

**DEPARTMENT OF THE TREASURY****Internal Revenue Service****26 CFR Part 54****TD 9578****RIN 1545-BJ60****DEPARTMENT OF LABOR****Employee Benefits Security Administration****29 CFR Part 2590****RIN 1210-AB44****DEPARTMENT OF HEALTH AND HUMAN SERVICES****CMS-9992-F****45 CFR Part 147****RIN 0938-AQ74****Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and 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:** These regulations finalize, without change, interim final regulations authorizing the exemption of group health plans and group health insurance coverage sponsored by certain religious employers from having to cover certain preventive health services under provisions of the Patient Protection and Affordable Care Act.

**DATES:** Effective date. These final regulations are effective on [**OFR: INSERT DATE 60 DAYS AFTER PUBLICATION IN FEDERAL REGISTER**].

Applicability dates. These final regulations generally apply to group health plans and group health insurance issuers on [**OFR: INSERT DATE 60 DAYS AFTER PUBLICATION IN FEDERAL REGISTER**].

**FOR FURTHER INFORMATION CONTACT:** Amy Turner or Beth Baum, Employee Benefits Security Administration (EBSA), Department of Labor, at (202) 693-8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 622-6080; Robert Imes, Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS), at (410) 786-1565.

**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 website (<http://www.dol.gov/ebsa>). In addition, information from HHS on private health insurance for consumers can be found on the CMS website (<http://cciio.cms.gov>), and on health reform can be found at <http://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 (collectively, 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 (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 make them applicable to group health plans.

Section 2713 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 group or individual health insurance coverage provide benefits for certain preventive health services without the imposition of cost sharing. These preventive health services include, with respect to women, preventive care and screening provided for in the comprehensive guidelines supported by the Health Resources and Services Administration (HRSA) that were issued on August 1, 2011 (HRSA Guidelines).<sup>1</sup> As relevant here, the HRSA Guidelines require coverage, without cost sharing, for “[a]ll Food and Drug Administration [(FDA)] approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity,” as prescribed by a provider. Except as discussed below, non-grandfathered group health plans and health insurance issuers are required to provide coverage consistent with the HRSA Guidelines, without cost sharing, in plan years (or, in the individual market, policy years) beginning on or after August 1, 2012.<sup>2</sup> These guidelines were based on recommendations of the independent Institute of Medicine, which undertook a review of the evidence on women’s preventive services.

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<sup>1</sup> The HRSA Guidelines can be found at: <http://www.hrsa.gov/womensguidelines>.

<sup>2</sup> The 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 (or, 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 or guideline is issued. 26 CFR 54.9815-2713T(b)(1); 29 CFR 2590.715-2713(b)(1); 45 CFR 147.130(b)(1).

The Departments of Health and Human Services, Labor, and the Treasury (the Departments) published interim final regulations implementing PHS Act section 2713 on July 19, 2010 (75 FR 41726). In the preamble to the interim final regulations, the Departments explained that HRSA was developing guidelines related to preventive care and screening for women that would be covered without cost sharing pursuant to PHS Act section 2713(a)(4), and that these guidelines were expected to be issued no later than August 1, 2011. Although comments on the anticipated guidelines were not requested in the interim final regulations, the Departments received considerable feedback regarding which preventive services for women should be covered without cost sharing. Some commenters, including some religiously-affiliated employers, recommended that these guidelines include contraceptive services among the recommended women's preventive services and that the attendant coverage requirement apply to all group health plans and health insurance issuers. Other commenters, however, recommended that group health plans sponsored by religiously-affiliated employers be allowed to exclude contraceptive services from coverage under their plans if the employers deem such services contrary to their religious tenets, noting that some group health plans sponsored by organizations with a religious objection to contraceptives currently contain such exclusions for that reason.

In response to these comments, the Departments amended the interim final regulations to provide HRSA with discretion to establish an exemption for group health plans established or maintained by certain religious employers (and any group health insurance coverage provided in connection with such plans) with respect to any requirement to cover contraceptive services that they would otherwise be required to cover without cost sharing consistent with the HRSA Guidelines. The amended interim final regulations were issued and effective on August 1,

2011.<sup>3</sup> The 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 non-profit organization described in section 6033(a)(1) and section 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. In the HRSA Guidelines, HRSA exercised its discretion under the amended interim final regulations such that group health plans established and maintained by these religious employers (and any group health insurance coverage provided in connection with such plans) are not required to cover contraceptive services.

In the preamble to the amended interim final regulations, the Departments explained that it was appropriate that HRSA take into account the religious beliefs of certain religious employers where coverage of contraceptive services is concerned. The Departments noted that a religious exemption is consistent with the policies in some States that currently both require contraceptive services coverage under State law and provide for some type of religious exemption from their contraceptive services coverage requirement. Comments were requested on the amended interim final regulations, specifically with respect to the definition of religious employer, as well as alternative definitions.

## **II. Overview of the Public Comments on the Amended Interim Final Regulations**

The Departments received over 200,000 responses to the request for comments on the amended interim final regulations. Commenters included concerned citizens, civil rights organizations, consumer groups, health care providers, health insurance issuers, sponsors of

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<sup>3</sup> The amendment to the interim final regulations was published on August 3, 2011, at 76 FR 46621.

group health plans, religiously-affiliated charities, religiously-affiliated educational institutions, religiously-affiliated health care organizations, other religiously-affiliated organizations, secular organizations, sponsors of group health plans, women's religious orders, and women's rights organizations.

Some commenters recommended that the exemption for the group health plans of a limited group of religious organizations as formulated in the amended interim final regulations be maintained. Other commenters urged that the definition of religious employer be broadened so that more sponsors of group health plans would qualify for the exemption. Others urged that the exemption be rescinded in its entirety. The Departments summarize below the major issues raised in the comments that were received.

Some commenters supported the inclusion of contraceptive services in the HRSA Guidelines and urged that the religious employer exemption be rescinded in its entirety due to the importance of extending these benefits to as many women as possible. For example, one provider association commented that all group health plans and group health insurance issuers should offer the same benefits to plan participants, without a religious exemption for some plans, and that religious beliefs are more appropriately taken into account by individuals when making personal health care decisions. Others urged that the exemption be eliminated because making contraceptive services available to all women would satisfy a basic health care need and would significantly reduce long-term health care costs associated with unplanned pregnancies.

Some of the commenters supporting the elimination of the exemption argued that section 2713 of the PHS Act does not provide any explicit basis for exempting a subset of group health plans. One commenter asserted that Congress's incorporation of section 2713 of the PHS Act into ERISA and the Code indicates its intent to require coverage of recommended preventive

services under section 2713 of the PHS Act in the broadest spectrum of group health plans possible.

Many commenters that opposed the exemption asked that, at a minimum, the Departments not expand the definition of religious employer. Alternatively, they asked that, if the Departments decided to base the relevant portion of the definition of religious employer on a Code section other than section 6033, the other portions of the definition of religious employer be retained to limit the exemption largely to houses of worship.

Some commenters urged the Departments not to modify the definition of religious employer. For example, some commenters asserted that the exemption is appropriately targeted at houses of worship, rather than a larger set of religiously-affiliated organizations. Others argued that, while the exemption addresses legitimate religious concerns, its scope is already broader than necessary and should not be expanded.

Commenters opposing any exemption stated that, if the exemption were to be retained, clear notice should be provided to the affected plan participants that their group health plans do not include benefits for contraceptive services. In addition, they urged the Departments to monitor plans to ensure that the exemption is not claimed more broadly than permitted.

On the other hand, a number of comments asserted that the religious employer exemption is too narrow. These commenters included some religiously-affiliated educational institutions, health care organizations, and charities. Some of these commenters expressed concern that the exemption for religious employers will not allow them to continue their current exclusion of contraceptive services from coverage under their group health plans. Others expressed concerns about paying for such services and stated that doing so would be contrary to their religious beliefs.

Commenters also claimed that Federal laws, including the Affordable Care Act, have provided for conscience clauses and religious exemptions broader than that provided for in the amended interim final regulations. Some commenters asserted that the narrower scope of the exemption raises concerns under the First Amendment and the Religious Freedom Restoration Act.

Other commenters, however, disputed claims that the contraceptive coverage requirement infringes on rights protected by the First Amendment or the Religious Freedom Restoration Act. These commenters noted that the requirement is neutral and generally applicable. They also explained that the requirement does not substantially burden religious exercise and, in any event, serves compelling governmental interests and is the least restrictive means to achieve those interests.

Some religiously-affiliated employers warned that, if the definition of religious employer is not broadened, they could cease to offer health coverage to their employees in order to avoid having to offer coverage to which they object on religious grounds.

Commenters supporting a broadening of the definition of religious employer proposed a number of options, generally intended to expand the scope of the exemption to include religiously-affiliated educational institutions, health care organizations, and charities. In some instances, in place of the definition that was adopted in the amended interim final regulations, commenters suggested other State insurance law definitions of religious employer. In other instances, commenters referenced alternative standards, such as tying the exemption to the definition of “church plan” under section 414(e) of the Code or to status as a nonprofit organization under section 501(c)(3) of the Code.

### **III. Overview of the Final Regulations**

In response to these comments, the Departments carefully considered whether to eliminate the religious employer exemption or to adopt an alternative definition of religious employer, including whether the exemption should be extended to a broader set of religiously-affiliated sponsors of group health plans and group health insurance coverage. For the reasons discussed below, the Departments are adopting the definition in the amended interim final regulations for purposes of these final regulations while also creating a temporary enforcement safe harbor, discussed below. During the temporary enforcement safe harbor, the Departments plan to develop and propose changes to these final regulations that would meet two goals – providing contraceptive coverage without cost-sharing to individuals who want it and accommodating non-exempted, non-profit organizations’ religious objections to covering contraceptive services as also discussed below.

PHS Act section 2713 reflects a determination by Congress that coverage of recommended preventive services by non-grandfathered group health plans and health insurance issuers without cost sharing is necessary to achieve basic health care coverage 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.<sup>4</sup> Further, Congress, by amending the Affordable Care Act during the Senate debate to ensure that recommended preventive services for women are covered adequately by non-grandfathered group health plans

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<sup>4</sup> Inst. of Med., *Clinical Preventive Services for Women: Closing the Gaps*, Wash., D.C.: Nat’l Acad. Press, 2011, at p.16.

and group health insurance coverage, recognized that women have unique health care needs and burdens. Such needs include contraceptive services.<sup>5</sup>

As documented in a report of the Institute of Medicine, “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 not be as motivated to discontinue behaviors that pose pregnancy-related risks (e.g., smoking, consumption of alcohol). Studies show a greater risk of preterm birth and low birth weight among unintended pregnancies compared with pregnancies that were planned.<sup>6</sup> 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 (e.g., treatment of menstrual disorders, acne, and pelvic pain).<sup>7</sup>

In addition, there are significant cost savings to employers from the coverage of contraceptives. A 2000 study estimated that it would cost employers 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 and reduced productivity.<sup>8</sup> In fact, when contraceptive coverage was added to

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<sup>5</sup> Inst. of Med., *Clinical Preventive Services for Women: Closing the Gaps*, Wash. D.C.: Nat'l Acad. Press, 2011, at p. 9; see also Sonfield, A., The Case for Insurance Coverage of Contraceptive Services and Supplies Without Cost Sharing, 14 *Guttmacher Pol'y Rev.* 10 (2011), available at <http://www.guttmacher.org/pubs/gpr/14/1/gpr140107.html>

<sup>6</sup> 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.

<sup>7</sup> Inst. of Med., *Clinical Preventive Services for Women: Closing the Gaps*, Wash., D.C.: Nat'l Acad. Press, 2011, at p.107.

<sup>8</sup> Testimony of Guttmacher Inst., submitted to the Comm. on Preventive Servs. for Women, Inst. of Med., Jan. 12, 2012, p.11 citing Bonoan, R + Gonen, JS, “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); Mavranzouli, I., Health Economics of Contraception, 23 *Best Practice & Res. Clinical Obstetrics & Gynaecology* 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).

the Federal Employees Health Benefits Program, premiums did not increase because there was no resulting health care cost increase.<sup>9</sup> Further, the cost savings of covering contraceptive services have already been recognized by States and also within the health insurance industry. Twenty-eight States now have laws requiring health insurance issuers to cover contraceptives. A 2002 study found that more than 89 percent of insured plans cover contraceptives.<sup>10</sup> A 2010 survey of employers revealed that 85 percent of large employers and 62 percent of small employers offered coverage of FDA-approved contraceptives.<sup>11</sup>

Furthermore, in directing non-grandfathered group health plans and health insurance issuers to cover preventive services and screenings for women described in HRSA-supported guidelines without cost sharing, Congress determined that both existing health coverage and existing preventive services recommendations often did not adequately serve the unique health needs of women. This disparity places women in the workforce at a disadvantage compared to their male co-workers. Researchers have shown that access to contraception improves the social and economic status of women.<sup>12</sup> Contraceptive coverage, by reducing the number of unintended and potentially unhealthy pregnancies, furthers the goal of eliminating this disparity by allowing women to achieve equal status as healthy and productive members of the job force.

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<sup>9</sup> Dailard, C., Special Analysis: The Cost of Contraceptive Insurance Coverage, *Guttmacher Rep. on Public Pol'y* (March 2003).

<sup>10</sup> 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.

<sup>11</sup> Claxton, G., et al., *Employer Health Benefits: 2010 Annual Survey*, Menlo Park, Cal.: Kaiser Family Found. and Chi., Ill.: Health Research & Educ. Trust, 2010.

<sup>12</sup> Testimony of Guttmacher Inst., submitted to the Comm. on Preventive Servs. for Women, Inst. of Med., Jan. 12, 2012, p.6, citing Goldin C and Katz L, Career and marriage in the age of the pill, *American Economic Review*, 2000, 90(2):461-465; Goldin C and Katz LF, The power of the pill: oral contraceptives and women's career and marriage decisions, *Journal of Political Economy*, 2002, 110(4):730-770; and Bailey MJ, More 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.

Research also shows that cost sharing can be a significant barrier to effective contraception.<sup>13</sup> As the Institute of Medicine noted, owing to reproductive and sex-specific conditions, women use preventive services more than men, generating significant out-of-pocket expenses for women.<sup>14</sup> The Departments aim to reduce these disparities by providing women broad access to preventive services, including contraceptive services.

The religious employer exemption in the final regulations does not undermine the overall benefits described above. A group health plan (and health insurance coverage provided in connection with such a plan) qualifies for the exemption if, among other qualifications, the plan is established and maintained by an employer that primarily employs persons who share the religious tenets of the organization. As such, the employees of employers availing themselves of the exemption would be less likely to use contraceptives even if contraceptives were covered under their health plans.

A broader exemption, as urged by some commenters, would lead to more employees having to pay out of pocket for contraceptive services, thus making it less likely that they would use contraceptives, which would undermine the benefits described above. Employers that do not primarily employ employees who share the religious tenets of the organization are more likely to employ individuals who have no religious objection to the use of contraceptive services and therefore are more likely to use contraceptives. Including these employers within the scope of the exemption would subject their employees to the religious views of the employer, limiting access to contraceptives, and thereby inhibiting the use of contraceptive services and the benefits of preventive care.

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<sup>13</sup> Postlethwaite, D., et al., A Comparison of Contraceptive Procurement Pre- and Post-Benefit Change, 76 *Contraception* 360 (2007).

<sup>14</sup> Inst. of Med., *Clinical Preventive Services for Women: Closing the Gaps*, Wash., D.C.: Nat'l Acad. Press, 2011, p.19.

The Departments note that this religious exemption is intended solely for purposes of the contraceptive services coverage requirement pursuant to PHS Act section 2713 and the companion provisions of ERISA and the Code.

The Departments also note that some group health plans sponsored by employers that do not satisfy the definition of religious employer in these final regulations may be grandfathered health plans<sup>15</sup> and thus are not subject to any of the preventive services coverage requirements of section 2713 of the PHS Act, including the contraceptive coverage requirement.

With respect to certain non-exempted, non-profit organizations with religious objections to covering contraceptive services whose group health plans are not grandfathered health plans, guidance is being issued contemporaneous with these final regulations that provides a one-year safe harbor from enforcement by the Departments.

Before the end of the temporary enforcement safe harbor, the Departments will work with stakeholders to develop alternative ways of providing contraceptive coverage without cost sharing with respect to non-exempted, non-profit religious organizations with religious objections to such coverage. Specifically, the Departments plan to initiate a rulemaking to require issuers to offer insurance without contraception coverage to such an employer (or plan sponsor) and simultaneously to offer contraceptive coverage directly to the employer's plan participants (and their beneficiaries) who desire it, with no cost-sharing. Under this approach, the Departments will also require that, in this circumstance, there be no charge for the contraceptive coverage. Actuaries and experts have found that coverage of contraceptives is at least cost neutral when taking into account all costs and benefits in the health plan.<sup>16</sup> The

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<sup>15</sup> See section 1251 of the Affordable Care Act and its implementing regulations at 26 CFR 54.9815-1251T; 29 CFR 2590.715-1251; 45 CFR 147.140.

<sup>16</sup> Bertko, John, F.S.A., M.A.A.A., Director of Special Initiatives and Pricing in the Center for Consumer Information and Insurance Oversight at the Centers for Medicare and Medicaid Services, Glied, Sherry, Ph.D.,

Departments intend to develop policies to achieve the same goals for self-insured group health plans sponsored by non-exempted, non-profit religious organizations with religious objections to contraceptive coverage.

A future rulemaking would be informed by the existing practices of some issuers and religious organizations in the 28 States where contraception coverage requirements already exist, including Hawaii. There, State health insurance law requires issuers to offer plan participants in group health plans sponsored by religious employers that are exempt from the State contraception coverage requirement the option to purchase this coverage in a way that religious employers are not obligated to fund it. It is our understanding that, in practice, rather than charging employees a separate fee, some issuers in Hawaii offer this coverage to plan participants at no charge. The Departments will work with stakeholders to propose and finalize this policy before the end of the temporary enforcement safe harbor.

Nothing in these final regulations precludes employers or others from expressing their opposition, if any, to the use of contraceptives, requires anyone to use contraceptives, or requires health care providers to prescribe contraceptives if doing so is against their religious beliefs. These final regulations do not undermine the important protections that exist under conscience clauses and other religious exemptions in other areas of Federal law. Conscience protections will continue to be respected and strongly enforced.

This approach is consistent with the First Amendment and Religious Freedom Restoration Act. The Supreme Court has held that the First Amendment right to free exercise of religion is not violated by a law that is not specifically targeted at religiously motivated conduct

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Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services (ASPE/HHS), Miller, Erin, MPH, (ASPE/HHS), Wilson, Lee, (ASPE/HHS), Simmons, Adelle, (ASPE/HHS), "The Cost of Covering Contraceptives through Health Insurance," (9 February 2012), available at: <http://aspe.hhs.gov/health/reports/2012/contraceptives/ib.shtml>

and that applies equally to conduct without regard to whether it is religiously motivated – a so-called neutral law of general applicability. The contraceptive coverage requirement is generally applicable and designed to serve the compelling public health and gender equity goals described above, and is in no way specially targeted at religion or religious practices. Likewise, this approach complies with the Religious Freedom Restoration Act, which generally requires a federal law to not substantially burden religious exercise, or, if it does substantially burden religious exercise, to be the least restrictive means to further a compelling government interest.

### **III. Economic Impact and Paperwork Burden**

#### **A. Executive Orders 13563 and 12866 - Department of Labor and Department of Health and Human Services**

Executive Orders 13563 and 12866, among other things, 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, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Executive Order 13563 also states that where “appropriate and permitted by law, each agency may consider (and discuss qualitatively) values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts.” These final regulations have been designated a “significant regulatory action,” although not economically significant, under section 3(f) of Executive Order 12866. Accordingly, these final regulations have been reviewed by the Office of Management and Budget.

#### **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 and health insurance coverage sponsored by certain religious employers from certain coverage requirements under PHS Act section 2713 (76 FR 46621, August 3, 2011). The Departments have determined that it is appropriate to finalize, without change, these amended interim final regulations authorizing the exemption of group health plans and health insurance coverage sponsored by certain religious employers from having to cover certain preventive health services under the Patient Protection and Affordable Care Act.

## 2. Anticipated Effects

The Departments expect that these final regulations will not result in any additional significant burden 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 for purposes of Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the APA (5 U.S.C. chapter 5) does not apply to these final regulations, and, because these regulations do not impose a collection of information on small entities, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required.

### C. Paperwork Reduction Act

These final regulations are not subject to the requirements of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.) because they do not contain a “collection of information” as defined in 44 U.S.C. 3502(11).

## **IV. Statutory Authority**

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

The Department of Labor final regulations are adopted pursuant to the authority contained in 29 U.S.C. 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a, 1185b, 1185c, 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. 512(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 3-2010, 75 FR 55354 (September 10, 2010).

The Department of Health and Human Services final regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 USC 300gg through 300gg-63, 300gg-91, and 300gg-92), as amended.

### **List of Subjects**

#### 26 CFR Part 54

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

#### 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.

**DEPARTMENT OF THE TREASURY**

**Internal Revenue Service**

26 CFR Chapter I

Accordingly, 26 CFR Part 54 is amended as follows:

**PART 54--PENSION EXCISE TAXES**

**Paragraph 1.** The authority citation for part 54 is amended by adding an entry for §54.9815-2713 in numerical order to read in part as follows:

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

Section 54.9815-2713 also issued under 26 U.S.C. 9833. \* \* \*

**Par. 2.** Section 54.9815-2713T is amended in paragraph (a)(1)(iii) by removing “; and” and adding a period in its place, and by removing paragraph (a)(1)(iv).

**Par. 3.** Section 54.9815-2713 is added to read as follows:

§54.9815-2713 Coverage of preventive health services.

(a) Services—(1) In general. [Reserved]

(i) [Reserved]

(ii) [Reserved]

(iii) [Reserved]

(iv) With respect to women, to the extent not described in paragraph (a)(1)(i) of §54.9815-2713T, preventive care and screenings provided for in binding comprehensive health plan coverage guidelines supported by the Health Resources and Services Administration and developed in accordance with 45 CFR 147.130(a)(1)(iv).

(2) Office visits. [Reserved]

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

(4) Reasonable medical management. [Reserved]

(5) Services not described. [Reserved]

(b) Timing. [Reserved]

(c) Recommendations not current. [Reserved]

(d) Effective/applicability date. [Insert date 60 days after date of publication in **Federal Register**.]

## **DEPARTMENT OF LABOR**

Employee Benefits Security Administration

29 CFR Chapter XXV

29 CFR part 2590 is amended as follows:

### **PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS**

1. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161-1168, 1169, 1181-1183, 1181 note, 1185, 1185a, 1185b, 1185c, 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. 512(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 3-2010, 75 FR 55354 (September 10, 2010).

2. Accordingly, the amendment to the interim final rule with comment period amending 29 CFR 2590.715-2713(a)(1)(iv) which was published in the Federal Register at 76 FR 46621-46626 on August 3, 2011, is adopted as a final rule without change.

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

45 CFR SUBTITLE A

**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:** 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. Accordingly, the amendment to the interim final rule with comment period amending 45 CFR 147.130(a)(1)(iv) which was published in the Federal Register at 76 FR 46621-46626 on August 3, 2011, is adopted as a final rule without change.

Steven T. Miller  
Deputy Commissioner for Services and Enforcement,  
Internal Revenue Service.

Approved: February 10, 2012

Emily S. McMahon  
Acting Assistant Secretary of the Treasury (Tax Policy).

Signed this \_\_ 10th \_\_\_\_ day of February, 2012.

Phyllis C. Borzi  
Assistant Secretary  
Employee Benefits Security Administration  
Department of Labor

Dated: February 10, 2012

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**Marilyn Tavenner,**

Acting Administrator,

Centers for Medicare & Medicaid Services.

Dated: February 10, 2012

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**Kathleen Sebelius,**

Secretary,

Department of Health and Human Services.

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