DEPARTMENT OF THE TREASURY
Internal Revenue Service
26 CFR Part 54
[TD–9690]
RIN 1545–BM38
DEPARTMENT OF LABOR
Employee Benefits Security Administration
29 CFR Parts 2510 and 2590
RIN 1210–AB67
DEPARTMENT OF HEALTH AND HUMAN SERVICES
45 CFR Parts 147
[CMS–9939–IFC]
RIN 0935–AR42

Coverage of Certain Preventive Services Under the Affordable Care Act

AGENCY: 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: Interim final rules.

SUMMARY: This document contains interim 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. Additionally, under current regulations, accommodations are available 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), and student health insurance coverage arranged by eligible organizations that are institutions of higher education, that effectively exempt them from this requirement. The regulations establish a mechanism for separately furnishing payments for contraceptive services on behalf of participants and beneficiaries of the group health plans of eligible organizations that avail themselves of an accommodation, and enrollees and dependents of student health coverage arranged by eligible organizations that are institutions of higher education that avail themselves of an accommodation. These interim final regulations augment current regulations in light of the Supreme Court’s interim order in connection with an application for an injunction in Wheaton College v. Burwell, 134 S. Ct. 2806 (2014) (Wheaton order). These interim final regulations provide an alternative process that an eligible organization may use to provide notice of its religious objections to providing contraceptive coverage, while preserving participants’ and beneficiaries’ (and enrollees’ and dependents’) access to coverage for the full range of Food and Drug Administration (FDA)-approved contraceptives, as prescribed by a health care provider, without cost sharing.

DATES: Effective date: These interim final regulations are effective on August 27, 2014.

Comments: Written comments on these interim final regulations are invited and must be received by October 27, 2014.

ADDRESSES: Written comments may be submitted to the Department of Labor as specified below. Any comment that is submitted will be shared with the Department of Health and Human Services and the Department of the Treasury, and will also be made available to the public. Warning: Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments may be posted on the Internet and can be retrieved by most Internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

Comments, identified by “Preventive Services,” may be submitted by one of the following methods:

Comments received will be posted without change to www.regulations.gov and available for public inspection at the Public Disclosure Room, N–1513, Employee Benefits Security Administration, 200 Constitution Avenue NW., Washington, DC 20210, including any personal information provided.

FOR FURTHER INFORMATION CONTACT:
David Mlawsky, 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.

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–EBESA (3272) or visit the Department of Labor’s Web site (www.dol.gov/ebwa).
Information from HHS on private health insurance coverage can be found on CMS’s Web site (www.cms.gov/cciio) 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 9813(a)(1) to the Internal Revenue Code (Code) to incorporate the provisions of part A of
Section 2731 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 coverage of certain specified preventive services without cost sharing, including under paragraph (a)(4), benefits for certain women’s preventive health services 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 contraceptives, sterilization procedures, and patient education and counseling for women with reproductive capacity, as prescribed by a health care provider (collectively, contraceptive services).

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 (or, in the individual market, policy years) beginning on or after August 1, 2012.

Interim final regulations implementing section 2731 of the PHS Act were published on July 19, 2010 (75 FR 41726) (2010 interim final 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 to 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). On the same date, HRSA exercised this authority in the HRSA Guidelines to exempt group health plans established or maintained by these religious employers (and group health insurance coverage provided in connection with such plans) from the HRSA Guidelines with respect to contraceptive services. The 2011 amended interim final regulations specified that, for purposes of this exemption, a religious employer was 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.


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).

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. At the same time, the Departments committed to rulemaking to achieve the goals of providing coverage of recommended preventive services, including contraceptive services, without cost sharing, while simultaneously ensuring that certain additional nonprofit organizations with religious objections to contraceptive coverage would not have 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 were proposed to simplify and clarify the definition of “religious employer” for purposes of the religious employer exemption. The regulations also proposed accommodations for group health plans established or maintained or arranged by certain nonprofit religious organizations with religious objections to contraceptive coverage (and group health insurance coverage provided in connection with such plans). 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 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 student health insurance coverage arranged by

available at: http://www.cdc.gov/CEO/HRSA/Resources/Regulations-and-Guidance/Downsides/preventive-services-guidance-6-26-2013.pdf. The guidance clarified, among other things, that plans that took some action before February 10, 2012, to try, without success, to exclude or limit contraceptive coverage were not precluded from eligibility for the safe harbor. The temporary enforcement safe harbor was also available to student health insurance coverage arranged by nonprofit institutions of higher education with religious objections to contraceptive coverage that met the conditions set forth in the guidance. See Student Health Insurance Coverage, 77 FR 16457 (Mar. 21, 2012).
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 provide or arrange for a third party 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 published final regulations on July 2, 2013 at 78 FR 39870 (July 2013 final regulations). The July 2013 final regulations simplified and clarified the definition of religious employer for purposes of the religious employer exemption and established accommodations for health coverage established or maintained or arranged by eligible organizations. A contemporaneously re-issued HHS guidance document extended 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 included a form to be used by an organization during this temporary period to self-certify that its plan qualified for the temporary enforcement safe harbor. In addition, HHS and the Department of Labor (DOL) issued a self-certification form, EBSA Form 700, to be executed by an organization seeking to be treated as an 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 issued a self-certification form, EBSA Form 700, to be executed by an organization seeking to be treated as an 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 are publishing elsewhere in this edition of the Federal Register a notice of proposed rulemaking (NPRM) that proposes possible amendments to the definition of the term “eligible organization” to include clearly held for-profit entities with religious objections to contraceptive coverage, in light of the Hobby Lobby decision.

On July 3, 2014, the Supreme Court issued an interim order in connection with an application for an injunction pending appeal in Wheaton College v. Burwell, 134 S. Ct. 2806 (2014), in which the plaintiff challenged under RFRA the requirement in the July 2013 final regulations that an eligible organization invoking the accommodation send EBSA Form 700 to the insurance issuer or third party administrator. The Court’s order stated that, “[i]f the [plaintiff] informs the Secretary of Health and Human Services in writing that it is a nonprofit organization that holds itself out as religious and has religious objections to providing coverage for contraceptive services, the [Departments of Labor, Health and Human Services, and the Treasury] are enjoined from enforcing against the [plaintiff]” certain provisions of the Affordable Care Act and related regulations requiring coverage without cost sharing of certain contraceptive services “pending final disposition of appellate review.” 134 S.Ct. at 2807. The order stated that Wheaton College need not use EBSA Form 700 or send a copy of the executed form to its health insurance issuers or third party administrators to meet the condition for this injunctive relief. Id.

The Court also stated that its interim order neither affected “the ability of the [plaintiff’s] employees and students to obtain, without cost, the full range of FDA approved contraceptives,” nor precluded the Government from relying on the notice by the plaintiff “to facilitate the provision of full contraceptive coverage under the Act.” Id. The Court’s order further stated that it “should not be construed as an expression of the Court’s views on the merits” of the plaintiff’s challenge to the accommodations. Id.

The Departments are issuing these interim final regulations in light of the Supreme Court’s interim order in Wheaton concerning notice to the Government that an eligible organization has a religious objection to providing contraceptive coverage, as an alternative to the EBSA Form 700 method of self-certification, and to preserve participants’ and beneficiaries’ (and, in the case of student health insurance coverage, enrollees’ and dependents’) access to coverage for the full range of FDA-approved contraceptives, as prescribed by a health care provider, without cost sharing.

II. Overview of the Interim Final Regulations

These interim final regulations amend the Departments’ July 2013 final regulations to provide an alternative process for the sponsor of a group health plan or an institution of higher education to provide notice of its religious objection to coverage of all or a subset of contraceptive services, as an alternative to the EBSA Form 700 method of self-certification. These interim final regulations continue to allow eligible organizations to use EBSA Form 700, as set forth in the July 2013 final regulations and guidance.

The alternative process permitted by these interim final regulations is consistent with the Wheaton order. It provides that an eligible organization may notify HHS in writing of its religious objection to coverage of all or a subset of contraceptive services. The notice must include the name of the eligible organization and the basis on which it qualifies for an accommodation; its objection based on sincerely held religious beliefs to providing coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable); the plan name and type (i.e., whether it is a student health insurance plan within the
meaning of 45 CFR 147.145(a) or a church plan within the meaning of ERISA section 3(33)); and the name and contact information for any of the plan’s third party administrators and health insurance issuers.4 A model notice to HHS that eligible organizations may, but are not required to, use is available at: http://www.cms.gov/cciio/resources/Regulations-and-Guidance/index.html#Prevention. If there is a change in any of the information required to be included in the notice, the organization must provide updated information to HHS. As with the process established in the July 2013 final regulations, nothing in this alternative notice process requires a government assessment of the sincerity of the religious belief underlying the eligible organization’s objection. The notice to HHS, and any subsequent updates, should be sent electronically to: marketreform@cms.hhs.gov, or by regular mail to: Centers for Medicare & Medicaid Services, Center for Consumer Information and Insurance Oversight, 200 Independence Avenue SW., Washington, DC 20201, Room 739H. The content required for the notice represents the minimum information necessary for the Departments to determine which entities are covered by the accommodation, to administer the accommodation, and to implement the policies in the July 2013 final regulations. When an eligible organization that establishes or maintains a self-insured plan subject to ERISA provides such a notice to HHS, DOL (working with HHS) will send a separate notification to each third party administrator of the ERISA plan. DOL’s notification will inform each third party administrator of the eligible organization’s religious objection to funding or administering some or all contraceptive coverage and will designate the relevant third party administrator(s) as plan administrator under section 3(16) of ERISA for those contraceptive benefits that the third party administrator would otherwise manage. The DOL notification will be an instrument under which the plan is operated and shall supersede any earlier designation. In establishing and implementing this alternative process, DOL is exercising its broad rulemaking authority under Title I of ERISA, which includes the ability to interpret and apply the definition of a plan administrator under ERISA section 3(16)(A).

If an eligible organization that establishes or maintains an insured health plan provides a notice to HHS under this alternative process, HHS will send a separate notification to the plan’s health insurance issuer(s) informing the issuer(s) that HHS has received a notice under § 2590.715–2713A(3)(i) and describing the obligations of the issuer(s) under § 2590.715–2713A. Issuers remain responsible for compliance with the statutory and regulatory requirement to provide coverage for contraceptive services to participants and beneficiaries, and to enrollees and dependents of student health plans, notwithstanding that the policyholder is an eligible organization with a religious objection to contraceptive coverage that will not have to contract, arrange, pay, or refer for such coverage.

Other questions have arisen regarding the requirement to provide coverage for contraceptive services without cost sharing and the accommodations for eligible organizations. In what has been described as the “non-interference provision,” the July 2013 final regulations provided that eligible organizations that establish or maintain self-insured group health plans “must not, directly or indirectly seek to interfere with a third party administrator’s arrangements to provide or arrange for separate payments for contraceptive services” and “must not, directly or indirectly, seek to influence a third party administrator’s decision to make any such arrangements.” 26 CFR 54.9815–2713A(b)[1][i][ii]; 29 CFR 2590.715–2713A(b)[1][ii]. The Departments interpret the July 2013 final regulations solely as prohibiting the use of bribery, threats, or other forms of economic coercion in an attempt to prevent a third party administrator from fulfilling its independent legal obligations to provide or arrange separate payments for contraceptive services. Because such conduct is generally unlawful and is prohibited under other state and federal laws, and to reduce unnecessary confusion, these interim final regulations delete the language prohibiting an eligible organization from interfering with or seeking to influence a third party administrator’s decision or efforts to provide separate payments for contraceptive services.

III. Interim Final Regulations and Request for Comments

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include PHS Act sections 2701 through 2728 and the incorporation of those sections into ERISA section 715 and Code section 9815.

In addition, under Section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 551 et seq.), a general notice of proposed rulemaking is not required when an agency, for good cause finds that notice and public comment thereon are impractical, unnecessary, or contrary to the public interest. The provisions of the APA that ordinarily require a notice of proposed rulemaking do not apply here because of the specific authority granted by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act. However, even if these provisions of the APA were applicable, the Secretaries have determined that it would be impracticable and contrary to the public interest to delay putting the provisions in these interim final regulations in place until a full public notice and comment process is completed. As discussed earlier, the Departments are issuing these interim final regulations in light of the Supreme Court’s order in Wheaton College concerning notice to the Federal government that an eligible organization has a religious objection to providing contraceptive coverage, as an alternative to the EBSSA Form 700, and to preserve participants’ and beneficiaries’ (and, in the case of student health insurance coverage, enrollees’ and dependents’) access to coverage for the full range of FDA-approved contraceptive services, as prescribed by a health care provider, without cost sharing. That order was issued and was effective on July 3, 2014. In order to provide other eligible organizations with an option equivalent to the one the Supreme Court provided to Wheaton College on an interim basis, regulations must be published and available to the public as soon as possible. Delaying the availability of the alternative process in order to allow for a full notice and comment period would delay the ability of eligible organizations to avail themselves of this alternative process and could delay women’s access to contraceptive

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4 Church plans are exempt from ERISA pursuant to ERISA section 4(b)(2). As such, a third party administrator of a self-insured church plan cannot become the plan administrator by operation of 29 CFR 2510.3–16, although such third party administrators may voluntarily provide or arrange separate payments for contraceptive services and seek reimbursement for associated expenses under the process set forth in 45 CFR 136.50.
coverage without cost sharing, thereby compromising their access to necessary contraceptive services. Issuing interim final regulations provides the public with an opportunity to comment on whether these regulations affording this alternative should be made permanent or subject to modification without delaying the effective date of the regulations.

For the foregoing reasons, the Departments have determined that it would be impracticable and contrary to the public interest to engage in full notice and comment rulemaking before putting these interim final regulations into effect, and that it is in the public interest to promulgate interim final regulations. For the same reasons, the Departments have determined, consistent with section 553(d) of the APA (5 U.S.C. 553(d)), that there is good cause to make these interim final regulations effective immediately upon publication in the Federal Register.

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). These interim 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

These interim final regulations amend the Departments’ July 2013 final regulations to provide an alternative process for an eligible organization to provide notice of its religious objection to coverage of all or a subset of contraceptive services.

2. Anticipated Effects

The Departments expect that these interim final regulations will not result in any additional burden on or costs to the affected entities. These interim final regulations do not change the fundamental ability of an eligible organization to exempt itself from contracting, arranging, paying, or referring for contraceptive coverage. Instead, the regulations merely provide alternative means for eligible organizations to provide notice of their religious objection to coverage of all, or a subset of, contraceptive services.

B. Special Analyses—Department of the Treasury

For purposes of the Department of the Treasury, it has been determined that this rule is not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13563. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the APA does not apply to these regulations. Pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), it is hereby certified that this rule will not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that the temporary regulations will not result in any additional costs to affected entities but will provide an alternative means for eligible organizations to provide notice of their religious objection to providing coverage of all, or a subset of, contraceptive services. Pursuant to section 7805(f) of the Code, these temporary regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

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

Under the Paperwork Reduction Act, an agency may not conduct or sponsor, and an individual is not required to respond to, a collection of information unless it displays a valid OMB control number. These interim final regulations contain an information collection request (ICR) that is subject to review by the Office of Management and Budget (OMB). A description of these provisions is given in the following section 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.

Each organization seeking to be treated as an eligible organization under these interim final regulations must either use the EBSA Form 700 method of self-certification or provide notice to HHS of its religious objection to coverage of all or a subset of contraceptive services. Specifically, these interim final regulations continue to allow eligible organizations to notify an issuer or third party administrator using EBSA Form 700, as set forth in the July 2013 final regulations. In addition, these interim final regulations permit an alternative process, consistent with the Supreme Court’s interim order in Wheaton College, by which an eligible organization may notify HHS of its religious objection to coverage of all or a subset of contraceptive services. HHS is aware, based on litigation, that there are approximately 122 eligible organizations that would now have the option to provide notice to HHS, rather than provide a self-certification to TPAs and/or issuers.

In order to complete this task, HHS assumes that clerical staff for each eligible organization will gather and enter the necessary information and send the self-certification to the issuer or third party administrator as appropriate, or send the notice to HHS. HHS assumes that a compensation and benefits manager and inside legal counsel will review the self-certification or notice to HHS and a senior executive would execute it. HHS estimates that an eligible organization would spend approximately 45 minutes (30 minutes of clerical labor at a cost of $30 per hour, 10 minutes for a compensation...
This approval allows respondents temporarily to utilize the additional flexibility these final regulations provide, while the Department seeks public comment on the collection methods—including their utility and burden. Contemporaneously with the publication of these interim final regulations, the Department of Labor published a notice elsewhere in today’s issue of the Federal Register informing the public of their intention to extend the OMB approval.

Consistent with the analysis in the HHS PRA section above the Department expects that each of the estimated 122 organizations will spend approximately 50 minutes in preparation time and incur $0.54 mailing cost to satisfy the requirements. The DOL information collections in this rule are found in 29 CFR 2510.3–16 and 2590.715–2713A and are summarized as follows:

Type of Review: Revised Collection. Agency: DOL—EBSA.

Title: Coverage of Certain Preventive Services Under the Affordable Care Act. OMB Numbers: 1210–0150.

Affected Public: Private Sector—businesses or other for profits.

Total Respondents: 61 (combined with HHS total is 122).

Total Responses: 61 (combined with HHS total is 122).

Frequency of Response: On occasion. 

Estimated Total Annual Burden Hours: 51 (combined with HHS total is 102 hours).

Estimated Total Annual Burden Cost: $33 (combined with HHS total is 66).

E. Regulatory Flexibility Act—Department of Labor and Department of Health and Human Services

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the APA (5 U.S.C. 551 et seq.) and that are likely to have a significant economic impact on a substantial number of small entities. Under Section 553(b) of the APA, a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. These interim final regulations are exempt from APA’s prior notice and comment requirement because the Departments made a good cause finding that a general notice of proposed rulemaking is not necessary earlier in this preamble. Therefore, the RFA does not apply and the Departments are not required to either certify that the rule would not have a significant economic impact on a substantial number of small entities or conduct a regulatory flexibility analysis.

Nevertheless, the Departments carefully considered the likely impact of the rule on small entities in connection with their assessment under Executive Order 12866. The Departments do not expect that these interim final regulations will have a significant economic effect on a substantial number of small entities, because they will not result in any additional costs to affected entities. Instead, the regulations merely provide an alternative means for eligible organizations to provide notice of their religious objection to coverage of all, or a subset of, contraceptive services.

F. 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 interim final regulations do not include any federal mandate that may result in expenditures by state, local, or tribal governments, nor do they impose any federal mandates that may impose an annual burden of $100 million, adjusted for inflation, or more on the private sector.10

G. 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.

These interim final regulations do not have any Federalism implications, since they only provide an eligible organization with an alternative process to provide notice of its religious objection to coverage of all or a subset of contraceptive services.

V. Statutory Authority

The Department of the Treasury temporary regulations are adopted

10In 2014, that threshold level is approximately $141 million.
pursuant to the authority contained in sections 7805 and 9833 of the Code.


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, State regulation of health insurance.

Signed this 20th day of August 2014.

John Dalrymple,
Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Mark J. Mazur,
Assistant Secretary of the Treasury (Tax Policy).

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

Marilyn Tavenner,
Administrator, Centers for Medicare & Medicaid Services.

Approved: August 20, 2014.


Sylvia M. Burwell,
Secretary, Department of Health and Human Services.

Mark J. Mazur,
Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

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

Marilyn Tavenner,
Administrator, Centers for Medicare & Medicaid Services.

Signed this 20th day of August 2014.

PART 54—PENSION EXCISE TAXES

§ 54.9815–2713A Accommodations in connection with coverage of preventive health services.

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

(b) [Reserved]. For further guidance, see § 54.9815–2713AT(c)(1).

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

(2) If a plan objects to coverage of some or all contraceptive services, it must provide updated information to the Secretary of Health and Human Services, the notice must include the name of the eligible organization and the basis on which it qualifies for an accommodation; its objection based on sincerely held religious beliefs to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable); the plan name and type (i.e., whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of ERISA section 3(33)); and the name and contact information for any of the plan’s third party administrators and health insurance issuers. If there is a change in any of the information required to be included in the notice, the organization must provide updated information to the Secretary of Health and Human Services. The Department of Labor (working with the Department of Health and Human Services), will send a separate notification to each of the plan’s third party administrators informing the third party administrator that the Secretary of Health and Human Services has received a notice under paragraph (b)(1)(ii) of this section and describing the obligations of the third party administrator under 29 CFR 2510.3–16 and this section and under § 54.9815–2713A.

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

§ 54.9815–2713AT Accommodations in connection with coverage of preventive health services (temporary).

(a) [Reserved]. For further guidance, see § 54.9815–2713A(a).

(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) are satisfied:

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

(ii) The eligible organization provides either a copy of the self-certification to each third party administrator or a notice to the Secretary of Health and Human Services that it is an eligible organization and of its religious objection to coverage of all or a subset of contraceptive services.

(A) When a copy of the self-certification is provided directly to a third party administrator, such self-certification must include notice that obligations of the third party administrator are set forth in 29 CFR 2510.3–16 and this section and under § 54.9815–2713A.

(B) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization and the basis on which it qualifies for an accommodation; its objection based on sincerely held religious beliefs to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable); the plan name and type (i.e., whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of ERISA section 3(33)); and the name and contact information for any of the plan’s third party administrators and health insurance issuers. If there is a change in any of the information required to be included in the notice, the organization must provide updated information to the Secretary of Health and Human Services. The Department of Labor (working with the Department of Health and Human Services), will send a separate notification to each of the plan’s third party administrators informing the third party administrator that the Secretary of Health and Human Services has received a notice under paragraph (b)(1)(ii) of this section and describing the obligations of the third party administrator under 29 CFR 2510.3–16 and this section and under § 54.9815–2713A.

(2) If a third party administrator receives a copy of the self-certification from an eligible organization or a notification from the Department of Labor, as described in paragraph (b)(1)(ii) of this section and agrees to enter into or remain in a contractual relationship with the eligible organization.
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, on 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, on 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 a copy of the self-certification from the eligible organization or notification from the Department of Labor described in paragraph (b)(1)(ii) of this section.

(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 § 54.9815–2713A(a)(1)(iv) to provide contraceptive coverage in accordance with § 54.9815–2713. An issuer may not require any further documentation from the eligible organization regarding its status as such.

(ii) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization and the basis on which it qualifies for an accommodation; its objection based on its sincerely held religious beliefs to coverage of some or all contraceptive services, as applicable (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable); the plan name and type (i.e., whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of ERISA section 3(33)); and the name and contact information for any of the plan’s third party administrators and health insurance issuers. If there is a change in any of the information required to be included in the notice, the organization must provide updated information to the Secretary of Health and Human Services. The Department of Health and Human Services will send a separate notification to each of the plan’s health insurance issuers informing the issuer that the Secretary of Health and Human Services has received a notice under paragraph (c)(1) of this section and describing the obligations of the issuer under this section and under § 54.9815–2713A.

(2) Payments for contraceptive services. (i) A group health insurance issuer that receives a copy of the self-certification or notification described in paragraph (b)(1)(ii) of this section with respect to a group health plan established or maintained by an eligible organization, as defined in § 2590.715–2713A(a) of this chapter, if the eligible organization provides a copy of the self-certification of its objection to administering or funding any contraceptive benefits in accordance with § 2590.715–2713A(b)(1)(i) of this chapter to a third party administrator, the self-certification 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 § 2590.715–2713A(a)(1)(iv) of this chapter to which the eligible organization objects on religious grounds, and shall supersede any earlier designation. If, instead, the eligible organization notifies the Secretary of Health and Human Services of its objection to administering or funding any contraceptive benefits in accordance with § 2590.715–2713A(b)(1)(i) of this chapter, the Department of Labor, working with the Department of Health and Human Services, shall separately provide notification to each third party administrator that such third party administrator shall be the plan administrator under section 3(16) of ERISA for any contraceptive services required to be covered under § 2590.715–2713A(a)(1)(iv) of this chapter to which the eligible organization objects on religious grounds, with
respect to benefits for contraceptive services that the third party administrator would otherwise manage. Such notification from the Department of Labor shall be an instrument under which the plan is operated and shall supersede any earlier designation.

(c) A third party administrator that becomes a plan administrator pursuant to this section shall be responsible for—

(1) Complying 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 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

§ 2590.715–2713A Accommodations in connection with coverage of preventive health services.

(a) * * * * *

(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 either a copy of the self-certification to each third party administrator or a notice to the Secretary of Health and Human Services that it is an eligible organization and of its religious objection to coverage of all or a subset of contraceptive services.

(A) When a copy of the self-certification is provided directly to a third party administrator, such self-certification must include notice that obligations of the third party administrator are set forth in § 2510.3–16 of this chapter and this section.

(B) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization and the basis on which it qualifies for an accommodation; its objection based on sincerely held religious beliefs to coverage of some or all contraceptive services (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable); the plan name and type (i.e., whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of ERISA section 3(33)); and the name and contact information for any of the plan’s third party administrators and health insurance issuers. If there is a change in any of the information required to be included in the notice, the organization must provide updated information to the Secretary of Health and Human Services. The Department of Labor (working with the Department of Health and Human Services), shall send a separate notification to each of the plan’s third party administrators informing the third party administrator that the Secretary of Health and Human Services has received a notice under paragraph (b)(1)(i) of this section and describing the obligations of the third party administrator under § 2510.3–16 of this chapter and this section.

(2) If a third party administrator receives a copy of the self-certification from an eligible organization or a notification from the Department of Labor, as described in paragraph (b)(1)(ii) 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 a copy of the self-certification from the eligible organization or notification from the Department of Labor described in paragraph (b)(1)(ii) of this section.

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

(i) When a copy of the self-certification is provided directly to an issuer, the issuer has sole responsibility for providing such coverage in accordance with § 2590.715–2713. An issuer may provide any further documentation from the eligible organization regarding its status as such.
§ 147.131 Exemption and accommodations in connection with coverage of preventive health services.

(c) * * * *(1) General rule. A group health plan established or maintained by an eligible organization that provides benefits through one or more group health insurance issuers complies for one or more plan years with any requirement under §147.130(a)(1)(iv) to provide contraceptive coverage if the eligible organization or group health plan provides either a copy of the self-certification to each issuer providing coverage in connection with the plan or a notice to the Secretary of Health and Human Services that it is an eligible organization and of its religious objection to coverage for all or a subset of contraceptive services.

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

(ii) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization and the basis on which it qualifies for an exemption; its objection based on its sincerely held religious beliefs to coverage of some or all contraceptive services, as applicable (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable); the plan name and type (i.e., whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of ERISA section 3(33)); and the name and contact information for any of the plan’s third party administrators and health insurance issuers. If there is a change in any of the information required to be included in the notice, the organization must provide updated information to the Secretary of Health and Human Services. The Department of Health and Human Services will send a separate notification to each of the plan’s health insurance issuers informing the issuer that the Secretary of Health and Human Services has received a notice under paragraph (c)(1) of this section and describing the obligations of the issuer under this section.

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

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

9. 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.

10. Section 147.131 is amended by revising paragraphs (c)(1) and (c)(2)(i) introductory text to read as follows:

(ii) When a notice is provided to the Secretary of Health and Human Services, the notice must include the name of the eligible organization and the basis on which it qualifies for an accommodation; its objection based on its sincerely held religious beliefs to coverage of some or all contraceptive services, as applicable (including an identification of the subset of contraceptive services to which coverage the eligible organization objects, if applicable); the plan name and type (i.e., whether it is a student health insurance plan within the meaning of 45 CFR 147.145(a) or a church plan within the meaning of ERISA section 3(33)); and the name and contact information for any of the plan’s third party administrators and health insurance issuers. If there is a change in any of the information required to be included in the notice, the organization must provide updated information to the Secretary of Health and Human Services. The Department of Health and Human Services will send a separate notification to each of the plan’s health insurance issuers informing the issuer that the Secretary of Health and Human Services has received a notice under paragraph (c)(1) of this section and describing the obligations of the issuer under this section.

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

* * * * *

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2014–0686]

Annual Marine Events in the Eighth Coast Guard District, Sabine River; Orange, TX

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce Special Local Regulations for the Southern Professional Outboard Racing Tour (S.P.O.R.T.) boat races to be held on the Sabine River in Orange, TX from 3 p.m. on September 19, 2014, through 6 p.m. on September 21, 2014. This action is necessary to provide for the safety of the participants, crew, spectators, participating vessels, non-participating vessels and other users of the waterway. During the enforcement period, the Coast Guard Patrol Commander will enforce restrictions upon, and control the movement of, vessels in the zone established by the Special Local Regulation.

DATES: The regulation in 33 CFR 100.801 will be enforced from 3 p.m. to 6 p.m. on September 19, 2014; and from 9 a.m. to 6 p.m. on September 20 and 21, 2014.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice of enforcement, call or email Mr. Scott Whalen, U.S. Coast Guard Marine Safety Unit Port Arthur, TX; telephone 409–719–5086, email scott.k.whalen@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce Special Local Regulation for the annual S.P.O.R.T. boat races in 33 CFR 100.801 (Table 3, Line 5) on September 19, 2014, from 3 p.m. to 6 p.m. and on September 20 and 21, 2014, from 9 a.m. to 6 p.m.

This Special Local Regulation encompasses all waters of the Sabine River south of latitude 30°05′33″ N and waters north of latitude 30°05′45″ N North American Datum (NAD 83).

Under the provisions of 33 CFR 100.801, a vessel may not enter the