[Billing Codes: 4830-01-P; 4510-29-P; 4120-01-P]

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 54

[REG-122707-12]

RIN 1545-BL07

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210-AB55

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 146 and 147

[CMS-9979-P]

RIN 0938-AR48

Incentives for Nondiscriminatory Wellness Programs in Group Health Plans

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: Notice of proposed rulemaking.

SUMMARY: This document proposes amendments to regulations, consistent with the Affordable Care Act, regarding nondiscriminatory wellness programs in group health coverage. Specifically, these proposed regulations would increase the maximum permissible reward under a health-contingent wellness program offered in connection with a group health plan (and any

related health insurance coverage) from 20 percent to 30 percent of the cost of coverage. The proposed regulations would further increase the maximum permissible reward to 50 percent for wellness programs designed to prevent or reduce tobacco use. These regulations also include other proposed clarifications regarding the reasonable design of health-contingent wellness programs and the reasonable alternatives they must offer in order to avoid prohibited discrimination.

DATES: Comments are due on or before [**INSERT DATE 60 DAYS AFTER PUBLICATION IN FEDERAL REGISTER**].

ADDRESSES: Written comments may be submitted to the Department of Labor as specified below. Any comment that is submitted will be shared with the other Departments 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 "Wellness Programs", may be submitted by one of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail or Hand Delivery: Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, Room N-5653, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210, Attention: Wellness Programs.

Comments received will be posted without change to www.regulations.gov and www.dol.gov/ebsa, 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: Amy Turner or Beth Baum, Employee Benefits Security Administration, Department of Labor, at (202) 693-8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 622-6080; or Jacob Ackerman, Centers for Medicare & Medicaid Services, Department of Health and Human Services, 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 (www.dol.gov/ebsa). In addition, information from HHS on private health insurance for consumers can be found on the Centers for Medicare & Medicaid Services (CMS) website (www.cciio.cms.gov/) and information on health reform can be found at www.HealthCare.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A. Introduction

The Patient Protection and Affordable Care Act, Pub. L. 111-148, was enacted on March 23, 2010; the Health Care and Education Reconciliation Act, Pub. L. 111-152, was enacted on March 30, 2010 (these 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 term "group health plan" includes both insured and self-insured group health plans.[1] 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 (the Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and to make them applicable to group health plans and health insurance issuers providing health insurance coverage in connection with group health plans. The PHS Act sections incorporated by these references are sections 2701 through 2728.

B. Wellness Exception to HIPAA Nondiscrimination Provisions

Prior to the enactment of the Affordable Care Act, Titles I and IV of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 104-191, added section 9802 of the Code, section 702 of ERISA, and section 2702 of the PHS Act (HIPAA nondiscrimination and wellness provisions). These provisions generally prohibit group health plans and group health insurance issuers from discriminating against individual participants and beneficiaries in eligibility, benefits, or premiums based on a health factor.[2] An exception to the general rule allows premium discounts or rebates or modification to otherwise applicable cost sharing (including copayments, deductibles or coinsurance) in return for adherence to certain programs of health promotion and disease prevention. The Departments of Labor, Health and Human Services (HHS), and the Treasury (collectively, the Departments) have implemented this exception by allowing benefits (including cost sharing), premiums, or contributions to vary based

[1] The term "group health plan" is used in title XXVII of the PHS Act, part 7 of ERISA, and chapter 100 of the Code, and is distinct from the term "health plan," as used in other provisions of title I of the Affordable Care Act. The term "health plan" does not include self-insured group health plans.

[2] The HIPAA nondiscrimination provisions set forth eight health status-related factors, which the December 13, 2006 final regulations on nondiscrimination and wellness programs refer to as "health factors." Under HIPAA and the 2006 regulations, the eight health factors are health status, medical condition (including both physical and mental illnesses), claims experience, receipt of health care, medical history, genetic information, evidence of insurability (including conditions arising out of acts of domestic violence), and disability. See 66 FR 1379, January 8, 2001.

on participation in a wellness program if such a program adheres to certain conditions set forth in regulations.

The Departments published joint final regulations on December 13, 2006 at 71 FR 75014 (the 2006 regulations) regarding the HIPAA nondiscrimination and wellness provisions.[3] The 2006 regulations divide wellness programs into two general categories. The first category is programs that either do not require an individual to meet a standard related to a health factor in order to obtain a reward or that do not offer a reward at all ("participatory wellness programs"). Participatory wellness programs comply with the nondiscrimination requirements without having to satisfy any additional standards if participation in the program is made available to all similarly situated individuals.[4] Examples of participatory wellness programs in the 2006 regulations include a fitness center reimbursement program,[5] a diagnostic testing program that does not base any reward on test outcomes, a program that waives cost sharing for prenatal or well-baby visits,[6] a program that reimburses employees for the costs of smoking cessation programs regardless of whether the employee quits smoking, and a program that provides

[3] See 26 CFR 54.9802-1; 29 CFR 2590.702; 45 CFR 146.121. Prior to issuance of the final 2006 regulations, the Departments published interim final regulations with request for comment implementing the HIPAA nondiscrimination provisions on April 8, 1997 at 62 FR 16894, followed by proposed regulations regarding wellness programs on January 8, 2001 at 66 FR 1421.

[4] See paragraph (f)(1) of the 2006 regulations. See also 26 CFR 54.9802-1(d), 29 CFR 2590.702(d), and 45 CFR 146.121(d), which provide that, generally, distinctions among groups of similarly situated participants in a health plan must be based on bona fide employment-based classifications consistent with the employer's usual business practice. A plan may also distinguish between beneficiaries based on, for example, their relationship to the plan participant (such as spouse or dependent child) or based on the age of dependent children. Distinctions are not permitted to be based on any of the health factors noted earlier.

[5] The Treasury and the IRS note that satisfying the rules for wellness programs does not determine the tax treatment of benefits provided by the wellness program. For example, fitness center fees are generally considered expenses for general good health and thus payment of the fee by the employer is not excluded from income as the reimbursement of a medical expense.

[6] Note that section 2713 of the PHS Act, as added by the Affordable Care Act, and the Departments' interim final regulations at 26 CFR 54.9815-2713T, 29 CFR 2590.715-2713, and 45 CFR 147.130 require non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage to provide benefits for certain preventive health services without the imposition of cost sharing. See also 26CFR 54.9815-1251T, 29 CFR 2590.715-1251, and 45 CFR 147.140 (regarding the definition of grandfathered health plan coverage).

rewards for attending a free health education seminar. There is no limit on the financial incentives for participatory wellness programs.

The second category of wellness programs under the 2006 regulations consists of programs that require individuals to satisfy a standard related to a health factor in order to obtain a reward ("health-contingent wellness programs"). This category includes wellness programs that require an individual to attain or maintain a certain health outcome in order to obtain a reward (such as not smoking, attaining certain results on biometric screenings, or meeting targets for exercise). As outlined in the 2006 regulations,[7] plans and issuers may vary benefits (including cost-sharing mechanisms), premiums, or contributions based on whether an individual has met the standards of a wellness program that meets the requirements of paragraph (f). Paragraph (f)(2) of the 2006 regulations prescribes the following consumer-protection conditions for health-contingent wellness programs:

1. The total reward for such wellness programs offered by a plan sponsor does not exceed 20 percent of the total cost of coverage under the plan.
2. The program is reasonably designed to promote health or prevent disease. For this purpose, it must have a reasonable chance of improving health or preventing disease, not be overly burdensome, not be a subterfuge for discriminating based on a health factor, and not be highly suspect in method.
3. The program gives eligible individuals an opportunity to qualify for the reward at least once per year.
4. The reward is available to all similarly situated individuals. For this purpose, a reasonable alternative standard (or waiver of the otherwise applicable standard) must be

[7] See 26 CFR 54.9802-1(b)(2)(ii) and (c)(3); 29 CFR 2590.702(b)(2)(ii) and (c)(3); and 45 CFR 146.121(b)(2)(ii) and (c)(3).

made available to any individual for whom it is unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard during that period (or for whom it is medically inadvisable to attempt to satisfy the otherwise applicable standard).

5. In all plan materials describing the terms of the program, the availability of a reasonable alternative standard (or the possibility of waiver of the otherwise applicable standard) is disclosed.

C. Amendments Made by the Affordable Care Act

The Affordable Care Act (section 1201) amended the nondiscrimination and wellness program provisions of the PHS Act (but not of ERISA section 702 or Code section 9802). (Affordable Care Act section 1201 also moved those provisions from PHS Act section 2702 to PHS Act section 2705). As amended by the Affordable Care Act, the nondiscrimination and wellness provisions of PHS Act section 2705 largely reflect the 2006 regulations (except as discussed later in this preamble), and extend the nondiscrimination protections to the individual market.[8] The wellness program exception to the prohibition on discrimination under PHS Act section 2705 applies with respect to group health plans (and any health insurance coverage offered in connection with such plans). Section 2705(l) separately provides for a 10-State wellness program demonstration project in the individual market, to be established not later than July 1, 2014 (as such, this proposed rule does not include wellness program policy for the individual market).

D. Application to Grandfathered Plans

Section 1251 of the Affordable Care Act provides that certain amendments made by the Affordable Care Act generally do not apply to plans or health insurance coverage that are in

[8] Section 1201 of the Affordable Care Act also moved the guaranteed availability provisions that were previously codified in PHS Act section 2711 to PHS Act section 2702, and extended those requirements to the individual market.

effect on the date of enactment (and that are not changed in ways specified in implementing regulations),[9] except as specified in section 1251(a)(3) and (4) of the Affordable Care Act. Specifically, section 1251(a)(2) of the Affordable Care Act provides that subtitles A and C of title I of the Affordable Care Act, and the amendments made by such subtitles, "shall not apply" to such grandfathered health plans.

Because the amendments made to the PHS Act in section 1201 of the Affordable Care Act do not apply to grandfathered health plans, the version of PHS Act section 2702 in effect at the time of enactment of the Affordable Care Act (and the 2006 regulations under that section) continues to apply to grandfathered health plans, while the provisions of the new PHS Act section 2705 apply to non-grandfathered health plans for plan years (in the individual market, policy years) beginning on or after January 1, 2014.[10] ERISA section 702 and Code section 9802 continue to govern all group health plans, including grandfathered health plans, and, for plan years beginning on or after January 1, 2014, ERISA section 715(a)(1) and Code section 9815(a)(1) will also apply new PHS Act section 2705 to non-grandfathered health plans.

However, because the Departments believe that the provisions of these proposed regulations would be authorized under either HIPAA or the Affordable Care Act, the Departments are proposing in this rulemaking to apply the same set of standards to both grandfathered and non-grandfathered health plans. As noted, PHS Act section 2705(j) largely adopts the wellness program provisions of the 2006 regulations with some modification and clarification. Consistent with the statutory approach, these proposed regulations would apply the

[9] See 26 CFR 54.9815-1251T, 29 CFR 2590.715-1251, and 45 CFR 147.140 (75 FR 34538, June 17, 2010), as amended (75 FR 70114, November 17, 2010). See also Q5 of Affordable Care Act Implementation FAQs Part II (October 8, 2010), available at http;//www.dol.gov/ebsa/faqs/faq-aca2.html and http://cciio.cms.gov/resources/factsheets/aca_implementation_faqs2.html.

[10] See 26 CFR 54.9815-1251T(c)(2), 29 CFR 2590.715-1251(c)(2), and 45 CFR 147.140(c)(2), providing that a grandfathered health plan must comply with the requirements of the PHS Act, ERISA, and the Code applicable prior to the changes enacted by the Affordable Care Act, to the extent not inconsistent with the rules applicable to a grandfathered health plan (75 FR 34538, June 17, 2010).

rules of PHS Act section 2705, governing rewards for adherence to certain wellness programs, to grandfathered health plans by regulation under authority in the HIPAA nondiscrimination and wellness provisions as was done in the 2006 regulations. This approach is intended to avoid inconsistency across group health coverage and to provide grandfathered plans the same flexibility to promote health and prevent disease as non-grandfathered plans.

II. Overview of the Proposed Rule

These regulations generally propose standards for group health plans and health insurance issuers offering group health insurance coverage with respect to wellness programs. These proposed regulations would replace the wellness program provisions of paragraph (f) of the 2006 regulations and would apply to both grandfathered and non-grandfathered group health plans and group health insurance coverage for plan years beginning on or after January 1, 2014. These regulations also propose to implement the nondiscrimination provisions made applicable to the individual market by section 1201 of the Affordable Care Act. This rulemaking does not propose to modify provisions of the 2006 regulations other than paragraph (f).

A. Two Categories of Wellness Programs

Consistent with the 2006 regulations and PHS Act section 2705(j), these proposed regulations would continue to divide wellness programs into two categories: "participatory wellness programs", which are a majority of wellness programs (as noted below) and "health-contingent wellness programs." Participatory wellness programs are programs that are made available to all similarly situated individuals and that either do not provide a reward or do not include any conditions for obtaining a reward that are based on an individual satisfying a standard that is related to a health factor. Several examples of participatory wellness programs are provided in these proposed regulations, including: (1) a program that reimburses for all or

part of the cost of membership in a fitness center; and (2) a program that provides a reward to employees for attending a monthly, no-cost health education seminar. Participatory programs are not required to meet the five requirements applicable to health-contingent wellness programs.

In contrast, health-contingent wellness programs require an individual to satisfy a standard related to a health factor to obtain a reward (or require an individual to do more than a similarly situated individual based on a health factor in order to obtain the same reward). Like the 2006 regulations, these proposed regulations would continue to permit rewards to be in the form of a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism (such as deductibles, copayments, or coinsurance), the absence of a surcharge, the value of a benefit that otherwise would not be provided under the plan, or other financial or nonfinancial incentives or disincentives. Examples of health-contingent wellness programs in these proposed regulations are: (1) a program that imposes a premium surcharge based on tobacco use; and (2) a program that uses a biometric screening or a health risk assessment to identify employees with specified medical conditions or risk factors (such as high cholesterol, high blood pressure, abnormal body mass index, or high glucose level) and provides a reward to employees identified as within a normal or healthy range (or at low risk for certain medical conditions), while requiring employees who are identified as outside the normal or healthy range (or at risk) to take additional steps (such as meeting with a health coach, taking a health or fitness course, adhering to a health improvement action plan, or complying with a health care provider's plan of care) to obtain the same reward. Under paragraphs (b)(2)(ii) and (c)(3) of the 2006 regulations (which remain unchanged),[11] health-contingent wellness programs

[11] 26 CFR 54.9802-1(b)(2)(ii) and (c)(3); 29 CFR 2590.702(b)(2)(ii) and (c)(3); and 45 CFR 146.121(b)(2)(ii) and (c)(3).

are permissible only if they comply with the provisions of paragraph (f)(3), which are proposed to be amended in this rulemaking.[12]

The Departments believe that appropriately designed wellness programs have the potential to contribute importantly to promoting health and preventing disease. Even after the issuance of the 2006 regulations and the enactment of the Affordable Care Act wellness provisions, however, stakeholder feedback suggests that there continues to be a degree of confusion regarding the scope of the rules governing wellness programs. The Departments hope that these proposed regulations will help dispel the confusion by reiterating that the five regulatory requirements relating to frequency of opportunity to qualify, size of reward, uniform availability and reasonable alternative standards, reasonable design, and notice of other means of qualifying for the reward (summarized below and contained in paragraph (f)(3) of the proposed regulations) apply only to those wellness programs that meet the definition of "health-contingent" programs. As discussed above, these are wellness programs that both provide a reward and condition the reward on satisfying a standard that is related to a health factor. Many wellness programs (those characterized in these regulations as "participatory wellness programs") do not both provide a reward and condition the reward on satisfying a standard that is related to a health factor. Accordingly, as noted, participatory wellness programs are not required to meet the five enumerated requirements applicable to health-contingent wellness programs, but they are required to be made available to all similarly situated individuals.

B. Requirements for Health-Contingent Wellness Programs

Consistent with the 2006 regulations, these proposed regulations generally would maintain the five requirements for health-contingent wellness programs with one significant

[12] Until these proposed regulations are finalized and effective, the provisions of the 2006 regulations, at 26 CFR 54.9802-1(f), 29 CFR 2590.702(f), and 45 CFR 146.121(f) generally remain applicable to group health plans and group health insurance issuers.

modification relating to the size of the reward. In addition, several regulatory provisions have been re-ordered, and clarifications are proposed to address questions and issues raised by stakeholders since the 2006 regulations were issued and to be consistent with the amendments made by the Affordable Care Act, as discussed below.

(1) Frequency of Opportunity to Qualify.

These proposed regulations would, consistent with the 2006 regulations and the amendments made by the Affordable Care Act, require health-contingent wellness programs to give individuals eligible for the program the opportunity to qualify for the reward at least once per year. As stated in the preamble to the 2006 regulations, the once-per-year requirement was included as a bright-line standard for determining the minimum frequency that is consistent with a reasonable design for promoting good health or preventing disease.[13]

(2) Size of Reward.

Like the 2006 regulations, these proposed regulations would continue to limit the total amount of the reward for health-contingent wellness programs with respect to a plan, whether offered alone or coupled with the reward for other health-contingent wellness programs. Specifically, the total reward offered to an individual under an employer's health-contingent wellness programs could not exceed a specified percentage (referred to as the "applicable percentage" in the proposed regulations) of the total cost of employee-only coverage under the plan, taking into account both employer and employee contributions towards the cost of coverage. If, in addition to employees, any class of dependents (such as spouses, or spouses and dependent children) may participate in the health-contingent wellness program, the reward could not exceed the applicable percentage of the total cost of the coverage in which the employee and any dependents are enrolled (such as family coverage or employee-plus-one coverage).

[13] See 71 FR at 75018.

Some stakeholders have raised questions about health-contingent wellness programs that allow dependents to participate, and what portion of the reward should be attributable to each participating dependent. If a class of dependents may participate in a health-contingent wellness program, some have suggested that there be a maximum reward attributable to the employee's participation in the wellness program, such as an amount that does not exceed the applicable percentage of the cost of employee-only coverage. The proposed regulation being issued contemporaneously by HHS proposes that, to comply with PHS Act section 2701, with respect to family coverage, any premium variation for tobacco use must be applied to the portion of premium attributable to each family member. The Departments invite comments on apportionment of rewards in health-contingent wellness programs (which may involve tobacco use and/or other health factors) – for example, should the reward be prorated if only one family member fails to qualify for it.

The 2006 regulations specify 20 percent as the maximum permissible reward for participation in a health-contingent wellness program. PHS Act section 2705(j)(3)(A), effective for plan years beginning on or after January 1, 2014, increases the maximum reward to 30 percent and authorizes the Departments to increase the maximum reward to as much as 50 percent if the Departments determine that such an increase is appropriate. In these proposed regulations, the increase in the applicable percentage from 20 percent to 30 percent, which is effective for plan years beginning on or after January 1, 2014, conforms to the new PHS Act section 2705(j)(3)(A). In addition, the Departments have determined that an increase of an additional 20 percentage points (to 50 percent) for health-contingent wellness programs designed to prevent or reduce tobacco use is warranted to conform to the new PHS Act section 2701, to avoid inconsistency across group health coverage, whether insured or self-insured, or offered in

the small group or large group market, and to provide grandfathered plans the same flexibility to promote health and prevent disease as non-grandfathered plans.

Specifically, PHS Act section 2701, the "fair health insurance premium" provision, sets forth the factors that issuers may use to vary premium rates in the individual or small group market.[14] PHS Act section 2701(a)(1)(A)(iv) provides that issuers in the individual and small group markets cannot vary rates for tobacco use by more than a ratio of 1.5 to 1 (that is, allowing up to a 50 percent premium surcharge for tobacco use). Contemporaneously with the publication of these proposed wellness program regulations, HHS is publishing a proposed regulation that would implement PHS Act section 2701. HHS proposes that a health insurance issuer in the small group market would be able to implement the tobacco use surcharge under PHS Act section 2701 to employees only in connection with a wellness program meeting the standards of PHS Act section 2705(j) and its implementing regulations. As discussed in the preamble to the proposed regulation implementing PHS Act section 2701, HHS is proposing in that rule that the definition of "tobacco use" for purposes of section 2701 be consistent with the approach taken with respect to health-contingent wellness programs designed to prevent or reduce tobacco use under section 2705(j). Comments are solicited in the preamble to the proposed rules implementing section 2701 on possible definitions of "tobacco use" that would be applied for purposes of PHS Act sections 2701 and 2705(j).

[14] Small group market means the health insurance market under which individuals obtain health insurance coverage (directly or through any arrangement) on behalf of themselves (and their dependents) through a group health plan maintained by a small employer. See PHS Act section 2791(e)(5); 45 CFR 144.103. For plan years beginning on or after January 1, 2014, amendments made by the Affordable Care Act provide that the term "small employer" means, in connection with a group health plan with respect to a calendar year and a plan year, an employer who employed an average of at least 1 but not more than 100 employees on business days during the preceding calendar year and who employs at least 1 employee on the first day of the plan year. See PHS Act section 2791(e)(4). In the case of plan years beginning before January 1, 2016, a State may elect to substitute "50 employees" for "100 employees" in its definition of a small employer. See section 1304(b)(3) of the Affordable Care Act.

To coordinate these proposed regulations with the tobacco use rating provisions of PHS Act section 2701, as proposed by HHS, these proposed wellness program regulations would use the new authority in PHS Act section 2705(j)(3)(A) (and, with respect to grandfathered health plans, the preexisting authority in the HIPAA nondiscrimination and wellness provisions) to increase the applicable percentage for determining the size of the reward for participating in a health-contingent wellness program by an additional 20 percentage points (to 50 percent) to the extent that the additional percentage is attributed to tobacco use prevention or reduction. Applying these proposed regulations to all group health plans would provide consistency across markets, giving large, self-insured, and grandfathered employment-based health plans the same added flexibility to promote tobacco-free workforces as small, insured, non-grandfathered health plans.

Examples included in these proposed regulations illustrate how to calculate the applicable percentage. The Departments invite comments on the proposed approach in general and other ideas for coordinating the implementation of the tobacco rating factor under PHS Act section 2701 with the nondiscrimination and wellness program provisions. The Departments also invite comments as to whether additional rules or examples would be helpful to demonstrate compliance with the limitation on the size of the reward when the amount of the reward is variable and is not determinable at the time the reward is established (for example, when the reward is waiver of a copayment for outpatient office visits, the frequency of which will not be predictable for any particular participant or beneficiary under the plan).

(3) Uniform Availability and Reasonable Alternative Standards.

A critical element of these proposed regulations is the requirement that the reward under a health-contingent wellness program be available to all similarly situated individuals. To meet

this requirement, a "reasonable alternative standard" (or waiver of the otherwise applicable standard) for obtaining the reward must be provided for any individual for whom, for that period, it is either unreasonably difficult due to a medical condition to meet the otherwise applicable standard, or for whom it is medically inadvisable to attempt to satisfy the otherwise applicable standard. That is, the same, full reward must be available to individuals who qualify by satisfying a reasonable alternative standard as is provided to individuals who qualify by satisfying the program's otherwise applicable standard. These proposed regulations would generally reiterate the requirements set forth in the 2006 regulations and codified in PHS Act section 2705(j), and provide several additional clarifications.

First, under these proposed regulations, as under the 2006 regulations, in lieu of providing a reasonable alternative standard, a plan or issuer may always waive the otherwise applicable standard and provide the reward. The plan or issuer may waive the otherwise applicable standard and provide a reward for an entire class of individuals or may do so on an individual-by-individual basis based on the facts and circumstances presented.

Second, these proposed regulations would not require plans and issuers to establish a particular alternative standard in advance of an individual's specific request for one. However, a reasonable alternative standard would have to be provided by the plan or issuer (or the condition for obtaining the reward would be required to be waived) upon an individual's request. In this connection, the Departments note that, as stated in the preamble to the 2006 regulations with respect to tobacco cessation, "overcoming an addiction sometimes requires a cycle of failure and renewed effort."[15] Plans and issuers cannot cease to provide a reasonable alternative standard merely because one was not successful before; they must continue to offer a reasonable

[15] See 71 FR 75019.

alternative standard, whether it is the same standard or a new reasonable alternative standard (such as a new weight-loss class or a new nicotine replacement therapy).[16]

All the facts and circumstances would be taken into account in determining whether a plan or issuer has provided a reasonable alternative standard, including but not limited to the following proposed factors:

- If the reasonable alternative standard is completion of an educational program, the plan or issuer must make the educational program available instead of requiring an individual to find such a program unassisted, and may not require an individual to pay for the cost of the program.
- If the reasonable alternative standard is a diet program, the plan or issuer is not required to pay for the cost of food but must pay any membership or participation fee.
- If the reasonable alternative standard is compliance with the recommendations of a medical professional who is an employee or agent of the plan or issuer, and an individual's personal physician states that the medical professional's recommendations are not medically appropriate for that individual, the plan or issuer must provide a reasonable alternative standard that accommodates the recommendations of the individual's physician with regard to medical appropriateness.[17] Plans and issuers may impose standard cost sharing under the plan or coverage for medical items and services furnished in accordance with the physician's recommendations.

[16] Id.

[17] As stated in the preamble to the Departments' regulations on internal claims and appeals and external review processes, adverse benefit determinations based on whether a participant or beneficiary is entitled to a reasonable alternative standard for a reward under a plan's wellness program are situations in which a claim is considered to involve medical judgment and therefore is eligible for Federal external review. See 76 FR 37216.

The Departments intend that these clarifications with respect to offering reasonable alternative standards will help prevent health-contingent wellness programs that provide little to no support to enrollees to improve individuals' health. In addition, as explained later in this preamble, clarifications are proposed to ensure that a health-contingent wellness program is reasonably designed to improve health and is not a subterfuge for underwriting or reducing benefits based on health status. Comments are invited on these provisions, as well as whether other facts and circumstances should be specifically addressed. For example, the Departments seek comment on whether any additional rules or clarifications are needed with respect to the process for determining a reasonable alternative standard.

Finally, the 2006 regulations provided that it is permissible for a plan or issuer to seek verification, such as a statement from the individual's personal physician, that a health factor makes it unreasonably difficult for the individual to satisfy, or medically inadvisable for the individual to attempt to satisfy, the otherwise applicable standard. The Affordable Care Act amendments codified this provision with one modification: PHS Act section 2705(j)(3)(D)(ii) makes clear that physician verification may be required by a plan or issuer "if reasonable under the circumstances." These proposed regulations clarify that it would not be reasonable for a plan or issuer to seek verification of a claim that is obviously valid based on the nature of the individual's medical condition that is known to the plan or issuer. Plans and issuers are permitted under the proposed regulations to seek verification of claims that require the use of medical judgment to evaluate. The Departments solicit comments on whether additional clarifications would be helpful regarding the reasonableness of physician verification.

(4) Reasonable Design.

Consistent with the 2006 regulations and PHS Act section 2705(j), these proposed regulations would continue to require that health-contingent wellness programs be reasonably designed to promote health or prevent disease, not be overly burdensome, not be a subterfuge for discrimination based on a health factor, and not be highly suspect in the method chosen to promote health or prevent disease. The preamble to the 2006 regulations stated that the "reasonably designed" standard was designed to prevent abuse, but otherwise was "intended to be an easy standard to satisfy … There does not need to be a scientific record that the method promotes wellness to satisfy this standard. The standard is intended to allow experimentation in diverse ways of promoting wellness."[18] The preamble also stated that the Departments did not "want plans and issuers to be constrained by a narrow range of programs … but want plans and issuers to feel free to consider innovative programs for motivating individuals to make efforts to improve their health."[19] These proposed regulations would continue to provide plans and issuers flexibility and encourage innovation. Also, as discussed later in this preamble, the regulations include several clarifications to ensure against subterfuge and discrimination. Comments are welcome on whether certain standards, including evidence- or practice-based standards, are needed to ensure that wellness programs are reasonably designed to promote health or prevent disease. The Departments also welcome comments on best practices guidance regarding evidence- and practice-based strategies in order to increase the likelihood of wellness program success. Resources for employers and plans include the Healthier Worksite Initiative of the Centers for Disease Control and Prevention (CDC) at http://www.cdc.gov/nccdphp/dnpao/hwi/.

Under the proposed regulations, the determination of whether a health-contingent wellness program is reasonably designed is based on all the relevant facts and circumstances. To

[18] 71 FR 75018.
[19] 71 FR 75019.

ensure that programs are not a subterfuge for discrimination or underwriting based on health factors such as weight, blood pressure, glucose levels, cholesterol levels, or tobacco use with no or insufficient support to improve individuals' health, the Departments propose that, to the extent a plan's initial standard for obtaining a reward (or a portion of a reward) is based on results of a measurement, test, or screening that is related to a health factor (such as a biometric examination or a health risk assessment), the plan is not reasonably designed unless it makes available to all individuals who do not meet the standard based on the measurement, test, or screening a different, reasonable means of qualifying for the reward. Accordingly, the general approach that was adopted in the 2006 regulations is preserved, which allows plans and issuers to conduct screenings and employ measurement techniques in order to target wellness programs effectively. For example, plans and issuers could target individuals with high cholesterol for participation in cholesterol reduction programs, or individuals who use tobacco for participation in tobacco cessation programs, rather than the entire population of participants and beneficiaries if individuals who do not meet a plan's target biometrics (or similar standards) are provided a different, reasonable means of qualifying for the same reward. The Departments invite comments on this approach, including on ways to ensure that employees will not be subjected to an unreasonable "one-size-fits-all" approach to designing the different means of qualifying for the reward that would fail to take an employee's circumstances into account to the extent that, as a practical matter, they would make it unreasonably difficult for the employee to access those different means of qualifying. Comments also are invited on whether any other consumer protections are needed to ensure that wellness programs are reasonably designed to promote health or prevent disease.

(5) Notice of Other Means of Qualifying for the Reward.

These proposed regulations, consistent with the 2006 regulations and the amendments made by the Affordable Care Act, would require plans and issuers to disclose the availability of other means of qualifying for the reward or the possibility of waiver of the otherwise applicable standard in all plan materials describing the terms of a health-contingent wellness program. If plan materials merely mention that a program is available, without describing its terms, this disclosure is not required. For example, a summary of benefits and coverage (SBC) required under section 2715 of the PHS Act that notes that cost sharing may vary based on participation in a diabetes wellness program, without describing the standards of the program, would not trigger this disclosure.

The 2006 regulations provided sample language that could be used to satisfy this requirement in both the regulatory text and in several examples. However, feedback and experience since the 2006 regulations were published have indicated that the sample language was complicated and confusing to some individuals and may have led fewer individuals to seek a reasonable alternative standard than were eligible. Accordingly, these proposed regulations provide new sample language in the regulatory text and in examples that is intended to be simpler for individuals to understand and to increase the likelihood that those who qualify for a different means of obtaining a reward will contact the plan or issuer to request it. The Departments invite comment on the sample language in both the regulatory text and in the examples.

C. Application to the Individual Health Insurance Market

PHS Act sections 2705(a) and (b), as added by section 1201 of the Affordable Care Act, apply the HIPAA nondiscrimination requirements to health insurance issuers in the individual health insurance market. Accordingly, the HHS proposed regulations include a new § 147.110

which applies the nondiscrimination protections of the 2006 regulations to non-grandfathered, individual health insurance coverage, effective for policy years beginning on or after January 1, 2014. By their terms, the wellness program provisions of PHS Act section 2705(j), however, do not apply to health insurance coverage in the individual market. Accordingly, the wellness program provisions of §146.121(f) apply only to group health plans and group health insurance coverage, not individual market coverage.

D. Applicability Date

These proposed regulations would apply for plan years (in the individual market, policy years) beginning on or after January 1, 2014, consistent with the statutory effective date of PHS Act section 2705, as well as PHS Act section 2701. Comments are invited on this proposed applicability date.

III. Economic Impact and Paperwork Burden

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

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, 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. The Office of Management and Budget (OMB) has determined that this proposed rule is a ‘‘significant regulatory action’’ under section 3(f)(4) of Executive Order 12866, because it raises novel legal or policy issues arising from the President’s priorities. Accordingly, the rule has been reviewed by the OMB.

TABLE 1.-- *Accounting Table*

Benefits	**Quantified**: Minimal due to low expected use of higher reward limits. **Qualitative**: Benefits include the ability to increase the reward based on a health factor to incentivize individuals to meet a health standard associated with improved health, which could reduce health care costs. Improved standards could reduce the use of wellness programs as a subterfuge for discrimination based on a health factor.
Costs	**Quantified**: Minimal since employers are expected to create or expand wellness programs only if the expected benefit exceeds the cost as well as due to low expected use of higher reward limits. **Qualitative**: Costs of the rule include clarifications regarding what costs individuals may pay as part of an alternative means of complying with the health standard. To the extent an individual faces an increased cost for not meeting a health standard, the individual would have reduced resources to use for other purposes.
Transfers	**Quantified**: Minimal due to low expected use of higher reward limits. **Qualitative**: Transfers resulting from the rule include transfers from those who do not meet a health standard to those who do meet the standard or the associated alternative standard.

Based on the Departments' review of the most recent literature and studies regarding wellness programs, the Departments reached the conclusion that the impact of the benefits, costs, and transfers associated with the proposed rules will be minimal. As discussed in this analysis, few health-contingent wellness programs today come close to meeting the 20 percent limit (based on the data, the usual reward percentage ranges from three to 11 percent); therefore, the Departments do not believe that expanding the limit to 30 percent (or 50 percent for programs designed to prevent or reduce tobacco use) will result in significantly higher participation of employers in such programs. The Departments provide a qualitative discussion below and cite the survey data used to substantiate this conclusion. Moreover, most wellness programs appear to be participatory programs that do not require an individual to meet a standard related to a health factor in order to obtain a reward. As stated earlier in this preamble, these participatory wellness programs are not required to meet the five requirements that apply to health-contingent wellness programs, but they are required to be made available to all similarly situated individuals.

Although the Departments believe few plans will expand the reward percentage, the Departments provide a qualitative discussion regarding the sources of benefits, costs, and transfers that could occur if plans were to expand the reward beyond the current maximum of 20 percent. Currently, insufficient broad-based evidence makes it difficult to definitively assess the impact of workplace wellness programs on health outcomes and cost, although , overall, employers largely report that workplace wellness programs in general (participatory programs and health-contingent programs) are delivering on their intended benefit of improving health and reducing costs.

The one source of potential additional cost discussed in the impact analysis is the clarification that plans must provide a reasonable alternative means of satisfying the otherwise applicable standard. The Departments present evidence that currently employers not only allow a reasonable alternative standard, but that most employers already pay for these alternatives. The Departments do not have an estimate of how many plans are not currently paying for alternatives consistent with the clarifications set forth in the proposed regulations, but the number appears to be small. The Departments also employ economic logic to conclude that employers will create or expand their wellness program and provide reasonable alternatives only if the expected benefits exceed the expected costs. Therefore, the Departments believe that the benefits of the proposed rule will justify the costs. The Departments invite comments on these conclusions and request input for improving the analysis, including additional data, surveys, or studies.

B. Background and Need for Regulatory Action—Department of Labor and Department of Health and Human Services

As discussed earlier in this preamble, on December 13, 2006, the Departments issued joint final regulations regarding the HIPAA nondiscrimination and wellness provisions. The

2006 regulations set forth the requirements for wellness programs that provide a reward to individuals who satisfy a standard related to a health factor or provide a reward to individuals to do more than a similarly situated individual based on a health factor. See section I.B. of this preamble for a detailed discussion of the HIPAA nondiscrimination and wellness provisions and the 2006 regulations.

PHS Act section 2705 largely reflects the provisions of the 2006 regulations with some modification and clarification. Most notably, it increased the maximum reward that can be provided under a health-contingent wellness program from 20 percent to 30 percent of the total cost of coverage under the plan and authorized the Departments to increase this percentage to as much as 50 percent of the total cost of coverage under the plan, if the Departments determine that such an increase is appropriate. Accordingly, as discussed in section II.B of this preamble, these proposed regulations increase the applicable percentage for the maximum reward from 20 percent to 30 percent, with an additional increase of 20 percentage points (to 50 percent) for health-contingent wellness programs designed to prevent or reduce tobacco use. The additional increase is warranted to conform to PHS Act section 2701, to avoid inconsistency across group health coverage, whether insured or self-insured, or offered in the small group or large group market, and to provide grandfathered plans the same flexibility to promote health and prevent disease as non-grandfathered plans.[20]

C. Regulatory Alternatives—Department of Labor and Department of Health and Human Services

As stated earlier in this preamble, the 2006 regulations prescribed several requirements for health-contingent wellness programs, including a limitation on the maximum reward of 20

[20] For a discussion of PHS Act section 2701 and the HHS proposed regulation being published contemporaneously with these proposed regulations, see section II.B.2. of this preamble.

percent of the total cost of coverage under the plan.[21] PHS Act section 2705 largely reflects the requirements for wellness programs from the 2006 regulations with some modification and clarification. Most notably, it increased the maximum reward that can be provided under a health-contingent wellness program from 20 percent to 30 percent of the total cost of coverage under the plan and authorized the Departments to increase this percentage to as much as 50 percent, if the Departments determine that such an increase is appropriate.

PHS Act section 2701(a)(1)(A)(iv) provides that issuers in the individual and small group markets cannot vary rates for tobacco use by more than a ratio of 1.5 to 1 (that is, allowing up to a 50 percent rating factor for tobacco use) for non-grandfathered plans. PHS Act section 2701 applies to the individual market and the small group market, but does not apply in the large group market or to self-insured plans. Contemporaneously with the publication of these proposed regulations, HHS is publishing a proposed rule that would provide that an issuer in the small group market would not be able to impose the tobacco rating factor on an individual in the plan under PHS Act section 2701 unless it was imposed as part of a wellness program meeting the standards of PHS Act section 2705(j) and its implementing regulations.

An important policy goal of the Departments is to provide the large group market and self-insured plans and grandfathered health plans with the same flexibility as non-grandfathered plans in the small group market to promote tobacco-free workforces. The Departments considered several regulatory alternatives to meet this objective, including the following:

(1) Stacking premium differentials. One alternative considered was to permit a 50 percent premium differential for tobacco use in the small group market under PHS Act section 2701 without requiring a reasonable alternative standard. Under PHS Act section 2705, an additional 30 percent premium differential would also be permitted if the five criteria for a

[21] See section I.B, earlier in this preamble.

health-contingent wellness program are met (including the offering of a reasonable alternative standard). Under this option, an 80 percent premium differential would have been allowable in the small group market based on factors related to health status. Large and self-insured plans would have been limited to the 30 percent maximum reward. Allowing such a substantial difference between what was permissible in the small group market and the large group market was not in line with the Departments' policy goal of providing consistency in flexibility for plans.

(2) Concurrent premium differentials with no reasonable alternative required to be offered for tobacco use. Another alternative would be to read sections 2701 and 2705 together such that, for non-grandfathered health plans in the small group market, up to a 50 percent premium differential would be permitted based on tobacco use, as authorized under PHS Act section 2701(a)(1)(A)(iv), with no reasonable alternative standard required for the tobacco use program. With respect to non-tobacco-related wellness programs, a reward could be offered only to the extent that a tobacco use wellness program were less than 30 percent of the cost of coverage because the two provisions apply concurrently, and a reward would not be permitted under PHS Act section 2705 if the maximum reward already were exceeded by virtue of PHS Act section 2701. Thus, the 50 percent tobacco surcharge under PHS Act section 2701 would be available only to non-grandfathered, insured, small group plans. The chosen approach is intended to avoid inconsistency and to provide grandfathered plans the same flexibility to promote health and prevent disease as non-grandfathered plans.

D. Current Use of Wellness Programs and Economic Impacts—Department of Labor and Department of Health and Human Services

The current use of wellness programs and economic impacts of these proposed regulations are discussed in this analysis.

Wellness programs[22] have become common among employers in the United States. The 2012 Kaiser/HRET survey indicates that 63 percent of all employers who offered health benefits also offered at least one wellness program.[23] The uptake of wellness programs continues to be more common among large employers. For example, the 2012 Kaiser/HRET survey found that health risk assessments are offered by 38 percent of large employers offering health benefits, but only 18 percent of employers with fewer than 200 workers.

The Kaiser/HRET survey indicates that 29 percent of all firms and 53 percent of large firms offered weight loss programs, while 30 percent and 64 percent, respectively, offered gym memberships or on-site exercise facilities. Meanwhile, 32 percent of all employers and 63 percent of large employers offered smoking cessation resources. Despite widespread availability, actual participation of employees in wellness programs remains limited. While no nationally representative data exist, a 2010 non-representative survey suggests that typically less than 20 percent of eligible employees participate in wellness interventions such as smoking cessation.[24]

Currently, insufficient broad-based evidence makes it difficult to definitively assess the impact of workplace wellness on health outcomes and cost. Yet, overall, employers largely report that workplace wellness programs are delivering on their intended benefit of improving health and reducing costs. According to the 2011 Kaiser/HRET survey, 65 percent of

[22] On behalf of the Departments, RAND researchers did a review of the current literature on this topic. "A Review of the U.S. Workplace Wellness Market" February 2012. The report can be found at http://www.dol.gov/ebsa/pdf/workplacewellnessmarketreview2012.pdf.
[23] Kaiser Family Foundation, *Employer Health Benefits: 2011 Annual Survey.* 2011, The Kaiser Family Foundation, Menlo Park, CA; Health Research & Educational Trust, Chicago, IL.
[24] Nyce, S. *Boosting Wellness Participation Without Breaking the Bank*. TowersWatson Insider. July, 2010:1-9.

respondents that offered wellness programs stated that these programs improved employee health, and 53 percent believed that they reduced costs. Larger firms (defined as those with more than 200 workers in the Kaiser/HRET survey) were significantly more positive, as 74 percent affirmed that workplace wellness programs improved health and 65 percent said that it reduced cost, as opposed to 65 percent and 52 percent, respectively, among smaller firms.[25] Forty percent of respondents to a survey by Buck Consultants indicated that they had measured the impact of their wellness program on the growth trend of their health care costs, and of these, 45 percent reported a reduction in that growth trend. The majority of these employers, 61 percent, reported that the reduction in growth trend of their health care costs was between two and five percentage points per year.[26] There are numerous accounts of the positive impact of workplace wellness programs in many industries, regions, and types of employers. For example, a recent article published by the *Harvard Business Review* cited positive outcomes reported by private-sector employers along several different dimensions, including health care savings, reduced absenteeism, and employee satisfaction.[27]

Several studies that looked at the impact of smoking cessation programs found significantly higher quit rates or less tobacco use.[28,29] Smoking cessation programs typically

[25] Kaiser Family Foundation, Employer Health Benefits: 2010 Annual Survey. 2010, The Kaiser Family Foundation, Menlo Park, CA; Health Research & Educational Trust, Chicago, IL

[26] Buck Consultants, Working Well: A Global Survey of Health Promotion and Workplace Wellness Strategies. 2010, Buck Consultants: San Francisco, CA.

[27] Berry, L., A. Mirabito, and W. Baun, What's the Hard Return on Employee Wellness Programs? Harvard Business Review, 2010. 88(12): p. 104.

[28] Heirich, M. and C.J. Sieck, Worksite cardiovascular wellness programs as a route to substance abuse prevention. J Occup Environ Med, 2000. 42(1): p. 47-56; 40; McMahon, S.D. and L.A. Jason, Social support in a worksite smoking intervention. A test of theoretical models. Behav Modif, 2000. 24(2): p. 184-201; Okechukwu, C.A., et al., MassBuilt: effectiveness of an apprenticeship site-based smoking cessation intervention for unionized building trades workers. Cancer Causes Control, 2009. 20(6): p. 887-94; Sorensen, G., et al., A comprehensive worksite cancer prevention intervention: behavior change results from a randomized controlled trial (United States). J Public Health Policy, 2003. 24(1): p. 5-25.

[29] Gold, D.B., D.R. Anderson, and S.A. Serxner, *Impact of a telephone-based intervention on the reduction of health risks.* Am J Health Promot, 2000. 15(2): p. 97-106; Herman, C.W., et al., *Effectiveness of an incentive-based online physical activity intervention on employee health status.* Journal of Occupational and Environmental Medicine,

offered education and counseling to increase social support.[30] Two studies reported that individuals in the intervention group quit smoking at a rate approximately 10 percentage points higher than those in the control group, and another reported that participants were almost four times as likely as nonparticipants to reduce tobacco use.[31,32] However, these effects should be interpreted with caution. One study showed significant differences in smoking rates at a one-month follow-up, but showed no significant differences in quit rates at six months, highlighting the importance of long-term follow-up to investigate the sustainability of results.[33]

While employer sponsors generally are satisfied with the results, more than half stated in a recent survey that they do not know their programs' return on investment.[34] The peer-reviewed literature, while predominantly positive, covers only a small proportion of the universe of programs, limiting the generalizability of the reported findings. Evaluating such complex interventions is difficult and poses substantial methodological challenges that can invalidate findings.

Overall, surveys suggest that a relatively small percentage of employers use incentives, dollar or otherwise, for wellness programs, although incentive use is more prevalent among larger employers. Data from the 2011 Kaiser/HRET Survey of Employer Health Benefits

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2006. 48(9): p. 889-895; Ozminkowski, R.J., et al., *The impact of the Citibank, NA, health management program on changes in employee health risks over time.* J Occup Environ Med, 2000. 42(5): p. 502-11.

[30] Heirich, M. and C.J. Sieck, Worksite cardiovascular wellness programs as a route to substance abuse prevention. J Occup Environ Med, 2000. 42(1): p. 47-56; McMahon, S.D. and L.A. Jason, Social support in a worksite smoking intervention. A test of theoretical models. Behav Modif, 2000. 24(2): p. 184-201.

[31] Heirich, M. and C.J. Sieck, Worksite cardiovascular wellness programs as a route to substance abuse prevention. J Occup Environ Med, 2000. 42(1): p. 47-56; Okechukwu, C.A., et al., MassBuilt: effectiveness of an apprenticeship site-based smoking cessation intervention for unionized building trades workers. Cancer Causes Control, 2009. 20(6): p. 887-94.

[32] In the study, 42% of participants reduced their risk for tobacco use. See Gold, D.B., D.R. Anderson, and S.A. Serxner, Impact of a telephone-based intervention on the reduction of health risks. Am J Health Promot, 2000. 15(2): p. 97-106.

[33] Kechukwu, C.A., et al., MassBuilt: effectiveness of an apprenticeship site-based smoking cessation intervention for unionized building trades workers. Cancer Causes Control, 2009. 20(6): p. 887-94.

[34] Buck Consultants, Working Well: A Global Survey of Health Promotion and Workplace Wellness Strategies. 2010, Buck Consultants: San Francisco, CA.

indicate that 14 percent of all employers offered cash, gift cards, merchandise, or travel as incentives for wellness program participation. Among large firms (greater than 200 workers), only 27 percent offered these kinds of incentives. Mercer Consulting's 2009 National Survey of Employer-Sponsored Health Plans found similar patterns, estimating that six percent of all firms and 21 percent of those with 500 or more employees provided financial incentives for participating in at least one program.[35] Employers are also looking to continue to add incentives to their wellness programs, for example 17 percent intend to add a reward or penalty based on tobacco-use status.[36] The use of incentives to promote employee engagement remains poorly understood, so it is not clear how type (e.g., cash or non-cash), direction (reward versus penalty), and strength of incentive are related to employee engagement and outcomes. The Health Enhancement Research Organization and associated organizations also recognized this deficiency and provided seven questions for future research.[37] There are also no data on potential unintended effects, such as discrimination against employees based on their health or health behaviors.

Currently, the most commonly incentivized program appears to be associated with completion of a health risk assessment. According to the 2009 Mercer survey, 10 percent of all firms and 23 percent of large employers that offered a health risk assessment provided an incentive for completing the assessment. For other types of health management programs that the survey assessed, only two to four percent of all employers and 13 to 19 percent of large

[35] Mercer, National Survey of Employer-Sponsored Health Plans: 2009 Survey Report. 2010, Mercer
[36] "Employer Survey on Purchasing Value in Health Care," 17th Annual Towers Watson/National Business Group on Health Employer Survey on Purchasing Value in Health Care.
[37] "Guidance for a Reasonably Designed, Employer-Sponsored Wellness Program Using Outcomes-Based Incentives," joint consensus statement of the Health Enhancement Research Organization, American College of Occupational and Environmental Medicine, American Cancer Society and American Cancer Society Cancer Action Network, American Diabetes Association, and American Heart Association.

employers offered incentives.[38] The 2011 Kaiser/HRET survey found that 10 percent of all employers and 42 percent of large firms that offered a health risk assessment provided a financial incentive to employees who completed it.

Incentives are offered in a variety of forms, such as cash, gift cards, merchandise, time off, awards, recognition, raffles or lotteries, reduced health plan premiums and co-pays, and contributions to flexible spending or health savings accounts. As noted previously, the Kaiser/HRET 2011 survey reported that among firms offering health benefits with more than 200 workers, 27 percent offered cash or cash equivalent incentives (including gift cards, merchandise, or travel incentives). In addition, 11 percent of these firms offered lower employee health plan premiums to wellness participants, two percent offered lower deductibles, and 11 percent offered higher health reimbursement account or health savings account contributions. Meanwhile, 13 percent of firms with fewer than 200 workers offered cash or equivalent incentives, and each of the other types of incentives were offered by only two percent or less of firms.

Cash and cash-equivalent incentives remain the most popular incentive for completion of a health risk assessment. The Kaiser/HRET 2011 survey reports that among employers incentivizing completion of a health risk assessment, 41 percent offered cash, gift cards, merchandise or travel, 23 percent allowed workers to pay a smaller proportion of premiums, 12 percent offered lower deductibles, and one percent offered lower coinsurance. Among large employers, 57 percent utilized cash incentives, 34 percent offered smaller premiums, six percent provided lower deductibles, and three percent provided lower coinsurance. Findings from Mercer's 2009 survey suggest similar trends, with five percent of all employers and ten percent of those with 500 or more workers providing cash incentives for completion of a health risk

[38] Mercer, National Survey of Employer-Sponsored Health Plans: 2009 Survey Report. 2010, Mercer.

assessment; one percent and two percent, respectively, offering lower cost sharing; and two percent and seven percent, respectively, offering lower premium contributions.[39] Note that in the Mercer survey, the results cited reflect the incentives provided by all firms that offer a health risk assessment, while the Kaiser/HRET results previously mentioned reflect only firms that incentivize completion of a health risk assessment.

Incentives may be triggered by a range of different levels of employee engagement. The simplest incentives are triggered by program enrollment—that is, by merely signing up for a wellness program. At the next level, incentives are triggered by program participation—for instance, attending a class or initiating a program, such as a smoking cessation intervention. Other incentive programs may require completion of a program, whether or not any particular health-related goals are achieved, to earn an incentive. The health-contingent incentive programs require successfully meeting a specific health outcome (or an alternative standard) to trigger an incentive, such as verifiably quitting smoking. There is little representative data indicating the relative prevalence of these different types of triggers. The most common form of outcome-based incentives is reportedly awarded for smoking cessation. The 2010 survey by NBGH and TowersWatson indicated that while 25 percent of responding employers offered a financial incentive for employees to become tobacco-free, only four percent offered financial incentives for maintaining a BMI within target levels, three percent did so for maintaining blood pressure within targets, and three percent for maintaining targeted cholesterol levels.[40]

The value of incentives can vary widely. Estimates from representative surveys of the average value of incentives per year range between $152[41] and $557,[42] or between three and 11

[39] Mercer, National Survey of Employer-Sponsored Health Plans: 2009 Survey Report. 2010, Mercer.
[40] TowersWatson, Raising the Bar on Health Care: Moving Beyond Incremental Change.
[41] Mercer, *National Survey of Employer-Sponsored Health Plans: 2009 Survey Report.* 2010, Mercer.

percent of the $5,049 average cost of individual coverage in 2010,[43] among employees who receive them. This suggests that companies typically are not close to reaching the 20 percent of the total cost of coverage threshold set forth in the 2006 regulations. These findings indicate that based on currently available data, increasing the maximum reward for particpating in a health-contingent wellness program to 30 percent (and the Departments' decision to propose an additional 20 percentage points for programs designed to prevent or reduce tobacco use) is unlikely to have a significant impact. Additionally, as discussed earlier in this preamble, today most incentive-based wellness programs are associated with completion of a health risk assessment irrespective of the results, and therefore are not subject to the limitation, because such programs are not health-contingent wellness programs.

The Departments lack sufficient information to assess how firms that currently are at the 20 percent limit will respond to the increased limits and welcome public comments regarding this issue. If firms already viewed the current 20 percent reward limit as sufficient, then the Depatments would not expect that increasing the limit would provide an incentive for program design changes.

It is possible that the increased wellness program reward limits will incentivize firms without health-contingent wellness programs to establish them. The Departments, however, do not expect a significant number of new programs to be created as a result of this change because firms without health-contingent wellness programs could already have provided rewards up to the 20 percent limit before the enactment of the Affordable Care Act, but did not.

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[42] Linnan, L., et al., *Results of the 2004 national worksite health promotion survey.* American Journal of Public Health, 2008. 98(8): p. 1503-1509.
[43] Kaiser Family Foundation, *Employer Health Benefits: 2010 Annual Survey.*

Two critical elements of these proposed regulations are (1) the standard that the reward under a health-contingent wellness program be available to all similarly situated individuals and (2) the standard that a program be reasonably designed to promote health or prevent disease.[44]

As discussed earlier in this preamble, the regulation does not prescribe a particular type of alternative standard that must be provided. Instead, it permits plan sponsors flexibility to provide any reasonable alternative. The Departments expect that plan sponsors will select alternatives that entail the minimum net costs (or, stated differently, the maximum net benefits) that are possible to achieve derive offsetting benefits, such as a higher smoking cessation success rate.

It seems reasonable to presume that the net cost plan sponsors will incur in the provision of alternatives, including transfers as well as new economic costs and benefits, will not exceed the transfer cost of waiving surcharges for all plan participants who qualify for alternatives. The Departments expect that many plan sponsors will find more cost effective ways to satisfy this requirement, should they exercise the option to provide incentives through a health-contingent wellness program and that the true net cost to them will therefore be much smaller than the transfer cost of waiving surcharges for all plan participants who qualify for alternatives. The Departments have no basis for estimating the magnitude of the cost of providing alternative standards or of potential offsetting benefits, however, and therefore solicit comments from the public on this question.

The Departments note that plan sponsors will have strong motivation to identify and provide alternative standards that have positive net economic effects. Plan sponsors will be disinclined to provide alternatives that undermine their overall wellness program and worsen

[44] See section II.B , earlier in this preamble for a more detailed discussion of these requirements.

behavioral and health outcomes, or that make financial rewards available absent meaningful efforts by participants to improve their health habits and overall health. Instead plan sponsors will be inclined to provide alternatives that sustain or reinforce plan participants' incentive to improve their health habits and overall health, and/or that help participants make such improvements. It therefore seems likely that gains in economic welfare from this requirement will equal or outweigh losses. The Departments intend that the requirement to provide reasonable alternatives will reduce instances where wellness programs serve only to shift costs to higher risk individuals and increase instances where programs succeed at helping high risk individuals improve their health. The Departments solicit comments on its assumption.

In considering the transfers that might derive from the availability of (and participants' satisfaction with) alternative means of qualifying for the reward, the transfers arising from this requirement may take the form of transfers to participants who satisfy new alternative wellness program standards from plan sponsors, to such participants from other participants, or some combination of these. The existence of a wellness program with a reward contigent on meeting a standard related to a health factor creates a transfer from those who do not meet the standard to those who do meet the standard. Allowing individuals to meet an alternative standard to receive the reward is a transfer to those who use the alternative standard from everyone else in the risk pool.

The reward associated with the wellness program is an incentive to encourage individuals to meet health standards associated with better or improved health, which in turn is associated with lower health care costs. If the rewards are effective, health care costs will be reduced as an individual's health improves. Some of these lower health care costs could translate into lower premiums paid by employers and employees, which could offset some of the transfers. To the

extent larger rewards are more effective at improving health and lowering costs, these proposed regulations would produce more benefits than the current regulations.

Rewards also could create costs to individuals and to the extent the new larger rewards create more costs than smaller rewards, these proposed regulations could increase the costs relative to the existing regulations. To the extent an individual does not meet a standard or satisfy an alternative standard, they could face higher costs, for example in the case of a surcharge for smoking they could face up to a 50 percent increase in their premiums.

Based on the foregoing discussion, the Departments expect the benefits, costs, and transfers associated with these proposed regulations to be minimal. However, the Departments are not able to provide aggregate estimates, because they do not have sufficent data to estimate the number of plans that will take advantage of the new limits.

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) applies to most Federal rules that are subject to the notice and comment requirements of section 553(b) of the Administrative Procedure Act (5 U.S.C. 551 et seq.). Unless an agency certifies that such a rule will not have a significant economic impact on a substantial number of small entities, section 603 of the RFA requires the agency to present an initial regulatory flexibility analysis at the time of the publication of the notice of proposed rulemaking describing the impact of the rule on small entities. Small entities include small businesses, organizations and governmental jurisdictions.

For purposes of analysis under the RFA, the Departments propose to continue to consider a small entity to be an employee benefit plan with fewer than 100 participants. The basis of this definition is found in section 104(a)(3) of ERISA, which permits the Secretary of Labor to

prescribe simplified annual reports for welfare benefit plans that cover fewer than 100 participants.[45]

Further, while some large employers may have small plans, in general, small employers maintain most small plans. Thus, the Departments believe that assessing the impact of these proposed regulations on small plans is an appropriate substitute for evaluating the effect on small entities.

The definition of small entity considered appropriate for this purpose differs, however, from a definition of small business that is based on size standards promulgated by the Small Business Administration (SBA) (13 CFR § 121.201) pursuant to the Small Business Act (15 U.S.C. 631 et seq.). The Departments therefore request comments on the appropriateness of the size standard used in evaluating the impact of these proposed regulations on small entities. The Departments have consulted with the SBA Office of Advocacy concerning use of this participant count standard for RFA purposes. See 13 CFR 121.902(b)(4).

The Departments expect that these proposed regulations will affect few small plans. While a large number of small plans offer a wellness program, the 2011 Kaiser/HRET survey reported that only 13 percent of employers with fewer than 200 employees had a wellness program that offered cash or cash equivalent incentives (including gift cards, merchandise, or travel incentives.)[46] In addition, only two percent of these firms offered lower employee health plan premiums to wellness participants, one percent offered lower deductibles, and one percent

[45] Under ERISA section 104(a)(2), the Secretary may also provide exemptions or simplified reporting and disclosure requirements for pension plans. Pursuant to the authority of ERISA section 104(a)(3), the Department of Labor has previously issued at 29 CFR 2520.104–20, 2520.104–21, 2520.104–41, 2520.104–46, and 2520.104b–10 certain simplified reporting provisions and limited exemptions from reporting and disclosure requirements for small plans, including unfunded or insured welfare plans, that cover fewer than 100 participants and satisfy certain other requirements.

[46] Kaiser Family Foundation, *Employer Health Benefits: 2011 Annual Survey.* 2011, The Kaiser Family Foundation, Menlo Park, CA; Health Research & Educational Trust, Chicago, IL.

offered higher health reimbursement account or health savings account contributions. Therefore, the Departments expect that few small plans will be affected by increasing the rewards threshold from 20 percent to 30 percent (50 percent for programs targeting tobacco use prevention or reduction), because a small percentage of plans have rewards-based wellness programs. Moreover, as discussed in the Economic Impacts section earlier in this preamble, few plans that offer rewards-based wellness programs come close to reaching the 20 percent limit, and most incentive-based wellness programs are associated with completing the health risk assessment irrespective of the results, which are not subject to the limitation.

The Kaiser/HRET survey also reports that about 88 percent of small plans had their wellness programs provided by the health plan provider. Industry experts indicated to the Departments that when wellness programs are offered by the health plan provider, they typically supply alternative education programs and offer them free of charge. This finding indicates that the requirement in the proposed rule for rewards-based wellness programs to provide and pay for a reasonable alternative standard for individuals for whom it is either unreasonably difficult or medically inadvisable to meet the original standard will impose little new costs or transfers to the affected plans.

Based on the foregoing, the Departments herby certify that these proposed regulations will not have a significant economic impact on a substantial number of small entities.

F. Paperwork Reduction Act– Department of Labor and Department of the Treasury

The 2006 final regulations regarding wellness programs did not include an information collection request (ICR). These proposed regulations, like the 2006 final regulations, provide that if a plan's wellness program requires individuals to meet a standard related to a health factor in order to qualify for a reward and if the plan materials describe this standard, the materials

must also disclose the availability of other means of qualifying for the reward or the possibility of waiver of the otherwise applicable standard. If plan materials merely mention that a program is available, the disclosure relating to alternatives is not required. These proposed regulations include samples of disclosures that could be used to satisfy this requirement.

In concluding that these proposed regulations did not include an ICR, the Departments reasoned that much of the information required was likely already provided as a result of state and local requirements or the usual business practices of group health plans and group health insurance issuers in connection with the offer and promotion of health care coverage. In addition, the sample disclosures would enable group health plans to make any necessary modifications with minimal effort.

Finally, although the proposed regulations do not include an ICR, the regulations could be interpreted to require a revision to an existing collection of information. Administrators of group health plans covered under Title I of ERISA are generally required to make certain disclosures about the terms of a plan and material changes in terms through a Summary Plan Description (SPD) or Summary of Material Modifications (SMM) pursuant to sections 101(a) and 102(a) of ERISA and related regulations. The ICR related to the SPD and SMM is currently approved by OMB under OMB control number 1210-0039, which is currently scheduled to expire on April 30, 2013. While these materials may in some cases require revisions to comply with the proposed regulations, the associated burden is expected to be negligible, and is already accounted for in the SPD, SMM, and the ICR by a burden estimation methodology, which anticipates ongoing revisions. Based on the foregoing, the Departments do not expect that any change to the existing ICR arising from these proposed regulations will be substantive or material. Accordingly, the Departments have not filed an application for approval of a revision

to the existing ICR with OMB in connection with these proposed regulations.

G. Paperwork Reduction Act– Department of Health and Human Services

Under the Paperwork Reduction Act of 1995, the Department is required to provide 60-day notice in the Federal Register and solicit public comment before a collection of information requirement is submitted to OMB for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires the Department to solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated techniques.

Section 146.121(f)(1)(iv) stipulates that the plan or issuer disclose in all plan materials describing the terms of the program the availability of a reasonable alternative standard to qualify for the reward under a wellness program. However, for plan materials that merely mention that a program is available, without describing its terms, the disclosure is not required. The burden associated with this requirement was previously approved under OMB control number 0938-0819. We are not seeking reinstatement of the information collection request under the aforementioned OMB control number, since we believe that much of the information required is likely already provided as a result of state and local requirements or the usual business practices of group health plans and group health insurance issuers in connection with the offer and promotion of health care coverage. In addition, the sample disclosures would

enable group health plans to make any necessary modifications with minimal effort.

H. Special Analyses – Department of the Treasury

For purposes of the Department of the Treasury it has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these proposed regulations, and, because these proposed 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. Pursuant to section 7805(f) of the Code, this notice of proposed rulemaking has been submitted to the Small Business Administration for comment on its impact on small business.

I. Congressional Review Act

These proposed regulations are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. § 801 et seq.) and, if finalized, will be transmitted to Congress and the Comptroller General for review. These regulations, do not constitute a "major rule," as that term is defined in 5 U.S.C. § 804 because they are unlikely to result in (1) an annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, or federal, State or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

J. 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 proposed regulations do not include any federal mandate that may result in expenditures by state, local, or tribal governments, nor does it include mandates which may impose an annual burden of $100 million, adjusted for inflation,[47] or more on the private sector.

K. Federalism Statement – Department of Labor and Department of Health and Human Services

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 the States, the relationship between the national government and States, or on the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with State and local officials, and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the regulation.

In the Departments' view, these proposed regulations have federalism implications, however, in the Departments' view, the federalism implications of these final regulations are substantially mitigated because, with respect to health insurance issuers, the vast majority of States have enacted laws, which meet or exceed the federal HIPAA standards prohibiting discrimination based on health factors. Therefore, the regulations are not likely to require substantial additional oversight of States by the Department of HHS.

In general, through section 514, ERISA supersedes State laws to the extent that they relate to any covered employee benefit plan, and preserves State laws that regulate insurance,

[47] In 2012, that threshold level is approximately $139 million.

banking, or securities. While ERISA prohibits States from regulating a plan as an insurance or investment company or bank, HIPAA added a new preemption provision to ERISA (as well as to the PHS Act) narrowly preempting State requirements for group health insurance coverage. With respect to the HIPAA nondiscrimination provisions, States may continue to apply State law requirements except to the extent that such requirements prevent the application of the portability, access, and renewability requirements of HIPAA, which include HIPAA's nondiscrimination requirements provisions. HIPAA's Conference Report states that the conferees intended the narrowest preemption of State laws with regard to health insurance issuers (H.R. Conf. Rep. No. 736, 104th Cong. 2d Session 205, 1996). State insurance laws that are more stringent than the federal requirements are unlikely to "prevent the application of" the HIPAA nondiscrimination provisions, and therefore are not preempted. Accordingly, States have significant latitude to impose requirements on health insurance issuers that are more restrictive than the federal law.

Guidance conveying this interpretation was published in the **Federal Register** on April 8, 1997 (62 FR 16904) and on December 30, 2004 (69 FR 78720), and these proposed regulations clarify and implement the statute's minimum standards and do not significantly reduce the discretion given the States by the statute. Moreover, the Departments understand that the vast majority of States have requirements that meet or exceed the minimum requirements of the HIPAA nondiscrimination provisions.

HIPAA provides that the States may enforce the provisions of HIPAA as they pertain to issuers, but that the Secretary of HHS must enforce any provisions that a State choose not to or fails to substantially enforce. When exercising its responsibility to enforce provisions of HIPAA, HHS works cooperatively with the State for the purpose of addressing the State's

concerns and avoiding conflicts with the exercise of State authority.[48] HHS has developed procedures to implement its enforcement responsibilities, and to afford the States the maximum opportunity to enforce HIPAA's requirements in the first instance. In compliance with Executive Order 13132's requirement that agencies examine closely any policies that may have federalism implications or limit the policy making discretion of the States, DOL and HHS have engaged in numerous efforts to consult with and work cooperatively with affected State and local officials.

In conclusion, throughout the process of developing these regulations, to the extent feasible within the specific preemption provisions of HIPAA, the Departments have attempted to balance the States' interests in regulating health plans and health insurance issuers, and the rights of those individuals that Congress intended to protect through the enactment of HIPAA.

IV. Statutory Authority

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

The Department of Labor regulations are proposed to be adopted pursuant to the authority contained in 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Secretary of Labor's Order 3–2010, 75 FR 55354 (September 10, 2010).

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

The Department of Health and Human Services regulations are proposed to be adopted, with respect to 45 CFR Part 146, pursuant to the authority contained in sections 2702 through 2705, 2711 through 2723, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg–1 through 300gg–5, 300gg–11 through 300gg–23, 300gg–91, and 300gg–92) prior to the amendments made by the Affordable Care Act and sections 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 by the Affordable Care Act; with respect to 45 CFR Part 147, pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended by the Affordable Care Act.

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 Parts 146 and 147

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

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

Signed this 8th day of November, 2012.

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

Dated: _August 1, 2012__

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Marilyn Tavenner,

Acting Administrator,

Centers for Medicare & Medicaid Services.

Dated: __August 7, 2012___

Kathleen Sebelius,

Secretary,

Department of Health and Human Services.

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Chapter I

Accordingly, 26 CFR part 54 is proposed to be amended as follows:

PART 54—PENSION EXCISE TAXES

Paragraph 1. The authority citation for Part 54 is amended by adding an entry for §54.9815-2705 in numerical order to read in part as follows:

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

Section 54.9815-2705 also issued under 26 U.S.C. 9833.

Par. 2. In §54.9802-1, paragraph (f) is revised to read as follows:

§54.9802-1 Prohibiting discrimination against participants and beneficiaries based on a health factor.

* * * * *

(f) Nondiscriminatory wellness programs – in general. A wellness program is a program of health promotion or disease prevention. Paragraphs (b)(2)(ii) and (c)(3) of this section provide exceptions to the general prohibitions against discrimination based on a health factor for plan provisions that vary benefits (including cost-sharing mechanisms) or the premium or contribution for similarly situated individuals in connection with a wellness program that

satisfies the requirements of this paragraph (f). If a wellness program is a participatory wellness program, as defined in paragraph (f)(1) of this section, that paragraph also makes clear that the wellness program does not violate this section if participation in the program is made available to all similarly situated individuals. If a wellness program is a health-contingent wellness program, as defined in paragraph (f)(2) of this section, the wellness program does not violate this section if the requirements of paragraph (f)(3) of this section are met. Except where expressly provided otherwise, references in this section to an individual obtaining a reward include both obtaining a reward (such as a premium discount or rebate, a waiver of all or part of a cost-sharing mechanism, an additional benefit, or any financial or other incentive) and avoiding a penalty (such as the absence of a premium surcharge, or other financial or nonfinancial disincentive). References in this section to a plan providing a reward include both providing a reward (such as a premium discount or rebate, a waiver of all or part of a cost-sharing mechanism, an additional benefit, or any financial or other incentive) and imposing a penalty (such as a surcharge or other financial or nonfinancial disincentive).

(1) Participatory wellness programs defined. If none of the conditions for obtaining a reward under a wellness program is based on an individual satisfying a standard that is related to a health factor (or if a wellness program does not provide a reward), the wellness program is a participatory wellness program and, if participation in the program is made available to all similarly situated individuals, does not violate this section. Examples of participatory wellness programs are:

(i) A program that reimburses all or part of the cost for membership in a fitness center.

(ii) A diagnostic testing program that provides a reward for participation and does not base any part of the reward on outcomes.

(iii) A program that encourages preventive care through the waiver of the copayment or deductible requirement under a group health plan for the costs of, for example, prenatal care or well-baby visits. (Note that, with respect to non-grandfathered plans, §54.9815-2713T requires benefits for certain preventive health services without the imposition of cost sharing.)

(iv) A program that reimburses employees for the costs of participating, or that otherwise provides a reward for participating, in a smoking cessation program without regard to whether the employee quits smoking.

(v) A program that provides a reward to employees for attending a monthly no-cost health education seminar.

(vi) A program that provides a reward to employees who complete a health risk assessment regarding current health status, without any further action (educational or otherwise) required by the employee with regard to the health issues identified as part of the assessment. (See also § 54.9802-3T for rules prohibiting collection of genetic information).

(2) Health-contingent wellness programs defined. If any of the conditions for obtaining a reward under a wellness program is based on an individual satisfying a standard that is related to a health factor, the wellness program is a health-contingent wellness program and the program is permissible under this section only if all of the requirements of paragraph (f)(3) of this section are satisfied. Examples of health-contingent wellness programs are:

(i) A program that imposes a premium surcharge based on tobacco use.

(ii) A program that uses a biometric screening or a health risk assessment to identify employees with specified medical conditions or risk factors (such as high cholesterol, high blood pressure, unhealthy body mass index, or high glucose level) and provides a reward to employees identified as within a normal or healthy range for biometrics (or at low risk for certain medical

conditions), while requiring employees who are identified as outside the normal or healthy range (or at risk) to take additional steps (such as meeting with a health coach, taking a health or fitness course, adhering to a health improvement action plan, or complying with a health care provider's plan of care) to obtain the same reward.

(3) Requirements for health-contingent wellness programs. A health-contingent wellness program does not violate this section if all of the following requirements are satisfied:

(i) Frequency of opportunity to qualify. The program must give individuals eligible for the program the opportunity to qualify for the reward under the program at least once per year.

(ii) Size of reward. The reward for a health-contingent wellness program, together with the reward for other health-contingent wellness programs with respect to the plan, must not exceed the applicable percentage of the total cost of employee-only coverage under the plan, as defined in this paragraph (f)(3)(ii). However, if, in addition to employees, any class of dependents (such as spouses, or spouses and dependent children) may participate in the wellness program, the reward must not exceed the applicable percentage of the total cost of the coverage in which an employee and any dependents are enrolled. For purposes of this paragraph (f)(3)(ii), the cost of coverage is determined based on the total amount of employer and employee contributions for the benefit package under which the employee is (or the employee and any dependents are) receiving coverage.

(A) Applicable percentage. For purposes of this paragraph (f)(3)(ii), the applicable percentage is 30 percent, except that the applicable percentage is increased an additional 20 percentage points (to 50 percent) to the extent that the additional percentage is in connection with a program designed to prevent or reduce tobacco use.

(B) Examples. The rules of this paragraph (f)(3)(ii) are illustrated by the following examples:

Example 1. (i) Facts. An employer sponsors a group health plan. The annual premium for employee-only coverage is $6,000 (of which the employer pays $4,500 per year and the employee pays $1,500 per year). The plan offers employees a health-contingent wellness program focused on exercise, blood sugar, weight, cholesterol, and blood pressure. The reward for compliance is an annual premium rebate of $600.

(ii) Conclusion. In this Example 1, the program satisfies the requirements of this paragraph (f)(3)(ii) because the reward for the wellness program, $600, does not exceed 30 percent of the total annual cost of employee-only coverage, $1,800. ($6,000 x 30% = $1,800.)

Example 2. (i) Facts. Same facts as Example 1, except the wellness program is exclusively a tobacco prevention program. Employees who have used tobacco in the last 12 months and who are not enrolled in the plan's tobacco cessation program are charged a $1,000 premium surcharge (in addition to their employee contribution towards the coverage). (Those who participate in the plan's tobacco cessation program are not assessed the $1,000 surcharge.)

(ii) Conclusion. In this Example 2, the program satisfies the requirements of this paragraph (f)(3)(ii) because the reward for the wellness program (absence of a $1,000 surcharge), does not exceed 50 percent of the total annual cost of employee-only coverage, $3,000. ($6,000 x 50% = $3,000.)

Example 3. (i) Facts. Same facts as Example 1, except that, in addition to the $600 reward for compliance with the health-contingent wellness program, the plan also imposes an additional $2,000 tobacco premium surcharge on employees who have used tobacco in the last 12 months and who are not enrolled in the plan's tobacco cessation program. (Those who participate in the plan's tobacco cessation program are not assessed the $2,000 surcharge.)

(ii) Conclusion. In this Example 3, the program satisfies the requirements of this paragraph (f)(3)(ii) because both: the total of all rewards (including absence of a surcharge for participating in the tobacco program) is $2,600 ($600 + $2,000 = $2,600), which does not exceed 50 percent of the total annual cost of employee-only coverage ($3,000); and, tested separately, the $600 reward for the wellness program unrelated to tobacco use does not exceed 30 percent of the total annual cost of employee-only coverage, $1,800.

Example 4. (i) Facts. An employer sponsors a group health plan. The total annual premium for employee-only coverage (including both employer and employee contributions towards the coverage) is $5,000. The plan provides a $250 reward to employees who complete a health risk assessment, without regard to the health issues identified as part of the assessment. The plan also offers a Healthy Heart program, which is a health-contingent wellness program under paragraph (f)(2) of this section, with an opportunity to earn a $1,500 reward.

(ii) Conclusion. In this Example 4, the plan satisfies the requirements of this paragraph (f)(3)(ii). Even though the total reward for all wellness programs under the plan is $1,750 ($250 + $1,500 = $1,750, which exceeds 30 percent of the cost of the annual premium for employee-only coverage ($5,000 x 30% = $1,500)), only the reward offered for compliance with the health-contingent wellness program ($1,500) is taken into account in determining whether the rules of this paragraph (f)(3)(ii) are met. (The $250 reward is offered in connection with a participatory wellness program and therefore is not taken into account under this paragraph (f)(3)(ii)). The health-contingent wellness program offers a reward that does not exceed 30 percent of the total annual cost of employee-only coverage.

(iii) Uniform availability and reasonable alternative standards. The reward under the program must be available to all similarly situated individuals.

(A) Under this paragraph (f)(3)(iii), a reward under a program is not available to all similarly situated individuals for a period unless the program meets both of the following requirements:

(1) The program allows a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard; and

(2) The program allows a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is medically inadvisable to attempt to satisfy the otherwise applicable standard.

(B) While plans are not required to determine a particular alternative standard in advance of an individual's request for one, if an individual is described in either paragraph (f)(3)(iii)(A)(1) or (2) of this section, a reasonable alternative standard must be furnished by the plan upon the individual's request or the condition for obtaining the reward must be waived. All the facts and circumstances are taken into account in determining whether a plan has furnished a reasonable alternative standard, including but not limited to the following:

(1) If the reasonable alternative standard is completion of an educational program, the plan must make the educational program available instead of requiring an individual to find such a program unassisted, and may not require an individual to pay for the cost of the program.

(2) If the reasonable alternative standard is a diet program, plans are not required to pay for the cost of food but must pay any membership or participation fee.

(3) If the reasonable alternative standard is compliance with the recommendations of a medical professional who is an employee or agent of the plan, and an individual's personal physician states that the plan's recommendations are not medically appropriate for that individual, the plan must provide a reasonable alternative standard that accommodates the recommendations of the individual's personal physician with regard to medical appropriateness. Plans may impose standard cost sharing under the plan or coverage for medical items and services furnished pursuant to the physician's recommendations.

(C) If reasonable under the circumstances, a plan may seek verification, such as a statement from an individual's personal physician, that a health factor makes it unreasonably difficult for the individual to satisfy, or medically inadvisable for the individual to attempt to satisfy, the otherwise applicable standard. It would not be reasonable, for example, for a plan to seek verification of a claim that is obviously valid based on the nature of the individual's medical condition that is known to the plan. However, plans may seek verification in the case of claims for which it is reasonable to determine that medical judgment is required to evaluate the validity of the claim.

(iv) Reasonable design. The program must be reasonably designed to promote health or prevent disease. A program satisfies this standard if it has a reasonable chance of improving the health of, or preventing disease in, participating individuals and it is not overly burdensome, is

not a subterfuge for discriminating based on a health factor, and is not highly suspect in the method chosen to promote health or prevent disease. This determination is based on all the relevant facts and circumstances. To the extent a plan's initial standard for obtaining a reward (including a portion of a reward) is based on the results of a measurement, test, or screening relating to a health factor (such as a biometric examination or a health risk assessment), the plan must make available to any individual who does not meet the standard based on the measurement, test, or screening a different, reasonable means of qualifying for the reward.

(v) Notice of availability of other means of qualifying for the reward. (A) The plan must disclose in all plan materials describing the terms of the program the availability of other means of qualifying for the reward or the possibility of waiver of the otherwise applicable standard. If plan materials merely mention that a program is available, without describing its terms, this disclosure is not required.

(B) The following language, or substantially similar language, can be used to satisfy the notice requirement of this paragraph (f)(3)(v): "Your health plan is committed to helping you achieve your best health status. Rewards for participating in a wellness program are available to all employees. If you think you might be unable to meet a standard for a reward under this wellness program, you might qualify for an opportunity to earn the same reward by different means. Contact us at [insert contact information] and we will work with you to find a wellness program with the same reward that is right for you in light of your health status." Additional sample language is provided in the examples of paragraph (f)(4) of this section.

(4) Examples. The rules of paragraphs (f)(3)(iii), (iv), and (v) of this section are illustrated by the following examples:

Example 1. (i) Facts. A group health plan provides a reward to individuals who participate in a reasonable specified walking program. If it is unreasonably difficult due to a

medical condition for an individual to participate (or if it is medically inadvisable for an individual to participate), the plan will waive the walking program requirement and provide the reward. All materials describing the terms of the walking program disclose the availability of the waiver.

(ii) Conclusion. The program satisfies the requirements of paragraph (f)(3)(iii) of this section because the reward under the program is available to all similarly situated individuals because it accommodates individuals who cannot participate in the walking program due to a medical condition (or for whom it would be medically inadvisable to attempt to participate) by providing them the reward even if they do not participate in the walking program (that is, by waiving the condition). The program satisfies the requirements of paragraph (f)(3)(iv) of this section because the walking program is reasonably designed to promote health and prevent disease. Last, the plan complies with the disclosure requirement of paragraph (f)(3)(v) of this section. Thus, the plan satisfies paragraphs (f)(3)(iii), (iv), and (v) of this section.

Example 2. (i) Facts. A group health plan offers a reward to individuals who achieve a count under 200 on a cholesterol test. If a participant does not achieve the targeted cholesterol count, the plan will make available a different, reasonable means of qualifying for the reward. In addition, all plan materials describing the terms of the program include the following statement: "Your health plan wants to help you take charge of your health. Rewards are available to all employees who participate in our Cholesterol Awareness Wellness Program. If your cholesterol count is under 200, you will receive the reward. If not, you will still have an opportunity to qualify for the reward. We will work with you to find a Health Smart program that is right for you." Individual D is identified as having a cholesterol count above 200. The plan partners D with a nurse who makes recommendations regarding diet and exercise, with which it is not unreasonably difficult due to a medical condition of D or medically inadvisable for D to comply, and which is otherwise reasonably designed, based on all the relevant facts and circumstances. In addition, the plan makes available to all other individuals who do not meet the cholesterol standard a different, reasonable means of qualifying for the reward which is not unreasonably burdensome or impractical. D will qualify for the discount if D follows the recommendations regardless of whether D achieves a cholesterol count that is under 200.

(ii) Conclusion. In this Example 2, the program satisfies the requirements of paragraphs (f)(3)(iii), (iv), and (v) of this section. The program's initial standard for obtaining a reward is dependent on the results of a cholesterol screening, which is related to a health factor. However, the program is reasonably designed under paragraphs (f)(3)(iii) and (iv) of this section because the plan makes available to all individuals who do not meet the cholesterol standard a different, reasonable means of qualifying for the reward and because the program is otherwise reasonably designed based on all the relevant facts and circumstances. The plan also discloses in all materials describing the terms of the program the opportunity to qualify for the reward through other means. Thus, the program satisfies paragraphs (f)(3)(iii), (iv), and (v) of this section.

Example 3. (i) Facts. Same facts as Example 2, except that, following diet and exercise, D again fails to achieve a cholesterol count that is under 200, and the program requires D to visit a doctor and follow any additional recommendations of D's doctor with respect to D's cholesterol. The program permits D to select D's own doctor for this purpose. D visits D's

doctor, who determines D should take a prescription medication for cholesterol. In addition, the doctor determines that D must be monitored through periodic blood tests to continually reevaluate D's health status. The plan accommodates D by making the discount available to D, but only if D actually follows the advice of D's doctor's regarding medication and blood tests.

(ii) Conclusion. In this Example 3, the program's requirements to follow up with, and follow the recommendations of, D's doctor do not make the program unreasonable under paragraphs (f)(3)(iii) or (iv) of this section. The program continues to satisfy the conditions of paragraphs (f)(3)(iii), (iv), and (v) of this section.

Example 4. (i) Facts. A group health plan will provide a reward to participants who have a body mass index (BMI) that is 26 or lower, determined shortly before the beginning of the year. Any participant who does not meet the target BMI is given the same discount if the participant complies with an exercise program that consists of walking 150 minutes a week. Any participant for whom it is unreasonably difficult due to a medical condition to comply with this walking program (and any participant for whom it is medically inadvisable to attempt to comply with the walking program) during the year is given the same discount if the individual satisfies an alternative standard that is reasonable taking into consideration the individual's medical situation, is not unreasonably burdensome or impractical to comply with, and is otherwise reasonably designed based on all the relevant facts and circumstances. All plan materials describing the terms of the wellness program include the following statement: "Fitness is Easy! Start Walking! Your health plan cares about your health. If you are overweight, our Start Walking program will help you lose weight and feel better. We will help you enroll. (**If your doctor says that walking isn't right for you, that's okay too. We will develop a wellness program that is.)" Individual E is unable to achieve a BMI that is 26 or lower within the plan's timeframe and is also not reasonably able to comply with the walking program. E proposes a program based on the recommendations of E's physician. The plan agrees to make the discount available to E, but only if E actually follows the physician's recommendations.

(ii) Conclusion. In this Example 4, the program satisfies the requirements of paragraphs (f)(3)(iii), (iv), and (v) of this section. The program's initial standard for obtaining a reward is dependent on the results of a BMI screening, which is related to a health factor. However, the plan complies with the requirements of paragraph (f)(3)(iv) of this section because it makes available to all individuals who do not satisfy the BMI standard a different reasonable means of qualifying for the reward (a walking program that is not unreasonably burdensome or impractical for individuals to comply with and that is otherwise reasonably designed based on all the relevant facts and circumstances). In addition, the plan complies with the requirements of paragraph (f)(3)(iii) of this section because, if there are individuals for whom it is unreasonably difficult due to a medical condition to comply, or for whom it is medically inadvisable to attempt to comply, with the walking program, the plan provides a reasonable alternative to those individuals. Moreover, the plan satisfies the requirements of paragraph (f)(3)(v) of this section because it discloses, in all materials describing the terms of the program, the availability of other means of qualifying for the reward or the possibility of waiver of the otherwise applicable standard. Thus, the plan satisfies paragraphs (f)(3)(iii), (iv), and (v) of this section.

Example 5. (i) Facts. In conjunction with an annual open enrollment period, a group health plan provides a premium differential based on tobacco use, determined using a health risk assessment. The following statement is included in all plan materials describing the tobacco premium differential: "Stop smoking today! We can help! If you are a smoker, we offer a smoking cessation program. If you complete the program, you can avoid this surcharge." The plan accommodates participants who smoke by facilitating their enrollment in a smoking cessation program that requires participation at a time and place that are not unreasonably burdensome or impractical for participants, and that is otherwise reasonably designed based on all the relevant facts and circumstances. The plan pays the cost of the program. Any participant can avoid the surcharge by participating in the program, regardless of whether the participant stops smoking.

(ii) Conclusion. In this Example 5, the premium differential satisfies the requirements of paragraphs (f)(3)(iii), (iv), and (v) of this section. The program's initial standard for obtaining a reward is dependent on the results of a health risk assessment, which is a screening. However, the plan is reasonably designed under paragraph (f)(3)(iv) because the plan provides a different, reasonable means of qualifying for the reward to all tobacco users. The plan discloses, in all materials describing the terms of the program, the availability of other means of qualifying for the reward. Thus, the plan satisfies paragraphs (f)(3)(iii), (iv), and (v) of this section.

Example 6. (i) Facts. Same facts as Example 5, except the plan does not facilitate F's enrollment in any program. Instead the plan advises F to find a program, pay for it, and provide a certificate of completion to the plan.

(ii) Conclusion. In this Example 6, the requirement for F to find and pay for F's own smoking cessation program means that the alternative program is not reasonable. Accordingly, the plan has not offered a reasonable alternative standard that complies with paragraphs (f)(3)(iii) and (iv) of this section and the premium differential violates paragraph (c) of this section.

* * * * *

Par. 3. Section 54.9815-2705 is added to read as follows:

§54.9815-2705 Prohibiting discrimination against participants and beneficiaries based on a health factor.

(a) In general. A group health plan and a health insurance issuer offering group health insurance coverage must comply with the requirements of §54.9802-1. Accordingly, with respect to health insurance issuers offering group health insurance coverage, the issuer is subject to the requirements of §54.9802-1 to the same extent as a group health plan.

(b) Applicability date. This section is applicable to group health plans and health insurance issuers offering group health insurance coverage for plan years beginning on or after

January 1, 2014. See §54.9815-1251T, which provides that the rules of this section do not apply to grandfathered health plans.

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Chapter XXV

29 CFR Part 2590 is proposed to be 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, 1185d, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104– 191, 110 Stat. 1936; sec. 401(b), Pub. L. 105– 200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 12(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111– 152, 124 Stat. 1029; Secretary of Labor's Order 3–2010, 75 FR 55354 (September 10, 2010).

Subpart B—Health Coverage Portability, Nondiscrimination, and Renewability

2. Section 2590.702 is amended by revising paragraph (f) to read as follows:

§ 2590.702 Prohibiting discrimination against participants and beneficiaries based on a health factor.

* * * * *

(f) Nondiscriminatory wellness programs – in general. A wellness program is a program of health promotion or disease prevention. Paragraphs (b)(2)(ii) and (c)(3) of this section provide exceptions to the general prohibitions against discrimination based on a health factor for

plan provisions that vary benefits (including cost-sharing mechanisms) or the premium or contribution for similarly situated individuals in connection with a wellness program that satisfies the requirements of this paragraph (f). If a wellness program is a participatory wellness program, as defined in paragraph (f)(1) of this section, that paragraph also makes clear that the wellness program does not violate this section if participation in the program is made available to all similarly situated individuals. If a wellness program is a health-contingent wellness program, as defined in paragraph (f)(2) of this section, the wellness program does not violate this section if the requirements of paragraph (f)(3) of this section are met. Except where expressly provided otherwise, references in this section to an individual obtaining a reward include both obtaining a reward (such as a premium discount or rebate, a waiver of all or part of a cost-sharing mechanism, an additional benefit, or any financial or other incentive) and avoiding a penalty (such as the absence of a premium surcharge, or other financial or nonfinancial disincentive). References in this section to a plan providing a reward include both providing a reward (such as a premium discount or rebate, a waiver of all or part of a cost-sharing mechanism, an additional benefit, or any financial or other incentive) and imposing a penalty (such as a surcharge or other financial or nonfinancial disincentive).

(1) Participatory wellness programs defined. If none of the conditions for obtaining a reward under a wellness program is based on an individual satisfying a standard that is related to a health factor (or if a wellness program does not provide a reward), the wellness program is a participatory wellness program and, if participation in the program is made available to all similarly situated individuals, does not violate this section. Examples of participatory wellness programs are:

(i) A program that reimburses all or part of the cost for membership in a fitness center.

(ii) A diagnostic testing program that provides a reward for participation and does not base any part of the reward on outcomes.

(iii) A program that encourages preventive care through the waiver of the copayment or deductible requirement under a group health plan for the costs of, for example, prenatal care or well-baby visits. (Note that, with respect to non-grandfathered plans, section 2590.715-2713 of this Part requires benefits for certain preventive health services without the imposition of cost sharing.)

(iv) A program that reimburses employees for the costs of participating, or that otherwise provides a reward for participating, in a smoking cessation program without regard to whether the employee quits smoking.

(v) A program that provides a reward to employees for attending a monthly no-cost health education seminar.

(vi) A program that provides a reward to employees who complete a health risk assessment regarding current health status, without any further action (educational or otherwise) required by the employee with regard to the health issues identified as part of the assessment. (See also § 2590.702-1 for rules prohibiting collection of genetic information).

(2) Health-contingent wellness programs defined. If any of the conditions for obtaining a reward under a wellness program is based on an individual satisfying a standard that is related to a health factor, the wellness program is a health-contingent wellness program and the program is permissible under this section only if all of the requirements of paragraph (f)(3) of this section are satisfied. Examples of health-contingent wellness programs are:

(i) A program that imposes a premium surcharge based on tobacco use.

(ii) A program that uses a biometric screening or a health risk assessment to identify employees with specified medical conditions or risk factors (such as high cholesterol, high blood pressure, unhealthy body mass index, or high glucose level) and provides a reward to employees identified as within a normal or healthy range for biometrics (or at low risk for certain medical conditions), while requiring employees who are identified as outside the normal or healthy range (or at risk) to take additional steps (such as meeting with a health coach, taking a health or fitness course, adhering to a health improvement action plan, or complying with a health care provider's plan of care) to obtain the same reward.

(3) Requirements for health-contingent wellness programs. A health-contingent wellness program does not violate this section if all of the following requirements are satisfied:

(i) Frequency of opportunity to qualify. The program must give individuals eligible for the program the opportunity to qualify for the reward under the program at least once per year.

(ii) Size of reward. The reward for a health-contingent wellness program, together with the reward for other health-contingent wellness programs with respect to the plan, must not exceed the applicable percentage of the total cost of employee-only coverage under the plan, as defined in this paragraph (f)(3)(ii). However, if, in addition to employees, any class of dependents (such as spouses, or spouses and dependent children) may participate in the wellness program, the reward must not exceed the applicable percentage of the total cost of the coverage in which an employee and any dependents are enrolled. For purposes of this paragraph (f)(3)(ii), the cost of coverage is determined based on the total amount of employer and employee contributions for the benefit package under which the employee is (or the employee and any dependents are) receiving coverage.

(A) Applicable percentage. For purposes of this paragraph (f)(3)(ii), the applicable percentage is 30 percent, except that the applicable percentage is increased an additional 20 percentage points (to 50 percent) to the extent that the additional percentage is in connection with a program designed to prevent or reduce tobacco use.

(B) Examples. The rules of this paragraph (f)(3)(ii) are illustrated by the following examples:

Example 1. (i) Facts. An employer sponsors a group health plan. The annual premium for employee-only coverage is $6,000 (of which the employer pays $4,500 per year and the employee pays $1,500 per year). The plan offers employees a health-contingent wellness program focused on exercise, blood sugar, weight, cholesterol, and blood pressure. The reward for compliance is an annual premium rebate of $600.

(ii) Conclusion. In this Example 1, the program satisfies the requirements of this paragraph (f)(3)(ii) because the reward for the wellness program, $600, does not exceed 30 percent of the total annual cost of employee-only coverage, $1,800. ($6,000 x 30% = $1,800.)

Example 2. (i) Facts. Same facts as Example 1, except the wellness program is exclusively a tobacco prevention program. Employees who have used tobacco in the last 12 months and who are not enrolled in the plan's tobacco cessation program are charged a $1,000 premium surcharge (in addition to their employee contribution towards the coverage). (Those who participate in the plan's tobacco cessation program are not assessed the $1,000 surcharge.)

(ii) Conclusion. In this Example 2, the program satisfies the requirements of this paragraph (f)(3)(ii) because the reward for the wellness program (absence of a $1,000 surcharge), does not exceed 50 percent of the total annual cost of employee-only coverage, $3,000. ($6,000 x 50% = $3,000.)

Example 3. (i) Facts. Same facts as Example 1, except that, in addition to the $600 reward for compliance with the health-contingent wellness program, the plan also imposes an additional $2,000 tobacco premium surcharge on employees who have used tobacco in the last 12 months and who are not enrolled in the plan's tobacco cessation program. (Those who participate in the plan's tobacco cessation program are not assessed the $2,000 surcharge.)

(ii) Conclusion. In this Example 3, the program satisfies the requirements of this paragraph (f)(3)(ii) because both: the total of all rewards (including absence of a surcharge for participating in the tobacco program) is $2,600 ($600 + $2,000 = $2,600), which does not exceed 50 percent of the total annual cost of employee-only coverage ($3,000); and, tested separately, the $600 reward for the wellness program unrelated to tobacco use does not exceed 30 percent of the total annual cost of employee-only coverage, $1,800.

Example 4. (i) Facts. An employer sponsors a group health plan. The total annual premium for employee-only coverage (including both employer and employee contributions towards the coverage) is $5,000. The plan provides a $250 reward to employees who complete a health risk assessment, without regard to the health issues identified as part of the assessment. The plan also offers a Healthy Heart program, which is a health-contingent wellness program under paragraph (f)(2) of this section, with an opportunity to earn a $1,500 reward.

(ii) Conclusion. In this Example 4, the plan satisfies the requirements of this paragraph (f)(3)(ii). Even though the total reward for all wellness programs under the plan is $1,750 ($250 + $1,500 = $1,750, which exceeds 30 percent of the cost of the annual premium for employee-only coverage ($5,000 x 30% = $1,500)), only the reward offered for compliance with the health-contingent wellness program ($1,500) is taken into account in determining whether the rules of this paragraph (f)(3)(ii) are met. (The $250 reward is offered in connection with a participatory wellness program and therefore is not taken into account under this paragraph (f)(3)(ii)). The health-contingent wellness program offers a reward that does not exceed 30 percent of the total annual cost of employee-only coverage.

(iii) Uniform availability and reasonable alternative standards. The reward under the program must be available to all similarly situated individuals.

(A) Under this paragraph (f)(3)(iii), a reward under a program is not available to all similarly situated individuals for a period unless the program meets both of the following requirements:

(1) The program allows a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard; and

(2) The program allows a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is medically inadvisable to attempt to satisfy the otherwise applicable standard.

(B) While plans and issuers are not required to determine a particular alternative standard in advance of an individual's request for one, if an individual is described in either paragraph (f)(3)(iii)(A)(1) or (2) of this section, a reasonable alternative standard must be

furnished by the plan or issuer upon the individual's request or the condition for obtaining the reward must be waived. All the facts and circumstances are taken into account in determining whether a plan or issuer has furnished a reasonable alternative standard, including but not limited to the following:

(1) If the reasonable alternative standard is completion of an educational program, the plan or issuer must make the educational program available instead of requiring an individual to find such a program unassisted, and may not require an individual to pay for the cost of the program.

(2) If the reasonable alternative standard is a diet program, plans and issuers are not required to pay for the cost of food but must pay any membership or participation fee.

(3) If the reasonable alternative standard is compliance with the recommendations of a medical professional who is an employee or agent of the plan or issuer, and an individual's personal physician states that the plan's recommendations are not medically appropriate for that individual, the plan or issuer must provide a reasonable alternative standard that accommodates the recommendations of the individual's personal physician with regard to medical appropriateness. Plans and issuers may impose standard cost sharing under the plan or coverage for medical items and services furnished pursuant to the physician's recommendations.

(C) If reasonable under the circumstances, a plan or issuer may seek verification, such as a statement from an individual's personal physician, that a health factor makes it unreasonably difficult for the individual to satisfy, or medically inadvisable for the individual to attempt to satisfy, the otherwise applicable standard. It would not be reasonable, for example, for a plan and issuer to seek verification of a claim that is obviously valid based on the nature of the individual's medical condition that is known to the plan or issuer. However, plans and issuers

may seek verification in the case of claims for which it is reasonable to determine that medical judgment is required to evaluate the validity of the claim.

(iv) Reasonable design. The program must be reasonably designed to promote health or prevent disease. A program satisfies this standard if it has a reasonable chance of improving the health of, or preventing disease in, participating individuals and it is not overly burdensome, is not a subterfuge for discriminating based on a health factor, and is not highly suspect in the method chosen to promote health or prevent disease. This determination is based on all the relevant facts and circumstances. To the extent a plan's initial standard for obtaining a reward (including a portion of a reward) is based on the results of a measurement, test, or screening relating to a health factor (such as a biometric examination or a health risk assessment), the plan must make available to any individual who does not meet the standard based on the measurement, test, or screening a different, reasonable means of qualifying for the reward.

(v) Notice of availability of other means of qualifying for the reward. (A) The plan or issuer must disclose in all plan materials describing the terms of the program the availability of other means of qualifying for the reward or the possibility of waiver of the otherwise applicable standard. If plan materials merely mention that a program is available, without describing its terms, this disclosure is not required.

(B) The following language, or substantially similar language, can be used to satisfy the notice requirement of this paragraph (f)(3)(v): "Your health plan is committed to helping you achieve your best health status. Rewards for participating in a wellness program are available to all employees. If you think you might be unable to meet a standard for a reward under this wellness program, you might qualify for an opportunity to earn the same reward by different means. Contact us at [insert contact information] and we will work with you to find a wellness

program with the same reward that is right for you in light of your health status." Additional sample language is provided in the examples of paragraph (f)(4) of this section.

(4) Examples. The rules of paragraphs (f)(3)(iii), (iv), and (v) of this section are illustrated by the following examples:

Example 1. (i) Facts. A group health plan provides a reward to individuals who participate in a reasonable specified walking program. If it is unreasonably difficult due to a medical condition for an individual to participate (or if it is medically inadvisable for an individual to participate), the plan will waive the walking program requirement and provide the reward. All materials describing the terms of the walking program disclose the availability of the waiver.

(ii) Conclusion. The program satisfies the requirements of paragraph (f)(3)(iii) of this section because the reward under the program is available to all similarly situated individuals because it accommodates individuals who cannot participate in the walking program due to a medical condition (or for whom it would be medically inadvisable to attempt to participate) by providing them the reward even if they do not participate in the walking program (that is, by waiving the condition). The program satisfies the requirements of paragraph (f)(3)(iv) of this section because the walking program is reasonably designed to promote health and prevent disease. Last, the plan complies with the disclosure requirement of paragraph (f)(3)(v) of this section. Thus, the plan satisfies paragraphs (f)(3)(iii), (iv), and (v) of this section.

Example 2. (i) Facts. A group health plan offers a reward to individuals who achieve a count under 200 on a cholesterol test. If a participant does not achieve the targeted cholesterol count, the plan will make available a different, reasonable means of qualifying for the reward. In addition, all plan materials describing the terms of the program include the following statement: "Your health plan wants to help you take charge of your health. Rewards are available to all employees who participate in our Cholesterol Awareness Wellness Program. If your cholesterol count is under 200, you will receive the reward. If not, you will still have an opportunity to qualify for the reward. We will work with you to find a Health Smart program that is right for you." Individual D is identified as having a cholesterol count above 200. The plan partners D with a nurse who makes recommendations regarding diet and exercise, with which it is not unreasonably difficult due to a medical condition of D or medically inadvisable for D to comply, and which is otherwise reasonably designed, based on all the relevant facts and circumstances. In addition, the plan makes available to all other individuals who do not meet the cholesterol standard a different, reasonable means of qualifying for the reward which is not unreasonably burdensome or impractical. D will qualify for the discount if D follows the recommendations regardless of whether D achieves a cholesterol count that is under 200.

(ii) Conclusion. In this Example 2, the program satisfies the requirements of paragraphs (f)(3)(iii), (iv), and (v) of this section. The program's initial standard for obtaining a reward is dependent on the results of a cholesterol screening, which is related to a health factor. However, the program is reasonably designed under paragraphs (f)(3)(iii) and (iv) of this section because

the plan makes available to all individuals who do not meet the cholesterol standard a different, reasonable means of qualifying for the reward and because the program is otherwise reasonably designed based on all the relevant facts and circumstances. The plan also discloses in all materials describing the terms of the program the opportunity to qualify for the reward through other means. Thus, the program satisfies paragraphs (f)(3)(iii), (iv), and (v) of this section.

Example 3. (i) Facts. Same facts as Example 2, except that, following diet and exercise, D again fails to achieve a cholesterol count that is under 200, and the program requires D to visit a doctor and follow any additional recommendations of D's doctor with respect to D's cholesterol. The program permits D to select D's own doctor for this purpose. D visits D's doctor, who determines D should take a prescription medication for cholesterol. In addition, the doctor determines that D must be monitored through periodic blood tests to continually reevaluate D's health status. The plan accommodates D by making the discount available to D, but only if D actually follows the advice of D's doctor's regarding medication and blood tests.

(ii) Conclusion. In this Example 3, the program's requirements to follow up with, and follow the recommendations of, D's doctor do not make the program unreasonable under paragraphs (f)(3)(iii) or (iv) of this section. The program continues to satisfy the conditions of paragraphs (f)(3)(iii), (iv), and (v) of this section.

Example 4. (i) Facts. A group health plan will provide a reward to participants who have a body mass index (BMI) that is 26 or lower, determined shortly before the beginning of the year. Any participant who does not meet the target BMI is given the same discount if the participant complies with an exercise program that consists of walking 150 minutes a week. Any participant for whom it is unreasonably difficult due to a medical condition to comply with this walking program (and any participant for whom it is medically inadvisable to attempt to comply with the walking program) during the year is given the same discount if the individual satisfies an alternative standard that is reasonable taking into consideration the individual's medical situation, is not unreasonably burdensome or impractical to comply with, and is otherwise reasonably designed based on all the relevant facts and circumstances. All plan materials describing the terms of the wellness program include the following statement: "Fitness is Easy! Start Walking! Your health plan cares about your health. If you are overweight, our Start Walking program will help you lose weight and feel better. We will help you enroll. (**If your doctor says that walking isn't right for you, that's okay too. We will develop a wellness program that is.)" Individual E is unable to achieve a BMI that is 26 or lower within the plan's timeframe and is also not reasonably able to comply with the walking program. E proposes a program based on the recommendations of E's physician. The plan agrees to make the discount available to E, but only if E actually follows the physician's recommendations.

(ii) Conclusion. In this Example 4, the program satisfies the requirements of paragraphs (f)(3)(iii), (iv), and (v) of this section. The program's initial standard for obtaining a reward is dependent on the results of a BMI screening, which is related to a health factor. However, the plan complies with the requirements of paragraph (f)(3)(iv) of this section because it makes available to all individuals who do not satisfy the BMI standard a different reasonable means of qualifying for the reward (a walking program that is not unreasonably burdensome or impractical for individuals to comply with and that is otherwise reasonably designed based on all the

relevant facts and circumstances). In addition, the plan complies with the requirements of paragraph (f)(3)(iii) of this section because, if there are individuals for whom it is unreasonably difficult due to a medical condition to comply, or for whom it is medically inadvisable to attempt to comply, with the walking program, the plan provides a reasonable alternative to those individuals. Moreover, the plan satisfies the requirements of paragraph (f)(3)(v) of this section because it discloses, in all materials describing the terms of the program, the availability of other means of qualifying for the reward or the possibility of waiver of the otherwise applicable standard. Thus, the plan satisfies paragraphs (f)(3)(iii), (iv), and (v) of this section.

Example 5. (i) Facts. In conjunction with an annual open enrollment period, a group health plan provides a premium differential based on tobacco use, determined using a health risk assessment. The following statement is included in all plan materials describing the tobacco premium differential: "Stop smoking today! We can help! If you are a smoker, we offer a smoking cessation program. If you complete the program, you can avoid this surcharge." The plan accommodates participants who smoke by facilitating their enrollment in a smoking cessation program that requires participation at a time and place that are not unreasonably burdensome or impractical for participants, and that is otherwise reasonably designed based on all the relevant facts and circumstances. The plan pays the cost of the program. Any participant can avoid the surcharge by participating in the program, regardless of whether the participant stops smoking.

(ii) Conclusion. In this Example 5, the premium differential satisfies the requirements of paragraphs (f)(3)(iii), (iv), and (v) of this section. The program's initial standard for obtaining a reward is dependent on the results of a health risk assessment, which is a screening. However, the plan is reasonably designed under paragraph (f)(3)(iv) because the plan provides a different, reasonable means of qualifying for the reward to all tobacco users. The plan discloses, in all materials describing the terms of the program, the availability of other means of qualifying for the reward. Thus, the plan satisfies paragraphs (f)(3)(iii), (iv), and (v) of this section.

Example 6. (i) Facts. Same facts as Example 5, except the plan does not facilitate F's enrollment in any program. Instead the plan advises F to find a program, pay for it, and provide a certificate of completion to the plan.

(ii) Conclusion. In this Example 6, the requirement for F to find and pay for F's own smoking cessation program means that the alternative program is not reasonable. Accordingly, the plan has not offered a reasonable alternative standard that complies with paragraphs (f)(3)(iii) and (iv) of this section and the premium differential violates paragraph (c) of this section.

* * * * *

Subpart C—Other Requirements

3. Section 2590.715-2705 is added to read as follows:

§ 2590.715-2705 Prohibiting discrimination against participants and beneficiaries based on a health factor.

(a) In general. A group health plan and a health insurance issuer offering group health insurance coverage must comply with the requirements of §2590.702.

(b) Applicability date. This section is applicable to group health plans and health insurance issuers offering group health insurance coverage for plan years beginning on or after January 1, 2014. See §2590.715-1251, which provides that the rules of this section do not apply to grandfathered health plans.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Subtitle A

For the reasons stated in the preamble, the Department of Health and Human Services proposes to amend 45 CFR Parts 146 and 147 as follows:

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

1. The authority citation for Part 146 continues to read as follows:

Authority: Secs. 2702 through 2705, 2711 through 2723, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg–1 through 300gg–5, 300gg–11 through 300gg–23, 300gg–91, and 300gg–92) (1996).

Section 146.121 is also issued under 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 (2010).

2. In § 146.121, paragraph (f) is revised to read as follows:

§ 146.121 Prohibiting discrimination against participants and beneficiaries based on a health factor.

* * * * *

(f) Nondiscriminatory wellness programs – in general. A wellness program is a program of health promotion or disease prevention. Paragraphs (b)(2)(ii) and (c)(3) of this section provide exceptions to the general prohibitions against discrimination based on a health factor for plan provisions that vary benefits (including cost-sharing mechanisms) or the premium or contribution for similarly situated individuals in connection with a wellness program that satisfies the requirements of this paragraph (f). If a wellness program is a participatory wellness program, as defined in paragraph (f)(1) of this section, that paragraph also makes clear that the wellness program does not violate this section if participation in the program is made available to all similarly situated individuals. If a wellness program is a health-contingent wellness program, as defined in paragraph (f)(2) of this section, the wellness program does not violate this section if the requirements of paragraph (f)(3) of this section are met. Except where expressly provided otherwise, references in this section to an individual obtaining a reward include both obtaining a reward (such as a premium discount or rebate, a waiver of all or part of a cost-sharing mechanism, an additional benefit, or any financial or other incentive) and avoiding a penalty (such as the absence of a premium surcharge, or other financial or nonfinancial disincentive). References in this section to a plan providing a reward include both providing a reward (such as a premium discount or rebate, a waiver of all or part of a cost-sharing mechanism, an additional benefit, or any financial or other incentive) and imposing a penalty (such as a surcharge or other financial or nonfinancial disincentive).

(1) Participatory wellness programs defined. If none of the conditions for obtaining a reward under a wellness program is based on an individual satisfying a standard that is related to a health factor (or if a wellness program does not provide a reward), the wellness program is a participatory wellness program and, if participation in the program is made available to all

similarly situated individuals, does not violate this section. Examples of participatory wellness programs are:

(i) A program that reimburses all or part of the cost for membership in a fitness center.

(ii) A diagnostic testing program that provides a reward for participation and does not base any part of the reward on outcomes.

(iii) A program that encourages preventive care through the waiver of the copayment or deductible requirement under a group health plan for the costs of, for example, prenatal care or well-baby visits. (Note that, with respect to non-grandfathered plans, §147.130 of this subchapter requires benefits for certain preventive health services without the imposition of cost sharing.)

(iv) A program that reimburses employees for the costs of participating, or that otherwise provides a reward for participating, in a smoking cessation program without regard to whether the employee quits smoking.

(v) A program that provides a reward to employees for attending a monthly no-cost health education seminar.

(vi) A program that provides a reward to employees who complete a health risk assessment regarding current health status, without any further action (educational or otherwise) required by the employee with regard to the health issues identified as part of the assessment. (See also §146.122 for rules prohibiting collection of genetic information).

(2) Health-contingent wellness programs defined. If any of the conditions for obtaining a reward under a wellness program is based on an individual satisfying a standard that is related to a health factor, the wellness program is a health-contingent wellness program and the program

is permissible under this section only if all of the requirements of paragraph (f)(3) of this section are satisfied. Examples of health-contingent wellness programs are:

(i) A program that imposes a premium surcharge based on tobacco use.

(ii) A program that uses a biometric screening or a health risk assessment to identify employees with specified medical conditions or risk factors (such as high cholesterol, high blood pressure, unhealthy body mass index, or high glucose level) and provides a reward to employees identified as within a normal or healthy range for biometrics (or at low risk for certain medical conditions), while requiring employees who are identified as outside the normal or healthy range (or at risk) to take additional steps (such as meeting with a health coach, taking a health or fitness course, adhering to a health improvement action plan, or complying with a health care provider's plan of care) to obtain the same reward.

(3) Requirements for health-contingent wellness programs. A health-contingent wellness program does not violate this section if all of the following requirements are satisfied:

(i) Frequency of opportunity to qualify. The program must give individuals eligible for the program the opportunity to qualify for the reward under the program at least once per year.

(ii) Size of reward. The reward for a health-contingent wellness program, together with the reward for other health-contingent wellness programs with respect to the plan, must not exceed the applicable percentage of the total cost of employee-only coverage under the plan, as defined in this paragraph (f)(3)(ii). However, if, in addition to employees, any class of dependents (such as spouses, or spouses and dependent children) may participate in the wellness program, the reward must not exceed the applicable percentage of the total cost of the coverage in which an employee and any dependents are enrolled. For purposes of this paragraph (f)(3)(ii), the cost of coverage is determined based on the total amount of employer and employee

contributions for the benefit package under which the employee is (or the employee and any dependents are) receiving coverage.

(A) Applicable percentage. For purposes of this paragraph (f)(3)(ii), the applicable percentage is 30 percent, except that the applicable percentage is increased an additional 20 percentage points (to 50 percent) to the extent that the additional percentage is in connection with a program designed to prevent or reduce tobacco use.

(B) Examples. The rules of this paragraph (f)(3)(ii) are illustrated by the following examples:

Example 1. (i) Facts. An employer sponsors a group health plan. The annual premium for employee-only coverage is $6,000 (of which the employer pays $4,500 per year and the employee pays $1,500 per year). The plan offers employees a health-contingent wellness program focused on exercise, blood sugar, weight, cholesterol, and blood pressure. The reward for compliance is an annual premium rebate of $600.

(ii) Conclusion. In this Example 1, the program satisfies the requirements of this paragraph (f)(3)(ii) because the reward for the wellness program, $600, does not exceed 30 percent of the total annual cost of employee-only coverage, $1,800. ($6,000 x 30% = $1,800.)

Example 2. (i) Facts. Same facts as Example 1, except the wellness program is exclusively a tobacco prevention program. Employees who have used tobacco in the last 12 months and who are not enrolled in the plan's tobacco cessation program are charged a $1,000 premium surcharge (in addition to their employee contribution towards the coverage). (Those who participate in the plan's tobacco cessation program are not assessed the $1,000 surcharge.)

(ii) Conclusion. In this Example 2, the program satisfies the requirements of this paragraph (f)(3)(ii) because the reward for the wellness program (absence of a $1,000 surcharge), does not exceed 50 percent of the total annual cost of employee-only coverage, $3,000. ($6,000 x 50% = $3,000.)

Example 3. (i) Facts. Same facts as Example 1, except that, in addition to the $600 reward for compliance with the health-contingent wellness program, the plan also imposes an additional $2,000 tobacco premium surcharge on employees who have used tobacco in the last 12 months and who are not enrolled in the plan's tobacco cessation program. (Those who participate in the plan's tobacco cessation program are not assessed the $2,000 surcharge.)

(ii) Conclusion. In this Example 3, the program satisfies the requirements of this paragraph (f)(3)(ii) because both: the total of all rewards (including absence of a surcharge for participating in the tobacco program) is $2,600 ($600 + $2,000 = $2,600), which does not exceed

50 percent of the total annual cost of employee-only coverage ($3,000); and, tested separately, the $600 reward for the wellness program unrelated to tobacco use does not exceed 30 percent of the total annual cost of employee-only coverage, $1,800.

Example 4. (i) Facts. An employer sponsors a group health plan. The total annual premium for employee-only coverage (including both employer and employee contributions towards the coverage) is $5,000. The plan provides a $250 reward to employees who complete a health risk assessment, without regard to the health issues identified as part of the assessment. The plan also offers a Healthy Heart program, which is a health-contingent wellness program under paragraph (f)(2) of this section, with an opportunity to earn a $1,500 reward.

(ii) Conclusion. In this Example 4, the plan satisfies the requirements of this paragraph (f)(3)(ii). Even though the total reward for all wellness programs under the plan is $1,750 ($250 + $1,500 = $1,750, which exceeds 30 percent of the cost of the annual premium for employee-only coverage ($5,000 x 30% = $1,500)), only the reward offered for compliance with the health-contingent wellness program ($1,500) is taken into account in determining whether the rules of this paragraph (f)(3)(ii) are met. (The $250 reward is offered in connection with a participatory wellness program and therefore is not taken into account under this paragraph (f)(3)(ii)). The health-contingent wellness program offers a reward that does not exceed 30 percent of the total annual cost of employee-only coverage.

(iii) Uniform availability and reasonable alternative standards. The reward under the program must be available to all similarly situated individuals.

(A) Under this paragraph (f)(3)(iii), a reward under a program is not available to all similarly situated individuals for a period unless the program meets both of the following requirements:

(1) The program allows a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard; and

(2) The program allows a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is medically inadvisable to attempt to satisfy the otherwise applicable standard.

(B) While plans and issuers are not required to determine a particular alternative standard in advance of an individual's request for one, if an individual is described in either paragraph (f)(3)(iii)(A)(1) or (2) of this section, a reasonable alternative standard must be furnished by the plan or issuer upon the individual's request or the condition for obtaining the reward must be waived. All the facts and circumstances are taken into account in determining whether a plan or issuer has furnished a reasonable alternative standard, including but not limited to the following:

(1) If the reasonable alternative standard is completion of an educational program, the plan or issuer must make the educational program available instead of requiring an individual to find such a program unassisted, and may not require an individual to pay for the cost of the program.

(2) If the reasonable alternative standard is a diet program, plans and issuers are not required to pay for the cost of food but must pay any membership or participation fee.

(3) If the reasonable alternative standard is compliance with the recommendations of a medical professional who is an employee or agent of the plan or issuer, and an individual's personal physician states that the plan's recommendations are not medically appropriate for that individual, the plan or issuer must provide a reasonable alternative standard that accommodates the recommendations of the individual's personal physician with regard to medical appropriateness. Plans and issuers may impose standard cost sharing under the plan or coverage for medical items and services furnished pursuant to the physician's recommendations.

(C) If reasonable under the circumstances, a plan or issuer may seek verification, such as a statement from an individual's personal physician, that a health factor makes it unreasonably difficult for the individual to satisfy, or medically inadvisable for the individual to attempt to

satisfy, the otherwise applicable standard. It would not be reasonable, for example, for a plan and issuer to seek verification of a claim that is obviously valid based on the nature of the individual's medical condition that is known to the plan or issuer. However, plans and issuers may seek verification in the case of claims for which it is reasonable to determine that medical judgment is required to evaluate the validity of the claim.

(iv) Reasonable design. The program must be reasonably designed to promote health or prevent disease. A program satisfies this standard if it has a reasonable chance of improving the health of, or preventing disease in, participating individuals and it is not overly burdensome, is not a subterfuge for discriminating based on a health factor, and is not highly suspect in the method chosen to promote health or prevent disease. This determination is based on all the relevant facts and circumstances. To the extent a plan's initial standard for obtaining a reward (including a portion of a reward) is based on the results of a measurement, test, or screening relating to a health factor (such as a biometric examination or a health risk assessment), the plan must make available to any individual who does not meet the standard based on the measurement, test, or screening a different, reasonable means of qualifying for the reward.

(v) Notice of availability of other means of qualifying for the reward. (A) The plan or issuer must disclose in all plan materials describing the terms of the program the availability of other means of qualifying for the reward or the possibility of waiver of the otherwise applicable standard. If plan materials merely mention that a program is available, without describing its terms, this disclosure is not required.

(B) The following language, or substantially similar language, can be used to satisfy the notice requirement of this paragraph (f)(3)(v): "Your health plan is committed to helping you achieve your best health status. Rewards for participating in a wellness program are available to

all employees. If you think you might be unable to meet a standard for a reward under this wellness program, you might qualify for an opportunity to earn the same reward by different means. Contact us at [insert contact information] and we will work with you to find a wellness program with the same reward that is right for you in light of your health status." Additional sample language is provided in the examples of paragraph (f)(4) of this section.

(4) Examples. The rules of paragraphs (f)(3)(iii), (iv), and (v) of this section are illustrated by the following examples:

Example 1. (i) Facts. A group health plan provides a reward to individuals who participate in a reasonable specified walking program. If it is unreasonably difficult due to a medical condition for an individual to participate (or if it is medically inadvisable for an individual to participate), the plan will waive the walking program requirement and provide the reward. All materials describing the terms of the walking program disclose the availability of the waiver.

(ii) Conclusion. The program satisfies the requirements of paragraph (f)(3)(iii) of this section because the reward under the program is available to all similarly situated individuals because it accommodates individuals who cannot participate in the walking program due to a medical condition (or for whom it would be medically inadvisable to attempt to participate) by providing them the reward even if they do not participate in the walking program (that is, by waiving the condition). The program satisfies the requirements of paragraph (f)(3)(iv) of this section because the walking program is reasonably designed to promote health and prevent disease. Last, the plan complies with the disclosure requirement of paragraph (f)(3)(v) of this section. Thus, the plan satisfies paragraphs (f)(3)(iii), (iv), and (v) of this section.

Example 2. (i) Facts. A group health plan offers a reward to individuals who achieve a count under 200 on a cholesterol test. If a participant does not achieve the targeted cholesterol count, the plan will make available a different, reasonable means of qualifying for the reward. In addition, all plan materials describing the terms of the program include the following statement: "Your health plan wants to help you take charge of your health. Rewards are available to all employees who participate in our Cholesterol Awareness Wellness Program. If your cholesterol count is under 200, you will receive the reward. If not, you will still have an opportunity to qualify for the reward. We will work with you to find a Health Smart program that is right for you." Individual D is identified as having a cholesterol count above 200. The plan partners D with a nurse who makes recommendations regarding diet and exercise, with which it is not unreasonably difficult due to a medical condition of D or medically inadvisable for D to comply, and which is otherwise reasonably designed, based on all the relevant facts and circumstances. In addition, the plan makes available to all other individuals who do not meet the cholesterol standard a different, reasonable means of qualifying for the reward which is not unreasonably

burdensome or impractical. D will qualify for the discount if D follows the recommendations regardless of whether D achieves a cholesterol count that is under 200.

(ii) Conclusion. In this Example 2, the program satisfies the requirements of paragraphs (f)(3)(iii), (iv), and (v) of this section. The program's initial standard for obtaining a reward is dependent on the results of a cholesterol screening, which is related to a health factor. However, the program is reasonably designed under paragraphs (f)(3)(iii) and (iv) of this section because the plan makes available to all individuals who do not meet the cholesterol standard a different, reasonable means of qualifying for the reward and because the program is otherwise reasonably designed based on all the relevant facts and circumstances. The plan also discloses in all materials describing the terms of the program the opportunity to qualify for the reward through other means. Thus, the program satisfies paragraphs (f)(3)(iii), (iv), and (v) of this section.

Example 3. (i) Facts. Same facts as Example 2, except that, following diet and exercise, D again fails to achieve a cholesterol count that is under 200, and the program requires D to visit a doctor and follow any additional recommendations of D's doctor with respect to D's cholesterol. The program permits D to select D's own doctor for this purpose. D visits D's doctor, who determines D should take a prescription medication for cholesterol. In addition, the doctor determines that D must be monitored through periodic blood tests to continually reevaluate D's health status. The plan accommodates D by making the discount available to D, but only if D actually follows the advice of D's doctor's regarding medication and blood tests.

(ii) Conclusion. In this Example 3, the program's requirements to follow up with, and follow the recommendations of, D's doctor do not make the program unreasonable under paragraphs (f)(3)(iii) or (iv) of this section. The program continues to satisfy the conditions of paragraphs (f)(3)(iii), (iv), and (v) of this section.

Example 4. (i) Facts. A group health plan will provide a reward to participants who have a body mass index (BMI) that is 26 or lower, determined shortly before the beginning of the year. Any participant who does not meet the target BMI is given the same discount if the participant complies with an exercise program that consists of walking 150 minutes a week. Any participant for whom it is unreasonably difficult due to a medical condition to comply with this walking program (and any participant for whom it is medically inadvisable to attempt to comply with the walking program) during the year is given the same discount if the individual satisfies an alternative standard that is reasonable taking into consideration the individual's medical situation, is not unreasonably burdensome or impractical to comply with, and is otherwise reasonably designed based on all the relevant facts and circumstances. All plan materials describing the terms of the wellness program include the following statement: "Fitness is Easy! Start Walking! Your health plan cares about your health. If you are overweight, our Start Walking program will help you lose weight and feel better. We will help you enroll. (**If your doctor says that walking isn't right for you, that's okay too. We will develop a wellness program that is.)" Individual E is unable to achieve a BMI that is 26 or lower within the plan's timeframe and is also not reasonably able to comply with the walking program. E proposes a program based on the recommendations of E's physician. The plan agrees to make the discount available to E, but only if E actually follows the physician's recommendations.

(ii) Conclusion. In this Example 4, the program satisfies the requirements of paragraphs (f)(3)(iii), (iv), and (v) of this section. The program's initial standard for obtaining a reward is dependent on the results of a BMI screening, which is related to a health factor. However, the plan complies with the requirements of paragraph (f)(3)(iv) of this section because it makes available to all individuals who do not satisfy the BMI standard a different reasonable means of qualifying for the reward (a walking program that is not unreasonably burdensome or impractical for individuals to comply with and that is otherwise reasonably designed based on all the relevant facts and circumstances). In addition, the plan complies with the requirements of paragraph (f)(3)(iii) of this section because, if there are individuals for whom it is unreasonably difficult due to a medical condition to comply, or for whom it is medically inadvisable to attempt to comply, with the walking program, the plan provides a reasonable alternative to those individuals. Moreover, the plan satisfies the requirements of paragraph (f)(3)(v) of this section because it discloses, in all materials describing the terms of the program, the availability of other means of qualifying for the reward or the possibility of waiver of the otherwise applicable standard. Thus, the plan satisfies paragraphs (f)(3)(iii), (iv), and (v) of this section.

Example 5. (i) Facts. In conjunction with an annual open enrollment period, a group health plan provides a premium differential based on tobacco use, determined using a health risk assessment. The following statement is included in all plan materials describing the tobacco premium differential: "Stop smoking today! We can help! If you are a smoker, we offer a smoking cessation program. If you complete the program, you can avoid this surcharge." The plan accommodates participants who smoke by facilitating their enrollment in a smoking cessation program that requires participation at a time and place that are not unreasonably burdensome or impractical for participants, and that is otherwise reasonably designed based on all the relevant facts and circumstances. The plan pays the cost of the program. Any participant can avoid the surcharge by participating in the program, regardless of whether the participant stops smoking.

(ii) Conclusion. In this Example 5, the premium differential satisfies the requirements of paragraphs (f)(3)(iii), (iv), and (v) of this section. The program's initial standard for obtaining a reward is dependent on the results of a health risk assessment, which is a screening. However, the plan is reasonably designed under paragraph (f)(3)(iv) because the plan provides a different, reasonable means of qualifying for the reward to all tobacco users. The plan discloses, in all materials describing the terms of the program, the availability of other means of qualifying for the reward. Thus, the plan satisfies paragraphs (f)(3)(iii), (iv), and (v) of this section.

Example 6. (i) Facts. Same facts as Example 5, except the plan does not facilitate F's enrollment in any program. Instead the plan advises F to find a program, pay for it, and provide a certificate of completion to the plan.

(ii) Conclusion. In this Example 6, the requirement for F to find and pay for F's own smoking cessation program means that the alternative program is not reasonable. Accordingly, the plan has not offered a reasonable alternative standard that complies with paragraphs (f)(3)(iii) and (iv) of this section and the premium differential violates paragraph (c) of this section.

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

3. 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 (2010).

4. Section 147.110 is added to read as follows:

§ 147.110 Prohibiting discrimination against participants, beneficiaries, and individuals based on a health factor.

(a) In general. A group health plan and a health insurance issuer offering group or individual health insurance coverage must comply with all the requirements under 45 CFR 146.121 applicable to a group health plan and a health insurance issuer offering group health insurance coverage. Accordingly, with respect to an issuer offering health insurance coverage in the individual market, the issuer is subject to the requirements of §146.121 to the same extent as an issuer offering group health insurance coverage, except that the exception contained in §146.121(f) does not apply.

(b) Applicability date. This section is applicable to a group health plan and a health insurance issuer offering group or individual health insurance coverage for plan years (in the individual market, policy years) beginning on or after January 1, 2014. See §147.140, which provides that the rules of this section do not apply to grandfathered health plans.

[FR Doc. 2012-28361 Filed 11/20/2012 at 11:15 am; Publication Date: 11/26/2012]