators with a copy of the self-certification (as described previously), to separate themselves from contracting, arranging, paying, or referring for contraceptive coverage. Additionally, by substituting payments for contraceptive services for health insurance policies, this approach avoids the complications that would be presented by requiring the creation of a contraceptive-only health insurance product, and allows third party administrators to avoid potentially becoming health insurance brokers. Accordingly, while the Departments appreciate commenters' concerns about the responsibilities that third party administrators must assume under this accommodation, they believe that this approach best ensures that plan participants and beneficiaries receive contraceptive coverage without cost sharing, and without the objecting employers paying for or administering such coverage.

Moreover, none of the comments changed the Department of Labor's view that it has legal authority to require the third party administrator to become the plan administrator under ERISA section 3(16) for the sole purpose of providing payments for contraceptive services if the third party administrator agrees to enter into or remain in a contractual relationship with the eligible organization to provide administrative services for the plan. The Department of Labor has broad rulemaking authority under Title I of ERISA, which includes

the ability to interpret the definition of plan administrator under ERISA section 3(16)(A)(i). The Department of Labor's interpretation of the self-certification described herein as one of the "instruments under which the plan is operated" is consistent with the plain meaning of the term because it identifies the limited set of plan benefits (that is, contraceptive coverage) that the employer refuses to provide and that the third party administrator must therefore provide or arrange for an issuer or another entity to provide.

e. Self-Insured Group Health Plans Without Third Party Administrators

Although some commenters addressed the solicitation for comments on whether and how to provide an accommodation for self-insured group health plans established or maintained by eligible organizations that do not use the services of a third party administrator, no comments indicated that such plans actually exist. Accordingly, the Departments continue to believe that there are no self-insured group health plans in this circumstance. However, to allow for the possibility that such a self-insured group health plan does exist, the Departments will provide any such plan with a safe harbor from enforcement of the contraceptive coverage requirement, contingent on: (1) the plan submitting to HHS information (as described later in this section) showing that it does not use the services of a third party administrator; and (2) if HHS agrees that the plan does not use the services of a third party administrator, the plan providing notice to plan participants and beneficiaries in any application materials distributed in connection with enrollment (or re-enrollment) in coverage that is effective beginning on the first day of each applicable plan year, indicating that it does not provide benefits for contraceptive services.

Such plans must submit to HHS at least 60 days prior to the first day of the first applicable plan year all of the following information:

- Identifying information for the plan, the eligible organization that acts as the plan sponsor, and an authorized representative of the organization, along with the authorized representative's telephone number and email address.
- A listing of the five most highly compensated non-clinical plan service providers (other than employees of the plan or plan sponsor), including contact information for each plan service provider, a concise description of the nature of the services provided by each service provider to the plan, and the annual amount of compensation paid to

⁴¹ Nothing in these final regulations prohibits an eligible organization from expressing its opposition to the use of contraceptives.

each plan service provider (examples of plan services include claims processing and adjudication, appeals management, provider network development, and pharmacy benefit management).

- An attestation (executed by an authorized representative of the organization) that the plan is established or maintained by an eligible organization, and is operated in compliance with all applicable requirements of part A of title XXVII of the PHS Act, as incorporated into ERISA and the Code.

Such information must be submitted electronically to marketreform@cms.hhs.gov.

If any such submission demonstrates that a self-insured group health plan established or maintained by an eligible organization does not use the services of a third party administrator, the Departments will provide a safe harbor from enforcement of the contraceptive coverage requirement while an additional accommodation is considered. If the Departments discover through any such submission that a self-insured group health plan established or maintained by an eligible organization does in fact use the services of a third party administrator, the eligible organization must either follow the procedures described in these final regulations to obtain an accommodation or otherwise comply with the contraceptive coverage requirement.

f. Notice of Availability of Separate Payments for Contraceptive Services

Consistent with the proposed regulations, the final regulations direct that, for any plan year to which an accommodation is to apply, a health insurance issuer providing separate payments for contraceptive services pursuant to the accommodation, or a third party administrator arranging or providing such payments (or its agent), must provide timely written notice about this fact to plan participants and beneficiaries in insured or self-insured group health plans (or student enrollees and their covered dependents in student health insurance coverage) of eligible organizations.

Under the proposed regulations, this notice would be provided by the issuer contemporaneous with (to the extent possible) but separate from any application materials distributed in connection with enrollment (or re-enrollment) in health coverage established or maintained or arranged by the eligible organization.

Commenters noted that employers, not issuers, typically distribute plan enrollment (or re-enrollment) materials to employees and that providing this

notice contemporaneous with plan enrollment (or re-enrollment) materials would not be possible because issuers typically do not receive enrollee information prior to enrollment.

Consistent with the simplified approach described previously, these final regulations provide that this notice must be provided by either the issuer providing separate payments for contraceptive services under the accommodation, or a third party administrator arranging or providing such payments (or its agent). The notice must be provided contemporaneous with (to the extent possible), but separate from, any application materials distributed in connection with enrollment (or re-enrollment) in coverage that is effective beginning on the first day of each plan year to which the accommodation applies, and it must indicate that the eligible organization does not fund or administer contraceptive benefits, but that the issuer or third party administrator will provide separate payments for contraceptive services at no cost. The Departments believe that the direction that the notice be provided contemporaneous with application materials “to the extent possible” provides sufficient flexibility to address the concerns raised by commenters about the timing of the notice.

The final regulations continue to provide model language that may be used to satisfy this notice requirement. Substantially similar language may also be used to satisfy the notice requirement. Some commenters suggested additions or modifications to the model language. Other commenters stated that the Departments should not allow the use of substantially similar language. Additionally, some commenters recommended the Departments set standards to ensure that the notice is accessible to persons with limited English proficiency and person with disabilities. The Departments believe that the model language in the final regulations, along with existing guidance concerning civil rights obligations, provide sufficient notice. The Departments also believe that the flexibility afforded by the final regulations to use substantially similar language is generally consistent with other federal notice requirements.

The notice must include contact information for the issuer or third party administrator in the event plan participants and beneficiaries (or student enrollees and their covered dependents) have questions or complaints. The Departments note that issuers and third party administrators may find it useful to provide additional

written information concerning how to obtain reimbursement for contraceptive services, appeals procedures, provider and pharmacy networks, prescription drug formularies, medical management procedures, and similar issues.⁴²

g. Student Health Insurance Coverage

Consistent with the HHS proposed regulation, paragraph (f) of the HHS final regulation provides that an accommodation applies 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 it applies to group health insurance coverage provided in connection with a group health plan established or maintained by an eligible organization that is an employer. For this purpose, any reference to plan participants and beneficiaries is a reference to student enrollees and their covered dependents.

Several commenters supported treating student health insurance like employer-sponsored group health insurance for purposes of these final regulations. Other commenters suggested that an accommodation should not extend to institutions of higher education that arrange student health insurance coverage, because student health insurance coverage is considered a type of individual rather than group health insurance coverage under federal law.⁴³ One commenter recommended that issuers offering coverage through the Exchanges be required to provide separate contraceptive coverage at no cost to students enrolled in nonprofit religious institutions of higher education with religious objections to contraceptive coverage (and their dependents).

Student health insurance coverage is administered differently than other individual health insurance coverage. Whereas most individual health insurance coverage is issued under a contract between an individual policyholder and a health insurance issuer, student health insurance coverage is available to student enrollees and their covered dependents pursuant to a written agreement between an institution of higher education and a health insurance issuer. Some religiously affiliated colleges and universities object to signing a written agreement or providing financial

⁴² Furthermore, as discussed previously, with respect to self-insured coverage, third party administrators that are plan administrators must operate in accordance with Part 1 of ERISA, including ERISA section 104, which generally requires certain disclosures regarding plan benefits and limitations.

⁴³ 45 CFR 147.147 (77 FR 16453).

assistance for student health insurance coverage that provides benefits for contraceptive services. For these reasons, HHS believes that it is appropriate to take into account religious objections to contraceptive coverage of eligible organizations that are institutions of higher education and is finalizing the provision applicable to student health insurance coverage as proposed. HHS notes that it does not have the authority to require issuers offering coverage through the Exchanges to provide separate contraceptive coverage at no cost to students (and their dependents).

The Departments note that any accommodation specific to a nonprofit religious institution of higher education is intended to accommodate the nonprofit religious institution of higher education only with respect to its arrangement of student health insurance coverage for its students and their covered dependents. With respect to the establishment or maintenance of a group health plan by a nonprofit religious institution of higher education for its employees and their dependents, the nonprofit religious institution of higher education is intended to be accommodated in the same manner as that in which any other eligible organization that has established or maintained a group health plan for its employees and their dependents is to be accommodated.

C. Adjustments of Federally-Facilitated Exchange User Fees—45 CFR 156.50(d) and 156.80(d)

These sections of the final HHS regulation set forth processes and standards to fund the payments for the contraceptive services that are provided for participants and beneficiaries in self-insured plans of eligible organizations under the accommodation described previously, at no cost to plan participants or beneficiaries, eligible organizations, third party administrators, or issuers, through an adjustment in the FFE user fee payable by an issuer participating in an FFE.⁴⁴

In response to the proposed regulations, some commenters questioned HHS's authority to establish the FFE user fee adjustment. Commenters also recommended that HHS ensure that the adjustments to user fee collections not undermine FFE operations. Commenters stated that the FFE user fee should not be increased to offset the user fee adjustment.

⁴⁴ The FFE user fee was established in the March 11, 2013 final rule entitled "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2014" (78 FR 15410) (2013 Payment Notice).

Commenters further stated that the FFE user fee adjustment must be adequate to provide financial incentives to ensure that women in self-insured plans of eligible organizations receive contraceptive coverage at no cost. Commenters suggested that the FFE user fee adjustment may not be an adequate long-term funding source as more states establish Exchanges over time, reducing the number of FFEs and therefore available FFE user fee revenue.

Office of Management and Budget (OMB) Circular No. A-25R establishes federal policy regarding these types of user fees. Consistent with that Circular, the revised FFE user fee calculation (which will result in an adjustment of the FFE user fee) will facilitate the accommodation of self-insured plans established or maintained by eligible organizations by ensuring that plan participants and beneficiaries are provided contraceptive coverage at no cost so that eligible organizations are not required to administer or fund such coverage. By financing the accommodation for self-insured plans of eligible organizations through the FFE user fee adjustment, participants and beneficiaries in such plans can retain their existing coverage, while gaining access to separate payments for contraceptive services at no cost. HHS does not believe that the adjustment to FFE user fee collections, as contemplated under this final regulation, will materially undermine FFE operations.

HHS notes that it is not raising the FFE user fee finalized in the 2014 Payment Notice to offset the FFE user fee adjustments, and estimates that payments for contraceptive services will represent only a small portion of total FFE user fees.

The FFE user fee adjustments support many of the goals of the Affordable Care Act, including improving the health of the population, reducing health care costs, providing access to health coverage, encouraging eligible organizations to continue to offer health coverage, and ensuring access to affordable qualified health plans (QHPs) via efficiently operated Exchanges. Moreover, as described earlier in these final regulations, there are significant benefits associated with contraceptive coverage without cost sharing. Such coverage significantly furthers the governmental interests in promoting public health and gender equality, and promotes the underlying goals of the Exchanges and the Affordable Care Act more generally.

In § 156.50(d) of the proposed regulations, HHS specified that, if an issuer were to provide contraceptive

coverage to participants and beneficiaries in self-insured plans of eligible organizations at no cost, and the issuer offers coverage through an FFE, the issuer would be able to seek an adjustment to the FFE user fee for the estimated cost of the contraceptive coverage. Moreover, HHS proposed that, if the issuer providing the contraceptive coverage did not offer coverage through an FFE—either because it was not a QHP issuer, or because it was a QHP issuer but operated in a state without an FFE—an issuer in the same issuer group that offered coverage through an FFE would have been able to seek an adjustment to the FFE user fee on behalf of the issuer providing the contraceptive coverage. HHS proposed to use the definition of issuer group in 45 CFR 156.20, that is, all entities treated under subsection (a) or (b) of section 52 of the Code as a member of the same controlled group of corporations as (or under common control with) a health insurance issuer, or issuers affiliated by the common use of a nationally licensed service mark. Several commenters expressed concern that not every issuer seeking to provide contraceptive coverage to participants and beneficiaries in self-insured plans of eligible organizations would be in the same issuer group as an issuer that offers coverage through an FFE. Commenters further noted that, even if the issuer providing the contraceptive coverage and the issuer offering coverage through an FFE were in the same issuer group, the issuers might incur significant administrative costs in establishing the necessary arrangements.

In response to these comments, and to account for the payments for contraceptive services for participants and beneficiaries in self-insured group health plans of eligible organizations under the accommodation described previously, HHS is finalizing a modification of the proposed policy. In § 156.50(d)(1), a participating issuer (defined at 45 CFR 156.50(a)⁴⁵) offering a plan through an FFE may qualify for an adjustment to the FFE user fee to the extent that the participating issuer either: (i) made payments for contraceptive services on behalf of a third party administrator pursuant to 26 CFR 54.9815-2713A(b)(2)(ii) or 29 CFR 2590.715-2713A(b)(2)(ii); or (ii) seeks an adjustment to the FFE user fee with respect to a third party administrator

⁴⁵ Under 45 CFR 156.50(a), a participating issuer includes QHP issuers, issuers of multi-state plans, and issuers of stand-alone dental plans. We note that an issuer of a Consumer Operated and Oriented Plan (CO-OP) offered on an FFE is also considered to be a participating issuer for the purpose of the FFE user fee adjustment.

that, following receipt of a copy of the self-certification referenced in 26 CFR 54.9815-2713A(a)(4) or 29 CFR 2590.715-2713A(a)(4), made or arranged for payments for contraceptive services pursuant to 26 CFR 54.9815-2713A(b)(2)(i) or (ii) or 29 CFR 2590.715-2713A(b)(2)(i) or (ii). Under the final regulation, neither the third party administrator, nor the participating issuer, nor any entity providing payments for contraceptive services (if neither the third party administrator nor the participating issuer is providing such payments) is required to be part of the same issuer group or otherwise affiliated. This modification allows greater flexibility in the arrangements among third party administrators, issuers, and other entities, while still ensuring that eligible organizations are not required to contract, arrange, pay, or refer for contraceptive coverage. Consistent with the proposed regulations, an allowance for administrative costs and margin in the FFE user fee adjustment accounts for the costs of arrangements among the third party administrator, the participating issuer, and any other entity providing payments for contraceptive services (if neither the third party administrator nor the participating issuer is providing such payments).

In § 156.50(d)(1) through (4) of the proposed regulations, HHS set forth a process through which an issuer seeking an FFE user fee adjustment would submit information to HHS to demonstrate the provision of contraceptive coverage and estimate the cost of such coverage. HHS further proposed that it would review this information and provide an adjustment to the issuer's monthly obligation to pay the FFE user fee in an amount equal to the approved estimated cost of the contraceptive coverage. HHS suggested that the cost of the contraceptive coverage, including administrative costs and margin, could be estimated on a per capita basis by either the issuer or HHS using either actuarial principles and methodologies or, for 2016 and beyond, previous experience. The per capita rate would then be multiplied by the monthly enrollment in the contraceptive coverage in order to calculate the total FFE user fee adjustment.

HHS sought comments on this proposed process for collecting information, calculating the cost of the contraceptive coverage, and applying the FFE user fee adjustment. HHS received several comments suggesting that issuers should be required to submit information only on an annual basis, rather than a monthly basis, to

reduce the administrative burden. Commenters also noted that it would likely be difficult to estimate the cost of the contraceptive coverage accurately, particularly in the initial years, given that the prohibition on cost sharing could affect utilization. In addition, commenters noted that costs would likely vary considerably based on differences in utilization patterns and administrative processes.

In response to these comments, HHS is making certain modifications to the process described previously. Rather than using a monthly process, the final regulation at § 156.50(d)(2) requires a participating issuer seeking an FFE user fee adjustment to submit to HHS, in the year following the calendar year in which the contraceptive services for which payments were made under the accommodation described previously were provided, for each self-insured plan, the total dollar amount of the payments for contraceptive services that were provided during the applicable calendar year. The issuer will then receive an adjustment to its obligation to pay the FFE user fee equal to the cost of the contraceptive services that were provided during the previous year, plus an allowance, as specified by HHS, for administrative costs and margin. For example, HHS expects that issuers seeking an FFE user fee adjustment for payments for contraceptive services that were provided in calendar year 2014 will be required to submit to HHS by July 15, 2015, the total dollar amount of the payments. This timing will allow adequate time for claims run-out and data collection. The FFE user fee adjustment will be applied starting in October 2015. Although this approach delays the application of the FFE user fee adjustment, it significantly reduces the administrative burden on issuers, third party administrators, and HHS. HHS believes that tying the FFE user fee adjustment to the actual costs of payments for contraceptive services, plus an allowance for administrative costs and margin, will provide reasonable assurance that the adjustment is adequate to cover the full costs of the payments for contraceptive services, furthering the goal of providing contraceptive coverage without cost sharing, as required by PHS Act section 2713 and the companion provisions in ERISA and the Code.

As discussed later in this section, HHS is also directing third party administrators to submit to HHS a notification that the third party administrator intends for a participating issuer to seek an FFE user fee adjustment. This notification must be provided by the later of January 1, 2014,

or the 60th calendar day following the date on which the third party administrator receives a copy of a self-certification from an eligible organization. The notification must be provided whether it is intended that the participating issuer will provide payments for contraceptive services on behalf of the third party administrator, or whether it is intended that the participating issuer will seek an adjustment to the FFE user fee with respect to such payments made or arranged for by the third party administrator. HHS will provide guidance on the manner of submission of the notification, as well as guidance on the application for the FFE user fee adjustment, through the process provided for under the Paperwork Reduction Act of 1995.

HHS is also modifying the standards proposed at § 156.50(d) to align with the final regulations regarding the accommodation for self-insured group health plans of eligible organizations. As discussed previously, under these final regulations, the third party administrator may make the payments for contraceptive services itself, or it may arrange for an issuer (including an issuer that does not offer coverage through an FFE) or another entity to make the payments on its behalf. Under either scenario, a third party administrator that seeks to offset the costs of such payments through an FFE user fee adjustment must enter into an arrangement with a participating issuer offering coverage through an FFE. The participating issuer and the third party administrator must each submit information to HHS, as described in § 156.50(d)(2) of the final regulation, to verify that the payments for contraceptive services were provided in accordance with these final regulations.

Specifically, in § 156.50(d)(2)(i), HHS finalizes submission standards for a participating issuer to receive the FFE user fee adjustment. The participating issuer must submit to HHS, in the manner and timeframe specified by HHS, in the year following the calendar year in which the contraceptive services were provided: (A) Identifying information for the participating issuer and each third party administrator that received a copy of the self-certification with respect to which the participating issuer seeks an adjustment in the FFE user fee (whether or not the participating issuer was the entity that made the payments for contraceptive services); (B) identifying information for each self-insured group health plan with respect to which a copy of the self-certification was received by a third party administrator and with respect to

which the participating issuer seeks an adjustment in the FFE user fee; and (C) for each such self-insured group health plan, the total dollar amount of the payments for contraceptive services that were provided during the applicable calendar year under the accommodation described previously. If such payments were made by the participating issuer directly, the total dollar amount should reflect the amount of the payments made by the participating issuer; if the third party administrator made or arranged for such payments, the total dollar amount should reflect the amount reported to the participating issuer by the third party administrator. Similarly, in § 156.50(d)(2)(ii) and (iii), HHS finalizes submission standards for the third party administrator with respect to which the participating issuer seeks an adjustment in the FFE user fee. In paragraph (d)(2)(ii), HHS finalizes a standard under which the third party administrator must notify HHS, by the later of January 1, 2014, or the 60th calendar day following the date on which it receives the applicable copy of the self-certification, that it intends to arrange for a participating issuer to seek an FFE user fee adjustment. HHS will provide guidance on the manner of this submission through the process provided for under the Paperwork Reduction Act of 1995. This notification is necessary to allow HHS to coordinate the development of the systems for administering the FFE user fee adjustment. In paragraphs (d)(2)(iii)(A) through (E), HHS specifies several other standards under which the third party administrator must submit to HHS, in the year following the calendar year in which the contraceptive services for which payments were made under the accommodation described previously were provided, the following information: (A) Identifying information for the third party administrator and the participating issuer; (B) identifying information for each self-insured group health plan with respect to which the participating issuer seeks an adjustment in the FFE user fee; (C) the total number of participants and beneficiaries in each self-insured group health plan during the applicable calendar year;⁴⁶ (D) for each self-insured group health plan with respect to which the third party administrator made payments for contraceptive services, the total dollar amount of such payments that were provided during the applicable calendar year under the accommodation described previously (if such payments

were made by the participating issuer directly, the total dollar amount should reflect the amount reported to the third party administrator by the participating issuer; if the third party administrator made or arranged for such payments, the total dollar amount should reflect the amount of the payments made by or on behalf of the third party administrator); and (E) an attestation that the payments for contraceptive services were made in compliance with 26 CFR 54.9815-2713A(b)(2) or 29 CFR 2590.715-2713A(b)(2). If the third party administrator does not meet these standards, the participating issuer may not receive an FFE user fee adjustment to offset the costs of the payments for contraceptive services incurred by or on behalf of the third party administrator. HHS believes that it is necessary to collect this information directly from the third party administrator that has the duty to ensure that the payments for contraceptive services are made to ensure the accuracy of the data provided, without requiring the participating issuer to attest to information to which it may not have access or over which it has little control.

In § 156.50(d)(3), HHS establishes the process by which a participating issuer will be provided a reduction in its obligation to pay the FFE user fee. As long as an authorizing exception under OMB Circular No. A-25R is in effect, the reduction will be calculated as the sum of the total dollar amount of the payments for contraceptive services submitted by the applicable third party administrators, as described in paragraph (d)(2)(iii)(D), and an allowance, specified by HHS, for administrative costs and margin. In the proposed regulations, HHS requested comments on the appropriate method for determining the administrative costs associated with providing the contraceptive coverage, as well as a margin to ensure that issuers receive appropriate compensation for providing the contraceptive coverage. Commenters agreed with the proposal to reimburse for administrative costs and to provide a margin. Commenters noted that administrative costs would be incurred because of the complexities inherent in arrangements between entities seeking the FFE user fee adjustment and entities providing the contraceptive coverage, particularly when the entities operate in different states. In addition, commenters stated that administrative costs incurred by the third party administrators could vary because of variations in billing processes.

As finalized in this regulation, for the initial years of this policy, HHS will specify an allowance for administrative

costs and margin, which will be incorporated into the FFE user fee adjustment, rather than request the third party administrator or the participating issuer to submit to HHS an estimate of the third party administrator and the participating issuer's administrative costs. This approach is consistent with the general approach in these final regulations to simplify administration of the accommodations for eligible organizations, while still ensuring that no eligible organization is required to contract, arrange, pay, or refer for contraceptive coverage. HHS notes that it intends to review the methodology for determining reimbursement for administrative costs and margin in future years to ensure that HHS is accurately capturing these costs. HHS will establish the allowance as a percentage of the cost of the payments for contraceptive services because HHS believes that the majority of administrative costs will be related to processing of payments to providers for contraceptive services, and because HHS believes that it is reasonable to measure margin on this business as a percentage of the cost of the contraceptive services. HHS will establish the allowance at no less than ten percent of such cost, and will specify the allowance for a particular calendar year in the annual HHS notice of benefit and payment parameters. The specific allowance for the 2014 calendar year will be proposed for public comment in the HHS Notice of Payment and Benefit Parameters for 2015 (which is scheduled to be published in the fall of 2013). This approach will allow HHS to provide for a reasonable allowance for administrative expenses for the third party administrator, the participating issuer, and any other entity providing the payments for contraceptive services on behalf of the third party administrator, as well as a margin for each entity. HHS welcomes feedback from third party administrators, participating issuers, and other relevant stakeholders on the allowance for administrative costs and margin, including the appropriate percentage and alternative methods for future determination of the allowance for administrative costs and margin.

Section 156.50(d)(4) is similar to the corresponding proposed provision, and specifies that, as long as an exception under OMB Circular No. A-25R is in effect, if the amount of the reduction under paragraph (d)(3) is greater than the amount of the obligation to pay the FFE user fee in a particular month, the participating issuer will be provided a credit in succeeding months in the

⁴⁶ No personally identifiable information will be collected from participating issuers or third party administrators pursuant to § 156.50(d)(2).

amount of the excess. HHS notes that the likelihood of this occurring will depend on the relative magnitudes of the cost of payments for contraceptive services and the FFE user fee, the number of participants and beneficiaries in self-insured plans with respect to which the participating issuer seeks an adjustment in the FFE user fee, and the number of individuals enrolled in coverage offered by the issuer through the FFE. HHS also notes that it intends to provide a monthly report, for the initial month in which the FFE user fee adjustment for a particular calendar year is applied, and for succeeding months until the credit is fully applied, to issuers that receive an FFE user fee adjustment. HHS contemplates that this monthly report will include information on the issuer's user fee obligation for the month, its total adjustment for the applicable calendar year, the user fee adjustment applied to date, and the value of the adjustment to be credited to future months (so long as the exception under OMB Circular No. A-25R is in effect). Additionally, HHS intends to provide a monthly report to each applicable third party administrator detailing any FFE user fee adjustment that will be provided to a participating issuer with respect to the costs for contraceptive services incurred by or on behalf of the third party administrator, as well as the portion of the user fee adjustment applied to date.

Section 156.50(d)(5) specifies that, within 60 calendar days of receipt of any adjustment in the FFE user fee, a participating issuer must pay each third party administrator with respect to which it received any portion of such adjustment an amount no less than the portion of the adjustment attributable to the total dollar amount of the payments for contraceptive services submitted by the third party administrator, as described in paragraph (d)(2)(iii)(D). HHS expects that the participating issuer will also agree to pay each third party administrator a portion of such allowance (and that the apportionment will be negotiated between the entities); HHS does not specify such payment in this final regulation, as HHS expects the entities to work out an arrangement that best fits their situation. Finally, HHS notes that this provision does not apply if the participating issuer made the payments for contraceptive services on behalf of the third party administrator, as described in paragraph (d)(1)(i), or is in the same issuer group (as defined in 45 CFR 156.20) as the third party administrator.

In § 156.50(d)(6) and (7), HHS establishes standards relating to documentation and program integrity,

similar to those proposed in § 156.50(d)(5), but modified slightly to align with the other changes in this final regulation. In paragraph (d)(6), HHS specifies that a participating issuer receiving an adjustment in the FFE user fee under this section for a particular calendar year must maintain for 10 years following that year, and make available upon request to HHS, the HHS Office of the Inspector General, the Comptroller General, and their designees, documentation demonstrating that it timely paid each third party administrator, with respect to which it received such adjustment, any amount required under paragraph (d)(5). In paragraph (d)(7), HHS specifies documentation standards for third party administrators with respect to which an FFE user fee adjustment is received under this section for a particular calendar year. Third party administrators must maintain for 10 years following the applicable calendar year, and make available upon request to HHS, the HHS Office of the Inspector General, the Comptroller General, and their designees, all of the following: (i) A copy of the self-certification provided by the eligible organization for each self-insured plan with respect to which an adjustment is received; (ii) documentation demonstrating that the payments for contraceptive services were made in compliance with 26 CFR 54.9815-2713A(b)(2) or 29 CFR 2590.715-2713A(b)(2); and (iii) documentation supporting the total dollar amount of the payments for contraceptive services submitted by the third party administrator, as described in paragraph (d)(2)(iii)(D). Although a commenter argued that the documentation retention standards should be shortened from 10 years to 6 years, to align with ERISA standards, we believe that the finalized standard is appropriate as it aligns with timeframes under the False Claims Act, 31 U.S.C. 3729-3733, and standards used for other Exchange programs. HHS notes that a participating issuer or a third party administrator may satisfy these standards by archiving these records and ensuring that they are accessible if needed in the event of an investigation, audit, or other review.

To summarize, costs of payments made for contraceptive services for participants and beneficiaries in self-insured group health plans of eligible organizations under the accommodation described previously will be reimbursed through an adjustment in FFE user fees as follows:

- The adjustment will be made to the FFE user fees of a participating issuer, if that participating issuer made the

payments for the contraceptive services under the accommodation on behalf of the third party administrator, or if it seeks the adjustment with respect to such payments made or arranged for by the third party administrator.

- A third party administrator must notify HHS that it intends for a participating issuer to seek the adjustment by the later of January 1, 2014, or the 60th calendar day following the date on which it received the copy of the applicable self-certification.

- For the participating issuer to receive the adjustment, the third party administrator and the participating issuer must notify HHS of the total amount of the payments made for the contraceptive services under the accommodation, and provide certain other information and documentation, including an attestation by the third party administrator that the payments for the contraceptive services were provided in compliance with 26 CFR 54.9815-2713A(b)(2) or 29 CFR 2590.715-2713A(b)(2), by July 15 of the year following the calendar year in which the contraceptive services were provided.

- If the necessary conditions are met, and if an exception under OMB Circular No. A-25R is in effect, the participating issuer will receive an adjustment to its FFE user fee obligation equal to the total amount of the payments for the contraceptive services provided under the accommodation, plus an allowance for administrative costs and margin. If the adjustment exceeds the FFE user fees owed in the month of the initial adjustment, any excess adjustment will be carried over to later months, for so long as the exception under OMB Circular No. A-25R is in effect.

- The allowance, which will be at least ten percent of the costs of the payments for the contraceptive services under the accommodation, will be specified by HHS in the annual HHS notice of benefit and payment parameters.

- Within 60 days of receipt of any adjustment, the participating issuer must pay the third party administrator the portion of the adjustment attributable to payments for contraceptive services made by the third party administrator. No payment is required with respect to the allowance for administrative costs and margin, although it is expected that the participating issuer will agree to pay each third party administrator a portion of such allowance. In addition, no payment is required if the participating issuer made the payments for the contraceptive services under the accommodation on behalf of the third

party administrator, or if the participating issuer and third party administrator are in the same issuer group.

Lastly, in response to comments received, HHS is finalizing a provision clarifying that participating issuers may add any amounts paid out to a third party administrator or incurred by or for the participating issuer in contraceptive claims costs under the accommodation for self-insured group health plans of eligible organizations provided in these final regulations, plus the allowance for administrative costs and margin provided under 45 CFR 156.50(d)(3)(ii), to their net FFE user fee paid to HHS, in calculations relating to the index rate for the single risk pool under 45 CFR 156.80(d), the medical loss ratio under 45 CFR part 158, and the risk corridors program under 45 CFR 153 subpart F. Several commenters noted that improperly incorporating the FFE user fee adjustment provided for under the final regulation into these calculations could lead to unintended consequences. For example, if a participating issuer were required to incorporate the FFE user fee adjustment into the calculation of the medical loss ratio, but not allowed to incorporate the cost of the accommodation for self-insured group health plans of eligible organizations, the adjustment would reduce the amount reported as licensing and regulatory fees (as described in 45 CFR 158.161(a)). This would result in a lower medical loss ratio. HHS agrees that such a result would not accurately reflect the ratio of claims to premiums, as estimated by the medical loss ratio, for the participating issuer's insurance business, because the FFE user fee adjustment occurs due to activity not directly related to the participating issuer's insurance business. Indeed, under § 156.50(d)(5), the participating issuer is required in many circumstances to pay out the greater share of the FFE user fee adjustments to third party administrators responsible for making (or arranging for another entity to make) the payments for contraceptive services. Therefore, HHS clarifies that, for purposes of the medical loss ratio and the risk corridors program, participating issuers should report the sum of: (1) The net FFE user fee paid to HHS; (2) any amounts paid out to a third party administrator or incurred by or for the participating issuer in contraceptive claims costs under the accommodation for self-insured group health plans of eligible organizations provided in these final regulations; and (3) the allowance for administrative costs and margin

provided under 45 CFR 156.50(d)(3)(ii), as licensing and regulatory fees referenced in 45 CFR 158.161(a), or taxes and regulatory fees in the case of the risk corridors program. For similar reasons, HHS is modifying the provision at 45 CFR 156.80(d) to clarify that, for the purpose of establishing a single risk pool index rate for a state market, any market-wide adjustments to the index rate for expected Exchange user fees should include: (1) The expected net FFE user fee to be paid to HHS; (2) any amounts paid out to a third party administrator or incurred by or for the participating issuer in contraceptive claims costs under the accommodation for self-insured group health plans of eligible organizations expected to be credited against user fees payable for that state market; and (3) the allowance for administrative costs and margin provided under 45 CFR 156.50(d)(3)(ii) expected to be credited against user fees payable for that state market.

HHS clarifies that, if an issuer provides payments for contraceptive services on behalf of a third party administrator, such payments are not directly linked to any of the health insurance coverage provided by the issuer, and the issuer should not incorporate the cost of such payments into their calculations for the numerator with respect to the medical loss ratio or the risk corridors program.

D. Treatment of Multiple Employer Group Health Plans

In the case of several employers offering coverage through a single group health plan, the Departments proposed that each employer be required to independently meet the definition of religious employer or eligible organization in order to avail itself of the exemption or an accommodation with respect to its employees and their covered dependents. Several commenters supported the proposed approach of applying the exemption and the accommodation on an employer-by-employer basis. Other commenters favored a plan-based approach, allowing any employer offering coverage through the same group health plan as a religious employer or eligible organization to qualify for the exemption or the accommodation, citing administrative challenges to an employer-by-employer approach. A few commenters recommended criteria for determining whether an employer is affiliated with a religious employer or eligible organization with which it offers coverage through a single group health plan, such as the control standards in Code section 52(a) and (b),

and therefore qualified for the exemption or an accommodation.⁴⁷

The final regulations continue to provide that the availability of the exemption or an accommodation be determined on an employer-by-employer basis, which the Departments continue to believe best balances the interests of religious employers and eligible organizations and those of employees and their dependents. The Departments are clarifying that, for purposes of these final regulations, any nonprofit organization with religious objections to contraceptive coverage that is part of the same controlled group of corporations or part of the same group of trades or businesses under common control (each within the meaning of section 52(a) or (b) of the Code) with a religious employer and/or an eligible organization, and that offers coverage through the same group health plan as such religious employer and/or eligible organization, is considered to hold itself out as a religious organization and therefore qualifies for an accommodation under these final regulations. Each such organization must independently satisfy the self-certification standard.

E. Religious Freedom Restoration Act and Other Federal Law

Some commenters expressed concerns about the proposed accommodations for eligible organizations under the Religious Freedom Restoration Act (RFRA) (Pub. L. 103-141) 107 Stat. 1488 (1993) (codified at 42 U.S.C. 2000bb-1).⁴⁸ All such concerns were considered. But the accommodations for group health plans established or maintained by eligible organizations (and group health insurance coverage provided in connection with such plans), or student health insurance coverage arranged by eligible organizations that are institutions of higher education, are not required under RFRA. In addition, the accommodations for eligible organizations under these final regulations do not violate RFRA because

⁴⁷ Code section 52(a) generally provides that all employees of all corporations that are members of the same controlled group of corporations, including corporations that are at least 50 percent controlled by a common parent corporation, are treated as employed by a single employer. Code section 52(b) generally provides that all employees of trades or businesses (whether or not incorporated) that are under common control are treated as employed by a single employer.

⁴⁸ RFRA provides that the federal government generally may not "substantially burden a person's exercise of religion, even if the burden results from a rule of general applicability," unless the burden: "(1) Is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest," 42 U.S.C. 2000bb-1.

they do not substantially burden religious exercise, and they serve compelling government interests and moreover are the least restrictive means to achieve those interests.

First, some commenters asserted that the proposed accommodations would substantially burden their exercise of religion by requiring their involvement in providing coverage of medical services to which they object on religious grounds. These final regulations do not require eligible organizations that provide self-certifications to their issuers or third party administrators to provide health coverage that includes benefits for contraceptive services, or to contract, arrange, pay, or refer for such coverage or services. Issuers and third party administrators cannot pass along the costs because these final regulations specifically prohibit an issuer or third party administrator from charging any premium or otherwise passing on any cost relating to payments for contraceptive services to an eligible organization. Thus, there is no burden on any religious exercise of the eligible organization. And even if the accommodations were found to impose some minimal burden on eligible organizations, any such burden would not be substantial for the purposes of RFRA because a third party pays for the contraceptive services and there are multiple degrees of separation between the eligible organization and any individual's choice to use contraceptive services.

One commenter contended that the mere act of self-certification would facilitate access to contraception, resulting in violation of its religious beliefs. But the self-certification under these final regulations simply confirms that an eligible organization is a nonprofit religious organization with religious objections to contraceptive coverage and so informs the issuer or third party administrator. Even prior to the proposed regulations, because contraceptive benefits are typically in standard product designs, many eligible organizations directed their issuers and third party administrators not to make payments for claims for medical services to which they object on religious grounds. In any event, in order for a burden on religious exercise to be "substantial" under RFRA, its effects on the objecting person cannot be as indirect and attenuated as they are here. Under these final regulations, third parties, not eligible organizations, provide the payments for contraceptive services, at no cost to eligible organizations. And whether such services will be utilized is the result of

independent choices by employees or students and their dependents, who have distinct interests and may have their own religious views that differ from those of the eligible organization.

Second, some commenters claimed that the proposed accommodations would force them to fund or subsidize contraceptive coverage because issuers or third party administrators would pass on the costs of such coverage to eligible organizations. Again, however, these final regulations specifically prohibit an issuer or third party administrator from charging any premium, or otherwise passing on any cost, to an eligible organization with respect to the payments for contraceptive services.

Third, some commenters asserted that the contraceptive coverage requirement fails to serve any compelling government interest. As noted previously, however, the contraceptive coverage requirement serves two compelling governmental interests. The contraceptive coverage requirement furthers the government's compelling interest in safeguarding public health by expanding access to and utilization of recommended preventive services for women. HHS tasked IOM with conducting an independent, science-based review of the available literature to determine what preventive services are necessary for women's health and well-being. IOM included in its recommendations for comprehensive guidelines for women's preventive services all FDA-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity. IOM determined that lack of access to contraceptive services has proven in many cases to have serious negative health consequences for women and newborn children.

The government also has a compelling interest in assuring that women have equal access to health care services. Women would be denied the full benefits of preventive care if their unique health care needs were not considered and addressed. For example, prior to the implementation of the preventive services coverage provision, women of childbearing age spent 68 percent more on out-of-pocket health care costs than men, and these costs resulted in women often forgoing preventive care. The IOM found that this disproportionate burden on women imposed financial barriers that prevented women from achieving health outcomes on an equal basis with men. The contraceptive coverage requirement helps remedy this problem by helping to equalize the provision of preventive health care services to women and, as a

result, helping women contribute to society to the same degree as men.

Fourth, some commenters suggested that certain provisions of the Affordable Care Act that, in their view, leave some women without contraceptive coverage with no cost sharing demonstrate that the government interests in providing such coverage cannot be truly compelling. But these commenters misunderstand the effect of these provisions.⁴⁹

Nor do the exemption for religious employers and the accommodations for eligible organizations undermine the government's compelling interests. With respect to the religious employer exemption, houses of worship and their integrated auxiliaries that object to contraceptive coverage on religious grounds are more likely than other employers to employ people who are of the same faith and/or adhere to the same objection, and who would therefore be less likely than other people to use contraceptive services even if such services were covered under their plan. Under the eligible organization accommodations, individuals in plans of eligible organizations, who are less likely than individuals in plans of religious employers to share their employer's (or institution of higher education's) faith and objection to contraceptive coverage on religious grounds, will still benefit from payments for contraceptive services, even though such payments will not be provided, funded, or subsidized by their employer (or institution of higher education).

⁴⁹ For example, the Affordable Care Act's grandfathering provision is only transitional in effect, and it is expected that a majority of plans will lose their grandfathered status by the end of 2013. (75 FR 34552; June 17, 2010); *see also* Kaiser Family Found. & Health Res. & Ed. Trust, *Employer Health Benefits 2012 Annual Survey at 7-8, 190*, available at <http://ehbs.kff.org/pdf/2012/8345.pdf>. Moreover, small employers that elect to offer non-grandfathered health coverage to their employees are not exempt from the requirement under the preventive health services coverage regulations to provide coverage for recommended preventive health services, including contraceptive services, without cost sharing (subject to the religious employer exemption and eligible organization accommodations in these final regulations). While the Affordable Care Act excludes small employers from the possibility of tax liability under the employer shared responsibility provision at Code section 4980H, it encourages such employers to offer health coverage to their employees by establishing new group health insurance options through the SHOPs, as well as new tax incentives to exercise such options. With respect to employees of small employers that do not offer health coverage to their employees, the Affordable Care Act establishes new individual health insurance options through the Exchanges, as well as new tax credits to assist the purchase of such insurance; such insurance will cover recommended preventive services, including contraceptive services, without cost sharing.

Fifth, some commenters asserted that the contraceptive coverage requirement is not the least restrictive means of advancing these compelling interests, and proposed various alternatives to these regulations. All of these proposals were considered, and it was determined that they were not feasible and/or would not advance the government's compelling interests as effectively as the mechanisms established in these final regulations and the preventive services coverage regulations more generally. For example, some commenters suggested that the government could provide contraceptive services to all women free of charge (through Medicaid or another program), establish a government-funded health benefits program for contraceptive services, or force drug and device manufacturers to provide contraceptive drugs and devices to women for free. The Departments lack the statutory authority and funding to implement these proposals. Moreover, the Affordable Care Act contemplates providing coverage of recommended preventive services through the existing employer-based system of health coverage so that women face minimal logistical and administrative obstacles. Imposing additional barriers to women receiving the intended coverage (and its attendant benefits), by requiring them to take steps to learn about, and to sign up for, a new health benefit, would make that coverage accessible to fewer women. The same concern undermines the effectiveness of other commenters' suggestion that the government require the multi-state plans on the Exchanges to offer a stand-alone, contraceptive-only benefit to all women without charge.

For another example, some commenters suggested that the government should establish tax incentives for women to use contraceptive services. Again, the Departments lack the statutory authority to implement such proposal. Reliance only on tax incentives would also depart from the existing employer-based system of health coverage, would require women to pay out of pocket for their care in the first instance, and would not benefit women who do not have sufficient income to be required to file a tax return. Such barriers would make a tax incentive structure less effective than the employer-based system of health coverage in advancing the government's compelling interests.

Finally, some commenters expressed concern that the final regulations violate the Religion Clauses of the First Amendment or certain federal restrictions relating to abortion. The regulations do not violate the Free

Exercise Clause because they are neutral and generally applicable. The regulations do not target religiously motivated conduct, but rather, are intended to improve women's access to preventive health care and lessen the disparity between men's and women's health care costs. And the regulations are generally applicable because they do not pursue their purpose only against conduct motivated by religious belief. The exemption and accommodations set forth in the regulations serve to accommodate religion, not to disfavor it.

The final regulations also do not violate the Establishment Clause. The exemption and accommodations set forth in the regulations are not restricted to organizations of a particular denomination or denominations. Instead, they are available on an equal basis to religious organizations affiliated with any and all religions.

Finally, the regulations do not violate federal restrictions relating to abortion because FDA-approved contraceptive methods, including Plan B, Ella, and IUDs, are not abortifacients within the meaning of federal law. (62 FR 8611; February 25, 1997) ("Emergency contraceptive pills are not effective if the woman is pregnant[.]"); 45 CFR 46.202(f) ("Pregnancy encompasses the period of time from implantation until delivery."). Further, these regulations do not require nonprofit religious organizations that object to such contraceptive methods to contract, arrange, pay, or refer for such services.

F. No Effect on Other Law

The religious employer exemption and eligible organization accommodations under these final regulations are intended to have meaning solely with respect to the contraceptive coverage requirement under section 2713 of the PHS Act and the companion provisions of ERISA and the Code. Whether an employer or organization (including an institution of higher education) is designated as religious for this purpose is not intended as a judgment about the mission, sincerity, or commitment of the employer or organization (including an institution of higher education), or intended to differentiate among the religious merits, mission, sincerity, commitment, or public or private standing of religious entities. The use of such designation is limited solely to defining the class of employers or organizations (including institutions of higher education) that qualify for the religious employer exemption and eligible organization accommodations under these final regulations. The definition of religious employer or

eligible organization in these final regulations should not be construed to apply with respect to, or relied upon for the interpretation of, any other provision of the PHS Act, ERISA, the Code, or any other provision of federal law, nor is it intended to set a precedent for any other purpose. For example, nothing in these final regulations should be construed as affecting the interpretation of federal or state civil rights statutes, such as Title VII of the Civil Rights Act of 1964 or Title IX of the Education Amendments of 1972.

Furthermore, nothing in these final regulations precludes employers or others from expressing any opposition to the use of contraceptives; requires anyone to use contraceptives; or requires health care providers to prescribe or provide contraceptives if doing so is against their religious beliefs.

The Departments received several comments requesting clarification about whether the religious employer exemption and eligible organization accommodations in these final regulations supersede state laws that require health insurance issuers to provide contraceptive coverage. The preemption provisions of section 731 of ERISA and section 2724 of the PHS Act (implemented at 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply such that the requirements of part 7 of ERISA and title XXVII of the PHS Act are not to be "construed to supersede any provision of state law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group or individual health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement" of federal law. With respect to issuers subject to state law, insurance laws that provide greater access to contraceptive coverage than federal standards are unlikely to "prevent the application of" the preventive services coverage provision, and therefore are unlikely to be preempted by these final regulations. On the other hand, in states with broader religious exemptions and accommodations with respect to health insurance issuers than those in the final regulations, the exemptions and accommodations will be narrowed to align with those in the final regulations. This is consistent with the application of other federal health insurance standards.

G. Applicability Dates and Transitional Enforcement Safe Harbor

These final regulations generally apply to group health plans and health insurance issuers for plan years beginning on or after January 1, 2014, except the amendments to the religious employer exemption apply to group health plans and health insurance issuers for plan years beginning on or after August 1, 2013.

The Departments are extending the current safe harbor from enforcement of the contraceptive coverage requirement by the Departments to encompass plan years beginning on or after August 1, 2013, and before January 1, 2014. This transitional enforcement safe harbor is intended to maintain the status quo with respect to organizations that qualify for the current safe harbor during the period that exists between the expiration of the current safe harbor⁵⁰ and the applicability date of the accommodations under these final regulations. This period is designed to provide issuers and third party administrators with sufficient time to prepare to implement the accommodations under these final regulations. Organizations that qualify under the current safe harbor are not required to execute another self-certification if one has already been executed, but are required to provide another notice to plan participants and beneficiaries in connection with plan years beginning on or after August 1, 2013, and before January 1, 2014. The guidance extending the current safe harbor can be found at: www.cms.gov/ccio and www.dol.gov/healthreform.

IV. Economic Impact and Paperwork Burden

A. Executive Orders 12866 and 13563—Department of Health and Human Services and Department of Labor

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of

quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a regulation: (1) Having an annual effect on the economy of \$100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis must be prepared for major rules with economically significant effects (\$100 million or more in any one year), and an “economically significant” regulatory action is subject to review by the Office of Management and Budget (OMB). The Departments have concluded that these final regulations are not likely to have economic impacts of \$100 million or more in any one year, and therefore do not meet the definition of “economically significant” under Executive Order 12866.

1. Need for Regulatory Action

As stated earlier in this preamble, the Departments previously issued amended interim final regulations authorizing an exemption for group health plans established or maintained by religious employers (and group health insurance coverage provided in connection with such plans) from certain coverage requirements under section 2713 of the PHS Act (76 FR 46621, August 3, 2011). The amended interim final regulations were finalized on February 15, 2012 (77 FR 8725). In these final regulations, the Departments are amending the definition of religious employer in the HHS regulation at 45 CFR 147.131(a) (incorporated by reference in the regulations of the Departments of Labor and the Treasury) by eliminating the first three prongs of the definition of religious employer that was established in the 2012 final regulations and clarifying the fourth prong. Accordingly, an employer that is organized and operates as a nonprofit entity and is referred to in section

6033(a)(3)(A)(i) or (iii) of the Code is a religious employer, and its group health plan qualifies for the exemption from the requirement to cover contraceptive services. In addition, the final regulations establish accommodations that provide women with access to such services, without cost sharing, while simultaneously protecting certain nonprofit religious organizations with religious objections to contraceptive coverage from having to contract, arrange, pay, or refer for such coverage (as detailed herein).

2. Anticipated Effects

The Departments expect that these final regulations will not result in any additional significant burden on or costs to the affected entities.

B. Special Analyses—Department of the Treasury

For purposes of the Department of the Treasury, it has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866, as amended by Executive Order 13563. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to this final regulation. It is hereby certified that the collections of information contained in this final regulation do not have a significant impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required.

These final regulations require each organization seeking to be treated as an eligible organization under the final regulations to self-certify that it meets the definition of eligible organization in the final regulations. The self-certification must be executed by an authorized representative of the organization. The organization must maintain the self-certification in its records in a manner consistent with ERISA section 107 and make it available for examination upon request. The final regulations also direct each eligible organization to provide a copy of its self-certification to the group health insurance issuer or third party administrator (as applicable) to avail itself of an accommodation. The Departments are unable to estimate the number of organizations that will seek to be treated as eligible organizations. Of the eligible organizations, some will likely be small entities. It is estimated that each eligible organization will need only approximately 50 minutes of labor to prepare and provide the information

⁵⁰ See Guidance on the Temporary Enforcement Safe Harbor for Certain Employers, Group Health Plans, and Group Health Insurance Issuers with Respect to the Requirement to Cover Contraceptive Services Without Cost Sharing Under Section 2713 of the Public Health Service Act, Section 715(a)(1) of the Employee Retirement Income Security Act, and Section 9815(a)(1) of the Internal Revenue Code, issued on February 10, 2012, and reissued on August 15, 2012.

in the self-certification. This will not be a significant economic impact. For these reasons, this information collection requirement will not have a significant impact on a substantial number of small entities.

These final regulations also require health insurance issuers providing payments for contraceptive services, or third party administrators arranging or providing such payments (or their agents), to provide written notice to plan participants and beneficiaries regarding the availability of such payments. The notice will be provided contemporaneous with (to the extent possible) but separate from any application materials distributed in connection with enrollment (or re-enrollment) in health coverage established, maintained, or arranged by the eligible organization in any plan year to which the accommodation is to apply. The final regulations contain model language for issuers and third party administrators to use to satisfy the notice requirement. It is unknown how many issuers provide health insurance coverage in connection with insured plans of eligible organizations or how many third party administrators provide plan services to self-insured plans of eligible organizations. However, the cost of preparation and distribution of the notices will not be significant. It is estimated that each issuer or third party administrator will need approximately 1 hour of clerical labor (at \$31.64 per hour) and 15 minutes of management review (at \$55.22 per hour) to prepare the notices for a total cost of approximately \$44. It is estimated that each notice will require \$0.46 in postage and \$0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail will be \$0.51. For these reasons, these information collection requirements will not have a significant impact on a substantial number of small entities.

Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding this final regulation was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small businesses.

C. Paperwork Reduction Act— Department of Health and Human Services

These final regulations contain information collection requirements (ICRs) that are subject to review by the Office of Management and Budget (OMB). A description of these provisions is given in the following paragraphs with an estimate of the annual burden. Average labor costs

(including fringe benefits) used to estimate the costs are calculated using data available from the Bureau of Labor Statistics.

HHS sought comments in the proposed regulations, but did not receive any information that would allow for an estimate of the number of organizations that would seek to be treated as eligible organizations, or an estimate of the number of health insurance issuers that would provide separate payments for contraceptive services. HHS is, nevertheless, seeking OMB approval for the following ICRs consistent with the Paperwork Reduction Act of 1995. The burden estimates will be updated in the future when more information is available.

1. Self-Certification (§§ 147.131(b)(4) and 147.131(c)(1))

Each organization seeking to be treated as an eligible organization under the final regulations must self-certify that it meets the definition of an eligible organization. The self-certification must be executed by an authorized representative of the organization. The self-certification will not be submitted to any of the Departments. The form that will be used by organizations for their self-certification was made available during the comment period for the proposed regulations at <http://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>. HHS is finalizing this form with updated instructions and notes, and eliminating the proposed field for listing the contraceptive services for which the organization will not establish, maintain, administer, or fund coverage. The organization must maintain the self-certification in its records in a manner consistent with ERISA section 107 and make it available for examination upon request. The eligible organization must provide a copy of its self-certification to a health insurance issuer for insured group health plans or student health insurance coverage.

HHS is unable to estimate the number of organizations that will seek to be treated as eligible organizations under the final regulations. Therefore, the burden for only one eligible organization, as opposed to all eligible organizations in total, is estimated. It is assumed that, for each eligible organization, clerical staff will gather and enter the necessary information, send the self-certification electronically to the issuer, and retain a copy for record-keeping; a manager and legal counsel will review it; and a senior executive will execute it. HHS estimates

that an organization will need approximately 50 minutes (30 minutes of clerical labor at a cost of \$30.64 per hour, 10 minutes for a manager at a cost of \$55.22 per hour, 5 minutes for legal counsel at a cost of \$83.10 per hour, and 5 minutes for a senior executive at a cost of \$112.43 per hour) to execute the self-certification. The certification may be electronically transmitted to the issuer at minimal cost. Therefore, the total annual burden for preparing and providing the information in the self-certification is estimated to be approximately \$41 for each eligible organization.

2. Notice of Availability of Separate Payments for Contraceptive Services (§ 147.131(d))

The proposed regulations sought comment on a notice of availability of contraceptive coverage. The final regulations instead direct a health insurance issuer providing payments for contraceptive services for participants and beneficiaries in insured plans (or student enrollees and covered dependents in student health insurance coverage) of eligible organizations to provide a written notice to such plan participants and beneficiaries (or such student enrollees and covered dependents) informing them of the availability of such payments. The notice must be provided 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 on the first day of each applicable plan year, and must specify that contraceptive coverage will not be funded or administered by the eligible organization but that the issuer provides separate payments for contraceptive services. The notice must also provide contact information for the issuer for questions and complaints. To satisfy the notice requirement, issuers may use the model language set forth in the final regulations or substantially similar language.

It is unknown how many issuers provide health insurance coverage in connection with insured plans of eligible organizations. In the proposed regulations, HHS estimated that each issuer would need approximately 1 hour of clerical labor (at \$31.64 per hour) and 15 minutes of management review (at \$55.22 per hour) to prepare the notices for a total cost of approximately \$44. It was estimated that each notice would require \$0.46 in postage and \$0.05 in materials cost (paper and ink) and the total postage and materials cost for each notice sent via mail would be \$0.51.

One commenter stated that the cost of preparing and sending these notices may be greater than estimated, but did not provide an estimate. HHS believes that using the model language provided in the final regulations will help minimize costs and declines to revise the estimate.

3. Collections for FFE User Fee Adjustment (§ 156.50(d))

The final HHS regulation describes information collections with respect to the FFE user fee adjustment under § 156.50(d). The information collection instruments are under development, and HHS will seek public comments and OMB approval on the instruments at a later date, consistent with the Paperwork Reduction Act of 1995.

4. Collections for Self-Insured Group Health Plans Without Third Party Administrators

The final regulations provide that a self-insured group health plan established or maintained by an eligible organization that does not use the services of a third party administrator will be provided a safe harbor from enforcement of the contraceptive coverage requirement by the Departments contingent on, among other things: (1) the plan providing certain information to HHS; and (2) the plan providing participants and beneficiaries with notice that it does not provide benefits for contraceptive services. As noted earlier in these final regulations, the Departments believe that there are no self-insured group health plans in this circumstance. Therefore, because the number of respondents is likely to be fewer than 10, HHS is not seeking OMB approval for this collection.

D. Paperwork Reduction Act—Department of Labor and Department of the Treasury

As noted previously, as under the proposed regulations, each organization seeking to be treated as an eligible organization under the final regulations must self-certify that it meets the definition of an eligible organization. This requirement is set out at 26 CFR 54.9815–2713A(a)(4) and 29 CFR 2590.715–2713A(a)(4) of the final regulations of the Departments of Labor and the Treasury.

In addition, the final regulations include a notice of availability of separate payments for contraceptive services. This notice requirement is identical to that set forth in 45 CFR 147.131(d), but it applies to third party administrators in connection with disclosures to participants and

beneficiaries in self-insured group health plans of eligible organizations, instead of applying to health insurance issuers in connection with disclosures to participants and beneficiaries in insured group health plans of eligible organizations. Therefore, we are seeking OMB approval for this notice, relying on the same estimates noted previously.

V. Unfunded Mandates Reform Act

For purposes of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), as well as Executive Order 12875, these final regulations do not include any federal mandate that may result in expenditures by state, local, or tribal governments, nor do they include any federal mandates that may impose an annual burden of \$100 million, adjusted for inflation, or more on the private sector.⁵¹

VI. Federalism—Department of Health and Human Services and Department of Labor

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by federal agencies in the process of their formulation and implementation of policies that have “substantial direct effects” on states, the relationship between the federal government and states, or the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with state and local officials, and describe the extent of their consultation and the nature of the concerns of state and local officials in the preamble to the regulation.

In the Departments’ view, these final regulations have federalism implications, but the federal implications are substantially mitigated because, with respect to health insurance issuers, 15 states have enacted specific laws, regulations, or bulletins that meet or exceed the federal standards requiring coverage of specified preventive services without cost sharing. The remaining states, which provide oversight for these federal law requirements, do so using their general authority to enforce these federal standards. Therefore, the final regulations are not likely to require substantial additional oversight of states by HHS.

In general, section 514 of ERISA provides that state laws are superseded to the extent that they relate to any

covered employee benefit plan, and preserves state laws that regulate insurance, banking, or securities. ERISA also prohibits states from regulating a covered plan as an insurance or investment company or bank. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) added a new preemption provision to ERISA (as well as to the PHS Act) narrowly preempting state requirements on group health insurance coverage. States may continue to apply state law requirements but not to the extent that such requirements prevent the application of the federal requirement that group health insurance coverage provided in connection with group health plans provide coverage for specified preventive services without cost sharing. HIPAA’s Conference Report states that the conferees intended the narrowest preemption of state laws with regard to health insurance issuers (H.R. Conf. Rep. No. 104–736, 104th Cong. 2d Session 205, 1996). State insurance laws that are more stringent than the federal requirement are unlikely to “prevent the application of” the preventive services coverage provision, and therefore are unlikely to be preempted. Accordingly, states have significant latitude to impose requirements on health insurance issuers that are more restrictive than those in federal law.

Guidance conveying this interpretation was published in the **Federal Register** on April 8, 1997 (62 FR 16904) and December 30, 2004 (69 FR 78720), and these final regulations implement the preventive services coverage provision’s minimum standards and do not significantly reduce the discretion given to states under the statutory scheme.

The PHS Act provides that states may enforce the provisions of title XXVII of the PHS Act as they pertain to issuers, but that the Secretary of HHS will enforce any provisions that a state does not have authority to enforce or that a state has failed to substantially enforce. When exercising its responsibility to enforce provisions of the PHS Act, HHS works cooperatively with the state to address the state’s concerns and avoid conflicts with the state’s exercise of its authority.⁵² HHS has developed procedures to implement its

⁵² This authority applies to insurance issued with respect to group health plans generally, including plans covering employees of church organizations. Thus, this discussion of federalism applies to all group health insurance coverage that is subject to the PHS Act, including those church plans that provide coverage through a health insurance issuer (but not to church plans that do not provide coverage through a health insurance issuer).

⁵¹ In 2013, that threshold level is approximately \$141 million.

enforcement responsibilities, and to afford states the maximum opportunity to enforce the PHS Act's requirements in the first instance. In compliance with Executive Order 13132's requirement that agencies examine closely any policies that may have federalism implications or limit the policymaking discretion of states, the Departments have engaged in numerous efforts to consult and work cooperatively with affected state and local officials.

In conclusion, throughout the process of developing these final regulations, to the extent feasible within the specific preemption provisions of ERISA and the PHS Act, the Departments have attempted to balance states' interests in regulating health coverage and health insurance issuers, and the rights of those individuals whom Congress intended to protect in the PHS Act, ERISA, and the Code.

VII. Statutory Authority

The Department of the Treasury regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor regulations are adopted pursuant to the authority contained in 29 U.S.C. 1002(16), 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Secretary of Labor's Order 3–2010, 75 FR 55354 (September 10, 2010).

The Department of Health and Human Services regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended; and Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, and 1412, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 2510

Employee benefit plans, Pensions.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Part 147

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory committees, Brokers, Conflict of interest, Consumer protection, Grant programs—health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, American Indian/Alaska Natives, Individuals with disabilities, Loan programs—health, Organization and functions (Government agencies), Medicaid, Public assistance programs, Reporting and recordkeeping requirements, State and local governments, Sunshine Act, Technical assistance, Women, and Youth.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Accordingly, 26 CFR part 54 is amended as follows:

PART 54—PENSION EXCISE TAXES

■ **Paragraph 1.** The authority citation for part 54 continues to read, in part, as follows:

Authority: 26 U.S.C. 7805. * * *

■ **Par. 2.** Section 54.9815–2713 is amended by revising paragraphs (a)(1) introductory text and (a)(1)(iv) to read as follows:

§ 54.9815–2713 Coverage of preventive health services.

(a) * * *

(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:

* * * * *

(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, in accordance with 45 CFR 147.131(a).

* * * * *

■ **Par. 3.** Section 54.9815–2713A is added to read as follows:

§ 54.9815–2713A 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) *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 § 54.9815–2713(a)(1)(iv) to provide contraceptive coverage if all of the requirements of this paragraph (b)(1) of this section 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 § 54.9815–2713(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 29 CFR 2510.3-16 and 26 CFR 54.9815-2713A.

(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 § 54.9815-2713(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 § 54.9815-2713(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 § 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 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 § 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.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

For the reasons stated in the preamble, the Department of Labor amends 29 CFR parts 2510 and 2590 as follows:

PART 2510—DEFINITION OF TERMS USED IN SUBCHAPTERS C, D, E, F, G AND L OF THIS CHAPTER

■ 1. The authority citation for part 2510 is revised to read as follows:

Authority: 29 U.S.C. 1002(2), 1002(16), 1002(21), 1002(37), 1002(38), 1002(40), 1031, and 1135; Secretary of Labor's Order 1–2003, 68 FR 5374; Sec. 2510.3–101 also issued under sec. 102 of Reorganization Plan No. 4 of 1978, 43 FR 47713, 3 CFR, 1978 Comp., p. 332 and E.O. 12108, 44 FR 1065, 3 CFR, 1978 Comp., p. 275, and 29 U.S.C. 1135 note. Sec. 2510.3–102 also issued under sec. 102 of Reorganization Plan No. 4 of 1978, 43 FR 47713, 3 CFR, 1978 Comp., p. 332 and E.O. 12108, 44 FR 1065, 3 CFR, 1978 Comp., p. 275. Sec. 2510.3–38 is also issued under sec. 1, Pub. L. 105–72, 111 Stat. 1457.

■ 2. Section 2510.3–16 is added to read as follows:

§ 2510.3–16 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 sponsor, 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 for 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.

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 3. The authority citation for part 2590 is revised to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 12(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Secretary of Labor's Order 1–2011, 77 FR 1088 (January 9, 2012).

■ 4. Section 2590.715–2713 is amended by revising paragraphs (a)(1) introductory text and (a)(1)(iv) to read as follows:

§ 2590.715–2713 Coverage of preventive health services.

(a) * * *

(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:

* * * * *

(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, in accordance with 45 CFR 147.131(a).

* * * * *

■ 5. Section 2590.715–2713A is added to read as follows:

§ 2590.715–2713A 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 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 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 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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

For the reasons stated in the preamble, the Department of Health and Human Services amends 45 CFR Subtitle A parts 147 and 156 as follows:

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 1. The authority citation for part 147 continues to read as follows:

Authority: Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

■ 2. Section 147.130 is amended by revising paragraphs (a)(1) introductory text and (a)(1)(iv) to read as follows:

§ 147.130 Coverage of preventive health services.

(a) * * *

(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:

* * * * *

(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.

* * * * *

■ 3. Section 147.131 is added to read as follows:

§ 147.131 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 furnishes a copy of the self-certification described in paragraph (b)(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 (b)(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 § 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 contraceptive 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.

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 4. The authority citation for part 156 continues to read as follows:

Authority: Title I of the Affordable Care Act, sections 1301–1304, 1311–1312, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, and 1412, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

■ 5. Section 156.50 is amended by adding paragraph (d) to read as follows:

§ 156.50 Financial support.

* * * * *

(d) *Adjustment of Federally-facilitated Exchange user fee*—(1) A participating issuer offering a plan through a Federally-facilitated Exchange may qualify for an adjustment in the Federally-facilitated Exchange user fee specified in paragraph (c) of this section to the extent that the participating issuer—

(i) Made payments for contraceptive services on behalf of a third party administrator pursuant to 26 CFR 54.9815–2713A(b)(2)(ii) or 29 CFR 2590.715–2713A(b)(2)(ii); or

(ii) Seeks an adjustment in the Federally-facilitated Exchange user fee with respect to a third party administrator that, following receipt of a copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4), made or arranged for payments for contraceptive services pursuant to 26 CFR 54.9815–2713A(b)(2)(i) or (ii) or 29 CFR 2590.715–2713A(b)(2)(i) or (ii).

(2) For a participating issuer described in paragraph (d)(1) of this section to receive the Federally-

facilitated Exchange user fee adjustment—

(i) The participating issuer must submit to HHS, in the manner and timeframe specified by HHS, in the year following the calendar year in which the contraceptive services for which payments were made pursuant to 26 CFR 54.9815–2713A(b)(2) or 29 CFR 2590.715–2713A(b)(2) were provided—

(A) Identifying information for the participating issuer and each third party administrator that received a copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4) with respect to which the participating issuer seeks an adjustment in the Federally-facilitated Exchange user fee, whether or not the participating issuer was the entity that made the payments for contraceptive services;

(B) Identifying information for each self-insured group health plan with respect to which a copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4) was received by a third party administrator and with respect to which the participating issuer seeks an adjustment in the Federally-facilitated Exchange user fee; and

(C) For each such self-insured group health plan, the total dollar amount of the payments that were made pursuant to 26 CFR 54.9815–2713A(b)(2) or 29 CFR 2590.715–2713A(b)(2) for contraceptive services that were provided during the applicable calendar year. If such payments were made by the participating issuer directly as described in paragraph (d)(1)(i) of this section, the total dollar amount should reflect the amount of the payments made by the participating issuer; if the third party administrator made or arranged for such payments, as described in paragraph (d)(1)(ii) of this section, the total dollar amount should reflect the amount reported to the participating issuer by the third party administrator.

(ii) Each third party administrator that intends for a participating issuer to seek an adjustment in the Federally-facilitated Exchange user fee with respect to the third party administrator for payments for contraceptive services must submit to HHS a notification of such intent, in a manner specified by HHS, by the later of January 1, 2014, or the 60th calendar day following the date on which the third party administrator receives the applicable copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4).

(iii) Each third party administrator identified in paragraph (d)(2)(i)(A) of

this section must submit to HHS, in the manner and timeframe specified by HHS, in the year following the calendar year in which the contraceptive services for which payments were made pursuant to 26 CFR 54.9815–2713A(b)(2) or 29 CFR 2590.715–2713A(b)(2) were provided—

(A) Identifying information for the third party administrator and the participating issuer;

(B) Identifying information for each self-insured group health plan with respect to which a copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4) was received by the third party administrator and with respect to which the participating issuer seeks an adjustment in the Federally-facilitated Exchange user fee;

(C) The total number of participants and beneficiaries in each such self-insured group health plan during the applicable calendar year;

(D) For each such self-insured group health plan with respect to which the third party administrator made payments pursuant to 26 CFR 54.9815–2713A(b)(2) or 29 CFR 2590.715–2713A(b)(2) for contraceptive services, the total dollar amount of such payments that were provided during the applicable calendar year. If such payments were made by the participating issuer directly as described in paragraph (d)(1)(i) of this section, the total dollar amount should reflect the amount reported to the third party administrator by the participating issuer; if the third party administrator made or arranged for such payments, as described in paragraph (d)(1)(ii) of this section, the total dollar amount should reflect the amount of the payments made by or on behalf of the third party administrator; and

(E) An attestation that the payments for contraceptive services were made in compliance with 26 CFR 54.9815–2713A(b)(2) or 29 CFR 2590.715–2713A(b)(2).

(3) If the requirements set forth in paragraph (d)(2) of this section are met, and as long as an authorizing exception under OMB Circular No. A–25R is in effect, the participating issuer will be provided a reduction in its obligation to pay the Federally-facilitated Exchange user fee specified in paragraph (c) of this section equal in value to the sum of the following:

(i) The total dollar amount of the payments for contraceptive services submitted by the applicable third party administrators, as described in paragraph (d)(2)(iii)(D) of this section.

(ii) An allowance for administrative costs and margin. The allowance will be

no less than 10 percent of the total dollar amount of the payments for contraceptive services specified in paragraph (d)(3)(i) of this section. HHS will specify the allowance for a particular calendar year in the annual HHS notice of benefit and payment parameters.

(4) As long as an exception under OMB Circular No. A–25R is in effect, if the amount of the adjustment under paragraph (d)(3) of this section is greater than the amount of the participating issuer’s obligation to pay the Federally-facilitated Exchange user fee in a particular month, the participating issuer will be provided a credit in succeeding months in the amount of the excess.

(5) Within 60 days of receipt of any adjustment in the Federally-facilitated Exchange user fee under this section, a participating issuer must pay each third party administrator with respect to which it received any portion of such adjustment an amount no less than the portion of the adjustment attributable to the total dollar amount of the payments for contraceptive services submitted by the third party administrator, as described in paragraph (d)(2)(iii)(D) of this section. No such payment is required with respect to the allowance for administrative costs and margin described in paragraph (d)(3)(ii) of this section. This paragraph does not apply if the participating issuer made the payments for contraceptive services on behalf of the third party administrator, as described in paragraph (d)(1)(i) of this section, or is in the same issuer group as the third party administrator.

(6) A participating issuer receiving an adjustment in the Federally-facilitated Exchange user fee under this section for a particular calendar year must maintain for 10 years following that year, and make available upon request to HHS, the Office of the Inspector General, the Comptroller General, and their designees, documentation demonstrating that it timely paid each third party administrator with respect to which it received any such adjustment any amount required to be paid to the third party administrator under paragraph (d)(5) of this section.

(7) A third party administrator with respect to which an adjustment in the Federally-facilitated Exchange user fee is received under this section for a particular calendar year must maintain for 10 years following that year, and make available upon request to HHS, the Office of the Inspector General, the Comptroller General, and their designees, all of the following documentation:

(i) A copy of the self-certification referenced in 26 CFR 54.9815–2713A(a)(4) or 29 CFR 2590.715–2713A(a)(4) for each self-insured plan with respect to which an adjustment is received.

(ii) Documentation demonstrating that the payments for contraceptive services were made in compliance with 26 CFR 54.9815–2713A(b)(2) or 29 CFR 2590.715–2713A(b)(2).

(iii) Documentation supporting the total dollar amount of the payments for contraceptive services submitted by the third party administrator, as described in paragraph (d)(2)(iii)(D) of this section.

■ 6. Section 156.80 is amended by revising paragraph (d)(1) to read as follows:

§ 156.80 Single risk pool.

* * * * *

(d) * * *

(1) *In general.* Each plan year or policy year, as applicable, a health insurance issuer must establish an index rate for a state market described in paragraphs (a) through (c) of this section based on the total combined claims costs for providing essential health benefits within the single risk pool of that state market. The index rate must be adjusted on a market-wide basis for the state based on the total expected market-wide payments and charges under the risk adjustment and reinsurance programs, and Exchange user fees (expected to be remitted under § 156.50(b) or § 156.50(c) and (d) of this subchapter as applicable plus the dollar amount under § 156.50(d)(3)(i) and (ii) of this subchapter expected to be credited against user fees payable for that state market). The premium rate for all of the health insurance issuer’s plans in the relevant state market must use the applicable market-wide adjusted index rate, subject only to the plan-level adjustments permitted in paragraph (d)(2) of this section.

* * * * *

Signed this 27th day of June 2013.

Beth Tucker,

*Deputy Commissioner for Operations
Support, Internal Revenue Service.*

Mark J. Mazur,

*Assistant Secretary of the Treasury (Tax
Policy).*

Signed this 26th day of June 2013.

Phyllis C. Borzi,

*Assistant Secretary, Employee Benefits
Security Administration, Department of
Labor.*

Dated: June 20, 2013

Marilyn Tavenner,

*Administrator, Centers for Medicare &
Medicaid Services.*

Approved: June 25, 2013.

Kathleen Sebelius,

*Secretary, Department of Health and Human
Services.*

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