

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
Center for Consumer Information & Insurance Oversight  
200 Independence Avenue SW  
Washington, DC 20201



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**From:** Samara Lorenz, Director, Oversight Group

**Title:** Insurance Standards Bulletin Series -- INFORMATION

**Subject:** Bulletin: Opportunity for States to Participate in a Wellness Program  
Demonstration Project to Implement Health-Contingent Wellness Programs in the Individual Market

## **I. Purpose**

The Department of Health and Human Services (HHS) is publishing this bulletin to announce an opportunity for States to apply to participate in a wellness program demonstration project. Participating States may implement nondiscriminatory health-contingent wellness programs in the individual market, as described in section 2705(l) of the Public Health Service Act (PHS Act). This bulletin outlines the participation requirements; the criteria HHS, in consultation with the Department of Labor (DOL) and the Department of the Treasury (the Treasury Department), will use to evaluate applications; instructions on application submissions and appeals; and potential future opportunities for additional States to apply.

## **II. Background**

Prior to the enactment of the Patient Protection and Affordable Care Act (PPACA), Titles I and IV of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) generally prohibited group health plans and group health insurance issuers from discriminating against individual participants and beneficiaries in determining eligibility, benefits, or premiums based on a health factor.<sup>1</sup> However, premium discounts, rebates, or modifications to otherwise applicable cost sharing (including copayments, deductibles, or coinsurance) were allowed in return for adherence to certain programs of health promotion and disease prevention, also referred to as wellness programs.<sup>2</sup>

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<sup>1</sup> PHS Act section 2702 (42 U.S.C. § 300gg-1), as enacted under HIPAA, prior to the PPACA amendments. *See also* Internal Revenue Code (Code) section 9802 and Employee Retirement Income Security Act (ERISA) section 702.

<sup>2</sup> The Departments of HHS, Labor, and the Treasury (collectively, the Departments) implemented this exception in the December 13, 2006 Final Rule, *Nondiscrimination and Wellness Programs in Health Coverage in the Group Market*, by allowing benefits, premiums, and contributions to vary based on participation in a wellness program if

PPACA amended and moved the PHS Act nondiscrimination provisions to section 2705 of the PHS Act<sup>3</sup> and extended the nondiscrimination provisions (but not the wellness program provisions) to the individual market.<sup>4</sup> Section 2705(j) of the PHS Act, as amended by PPACA, outlines the requirements for wellness programs for group health plans and health insurance coverage in the group market.

On June 3, 2013, the Departments published the Final Rule, *Incentives for Nondiscriminatory Wellness Programs in Group Health Plans* (the 2013 Final Rule), implementing the wellness program provisions of section 2705 of the PHS Act.<sup>5</sup> The 2013 Final Rule sets forth the criteria that a wellness program must satisfy in order for a group health plan or group health insurance issuer to qualify for an exception to the prohibition on discrimination based on health status.

A wellness program, defined as a program of health promotion or disease prevention, can be (1) participatory or (2) health-contingent. Participatory wellness programs are wellness programs where none of the conditions for obtaining a reward<sup>6</sup> under the wellness program are based on an individual satisfying a standard that is related to a health factor, or wellness programs that do not provide a reward.<sup>7</sup> For instance, a participatory wellness program would include a program that reimburses participants for a portion of the cost of a fitness center membership or a program that provides participants a \$50 gift card for participating in a smoking cessation program without regard to whether the participant quits smoking.

In contrast, health-contingent wellness programs are wellness programs that provide a reward and require an individual to satisfy a standard related to a health factor to obtain the reward (or require an individual to undertake more than a similarly situated individual based on a health factor in order to obtain the same reward).<sup>8</sup> There are two types of health-contingent wellness

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such a program adheres to certain conditions set forth in the regulations. See 71 FR 75014 (Dec. 13, 2006).

<sup>3</sup> The PHS Act nondiscrimination and wellness program statutory provisions are now codified at 42 U.S.C. § 300gg-4. Although section 9802 of the Code and section 702 of ERISA were not amended by PPACA, section 2705 of the PHS Act is incorporated by reference into section 9815 of the Code and section 715 of ERISA. Thus, the nondiscrimination and wellness program provisions under section 2705 of the PHS Act, as added by PPACA, as well as those under section 702 of ERISA and section 9802 of the Code, as added by HIPAA, are applicable to private employment-based group health plans and health insurance issuers providing health insurance coverage in connection with such plans.

<sup>4</sup> PPACA increased the maximum permissible amounts for rewards in health-contingent wellness programs from 20% to 30% of the cost of the health coverage and provided the Departments with the authority to increase the maximum permissible reward to 50% of the cost of the health coverage if the Departments determine such an increase is appropriate.

<sup>5</sup> 78 FR 33158 (June 3, 2013). In the 2013 Final Rule, the Departments exercised their authority and increased the maximum permissible health-contingent wellness programs reward amount to 50% of the cost of the health coverage for wellness programs designed to prevent or reduce tobacco use. See 45 C.F.R. § 146.121(f)(5).

<sup>6</sup> The reward may be a positive reward, such as a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism, an additional benefit, or any financial or other incentive. The reward may also be avoidance of a penalty, such as the absence of a premium surcharge or other financial or nonfinancial disincentive. See 45 C.F.R. § 146.121(f)(1)(i).

<sup>7</sup> See 45 C.F.R. § 146.121(f)(1)(ii).

<sup>8</sup> See 45 C.F.R. § 146.121(f)(1)(iii)-(v). The requirements for an activity-only wellness program are set forth in 45

programs: (1) activity-only and (2) outcome-based. Activity-only wellness programs require an individual to perform or complete an activity related to a health factor in order to obtain a reward but do not require the individual to attain or maintain a specific health outcome, such as rewarding participants in a walking, diet, or exercise program. Outcome-based wellness programs require an individual to attain or maintain a specific health outcome in order to obtain a reward, such as rewarding participants for not smoking or for losing weight.

HHS stated in the preamble to the 2013 Final Rule that participatory wellness programs in the individual market do not violate the nondiscrimination provisions, provided that such programs are consistent with State law and available to all similarly situated individuals enrolled in the individual health insurance coverage.<sup>9</sup> HHS stated that this type of wellness program is permissible because participatory wellness programs do not base rewards on achieving a standard related to a health factor, and thus do not discriminate based upon an individual's health status. Therefore, participatory wellness programs that meet the criteria set out in the preamble to the 2013 Final Rule are permitted in the individual market under federal law.

Although health-contingent wellness programs have not been permitted in the individual market, PPACA added section 2705(l) of the PHS Act, which provides for a wellness program demonstration project in the individual market. More specifically, section 2705(l) of the PHS Act requires HHS, in consultation with DOL and the Treasury Department, to establish a ten-State wellness program demonstration project. Under this demonstration project, participating States may implement nondiscriminatory health-contingent wellness programs in the individual market, subject to the wellness program provisions of section 2705(j) of the PHS Act.<sup>10</sup> Requirements for participation in the demonstration project are set forth in section 2705(l)(3) of the PHS Act, as explained later in this bulletin.

### Tobacco Surcharge

PHS Act section 2701, as amended by PPACA, allows issuers to apply a tobacco use rating factor of 1.5 to 1 in the individual and small group market that, if applied, effectively imposes a 50 percent premium surcharge for tobacco use. Regulations issued in 2013 implementing section 2701 of the PHS Act established a requirement that issuers in the small group market can only implement the tobacco use surcharge in connection with a wellness program meeting the standards of section 2705(j) of the PHS Act and its implementing regulations.<sup>11</sup> Thus, for a small group issuer to apply the tobacco surcharge, the issuer must also offer a tobacco cessation program in connection with the health plan. This requirement does not apply to issuers offering coverage in the individual market; issuers may, subject to applicable State law, implement the

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C.F.R. § 146.121(f)(3), and the requirements for an outcome-based wellness program are set forth in 45 C.F.R. § 146.121(f)(4).

<sup>9</sup> See 78 FR at 33167.

<sup>10</sup> Section 2705(l)(1) and (2) of the PHS Act requires such wellness program demonstration project to be established by July 1, 2014, and permits HHS, in consultation with DOL and the Treasury Department, to expand the wellness program demonstration project to include additional States beginning July 1, 2017, if HHS, in consultation with DOL and the Treasury Department, determines that the wellness program demonstration project is effective. To date, prior to this bulletin, HHS has not implemented section 2705(l) of the PHS Act.

<sup>11</sup> 45 C.F.R. § 147.102(a)(1)(iv); 78 FR 13406, 13414 (Feb. 27, 2013).

tobacco use surcharge in the individual market with or without offering a tobacco cessation program.

### **III. Project Requirements**

States interested in allowing health-contingent wellness programs in the individual market may apply to participate in the wellness program demonstration project. Consistent with section 2705(l)(1) of the PHS Act, States that participate in the demonstration project must apply the requirements established under section 2705(j) of the PHS Act to wellness programs offered by health insurance issuers in the individual market in the State. Issuers in the individual market in such States will be required to comply with the provisions of 45 C.F.R § 146.121(f) for group health plans and health insurance coverage in the group market. Demonstration projects are subject to approval by HHS.

#### *A. Implementation Approaches*

There are two approaches States can use to implement health-contingent wellness programs. States may implement a State-designed wellness program (standard demonstration project). Under this option, the State would set the terms and rewards of the wellness program(s), consistent with the requirements of sections 2705(j) and (l) of the PHS Act and 45 C.F.R. § 146.121(f) applicable to the group market, and health insurance issuers offering wellness programs in the individual market under the demonstration project would not be permitted to deviate from the terms and rewards as required by the State. The design of the wellness program would be subject to approval by HHS.

Alternatively, a State that wants to provide health insurance issuers with more flexibility may allow issuers to design wellness programs (issuer-based demonstration project). Under this approach, States may submit to HHS the parameters the State will use to evaluate health-contingent wellness programs designed by health insurance issuers to be offered in the individual market of the applicable State. States would establish requirements and the standard of review applicable to health-contingent wellness programs created by issuers for the individual market in the applicable State. Those requirements and the standard of review would have to be consistent with the provisions of 45 C.F.R. § 146.121(f) applicable to wellness programs offered in the group market and would be subject to approval by HHS.

#### *B. Application Requirements*

This section outlines the requirements that States must meet in order to be approved for participation in the wellness program demonstration project.

As provided by section 2705(l)(3)(A) of the PHS Act, any State that applies to participate in the wellness program demonstration project must demonstrate, and HHS, in consultation with DOL and the Treasury Department, must determine, that the State's demonstration project is designed in a manner that will not result in any decrease in coverage and will not increase the cost to the Federal Government in providing the premium tax credit under section 36B of the Code or cost-

sharing assistance under section 1402 of PPACA.<sup>12</sup>

A State that develops a *standard demonstration project* may meet this requirement by submitting in its application the following information:

- The terms and rewards of the wellness program(s) and any applicable guidance the State intends to publish or otherwise provide to its individual market issuers;
- An analysis, such as an actuarial or economic analysis, demonstrating that the standard demonstration project is not anticipated to decrease coverage levels or increase costs to the Federal Government; and
- The expected number of participants, rewards provided, and anticipated impacts on utilization or medical claims costs over a three-year period. As noted in this section, following approval of the application, States will be required to submit these data points and an accompanying analysis starting three years from the date of the State's approval to participate in the wellness program demonstration project.

A State that develops an *issuer-based demonstration project* may meet the requirements of PHS Act section 2705(1)(3)(A) by submitting in its application the following information:

- Any guidance establishing requirements applicable to health-contingent wellness programs in the individual market that the State intends to publish or otherwise provide to its individual market issuers;
- An analysis, such as an actuarial or economic analysis, demonstrating that the issuer-based demonstration project is not anticipated to decrease coverage levels or increase costs to the Federal Government; and
- The expected number of participants, rewards provided, and anticipated impacts on utilization or medical claims costs over a three-year period. As noted in this section, following approval of the application, States will be required to submit these data points and an accompanying analysis starting three years from the date of the State's approval to participate in the wellness program demonstration project.

### C. Project Requirements

#### 1. Standards for Wellness Program Demonstration Projects

In order to ensure that issuers in the wellness program demonstration project qualify for an exception to the prohibition on discrimination based on health status, HHS, in consultation with DOL and the Treasury Department, will evaluate whether the State's standard demonstration

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<sup>12</sup> For an individual who is otherwise eligible for the premium tax credit, the amount of the premium tax credit for a month is the lesser of the enrollment premium for the month for the qualified health plan or plans in which the individual, or the individual's spouse or dependents, enrolled or the amount of the monthly applicable second lowest cost silver plan (SLCSP) premium less the individual's contribution amount. The applicable SLCSP premium used for this purpose is determined without regard to any premium discount or rebate under a wellness program demonstration project under section 2705(1) of the PHS Act. *See* Code section 36B(b)(3)(C) and 26 C.F.R. § 1.36B-3(e). However, wellness program demonstration project rewards could affect an individual's enrollment premium and therefore, depending on the facts, could affect the calculation of the premium tax credit.

project or issuer-based demonstration project complies with the standards outlined in 45 C.F.R. § 146.121(f)(3)(i) – (v) (for activity-only wellness programs) or (f)(4)(i) – (v) (for outcome-based wellness programs), as applicable. More specifically, wellness programs offered in the individual market through this demonstration project must meet the following requirements:

- *Frequency of Opportunity to Qualify.* The program must give eligible individuals the opportunity to qualify for the reward under the program at least once per year;
- *Size of Reward.* The reward for the wellness program, together with the reward for other health-contingent wellness programs, must not exceed 30 percent (or 50 percent if the additional 20 percentage points are in connection with a program designed to prevent or reduce tobacco use) of the total cost of self-only coverage under the plan in which the individual enrolls;<sup>13</sup>
- *Reasonable Design.* The program must be reasonably designed to promote health or prevent disease, and this determination must be based on all the relevant facts and circumstances. A program satisfies this standard if it has a reasonable chance of improving the health of, or preventing disease in, participating individuals and is not overly burdensome, is not a subterfuge for discrimination based on a health factor, and is not highly suspect in the method chosen to promote health or prevent disease;
- *Uniform Availability and Reasonable Alternative Standards.* The full reward must be made available to all individuals (and, as applicable, dependents) enrolled in the coverage, regardless of health status. Activity-only wellness programs must provide a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward to any individual for whom it is unreasonably difficult due to a medical condition or medically inadvisable to attempt to satisfy the otherwise applicable standard. Outcome-based wellness programs must provide a reasonable alternative standard to any individual who does not meet the initial standard based on a measurement, test, or screening that is related to a health factor; and
- *Notice of Availability of Reasonable Alternative Standard.* The issuer must disclose in all plan materials describing the terms of the wellness program, the availability of a reasonable alternative standard to qualify for the reward (and, if applicable, the possibility of waiver of the otherwise applicable standard), including the relevant contact information for obtaining a reasonable alternative standard, and a statement that recommendations of an individual’s personal physician will be accommodated. For outcome-based wellness programs, this disclosure must also be included in any disclosure that an individual did not satisfy an initial outcome-based standard.

## 2. Special Rule for Wellness Program with Tobacco Surcharge

States that are approved to participate in the wellness program demonstration project have the

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<sup>13</sup> This percentage limitation applies to the total cost of coverage in which an individual and his or her dependents are enrolled, if the dependents participate in the wellness program, without regard to any premium tax credit allowed under section 36B of the Code.

option, but are not required, to extend the requirement for issuers to offer a tobacco cessation program in order to apply a tobacco surcharge in connection with the health plan to the individual market. Specifically, States participating in the wellness program demonstration project may require issuers in the individual market to offer a wellness program that is designed to prevent or reduce tobacco use and meets the standards of section 2705(j) of the PHS Act in order to impose a tobacco surcharge under section 2701 of the PHS Act, or they can allow issuers to impose the tobacco surcharge outside the context of a wellness program.

### 3. Requirements for Participating States and Data Submission

States with an approved demonstration project must comply with the requirements of section 2705(l)(3)(B) of the PHS Act. These States will be required to submit to HHS data, including:

- Data regarding the participation in, the discounts or rewards provided under, and the overall issuer cost savings and changes in participant behavior and utilization or medical claims costs resulting from the health-contingent wellness programs in the individual market. This data must be accompanied by an analysis comparing these resultant data points to the expectations provided in the State's application materials. This data will be required starting three years from the date of the State's approval to participate in the wellness program demonstration project and on an annual basis thereafter. Further details on this data submission requirement will be provided to participating States once their application has been approved by HHS; and
- Summary data, on an annual basis, regarding the number and types of substantiated complaints regarding health-contingent wellness programs in the individual market received during the preceding 12 month period. States must also provide the number of and a summary of any market conduct examinations, or other investigations of issuers that offer health-contingent wellness programs in the individual market, particularly, examinations or investigations where there was a finding of a violation concerning compliance with the health-contingent wellness program standards of section 2705(j) of the PHS Act, as implemented at 45 C.F.R. § 146.121(f). Further details on this data submission requirement will be provided to participating States once their application has been approved by HHS.

## **IV. Criteria HHS Will Use to Evaluate Applications**

HHS, in consultation with DOL and the Treasury Department, will evaluate each complete application in the order received to identify up to ten States that will be approved to participate in the wellness program demonstration project. A complete application includes the documentation, analysis, and data, as described in section III as well as any additional information requested by the Departments.

HHS will review each State's complete application materials, and any applicable responses to HHS's questions or requests for additional information and determine, in consultation with DOL and the Treasury Department, whether or not the application satisfies the statutory requirements, as implemented in the requirements outlined in section III of this bulletin.

HHS will begin accepting applications for wellness program demonstration projects on September 30, 2019. States will be notified in writing once their applications have been approved or denied. HHS will publish on its website a list of States with an approved wellness program demonstration project as they are approved. The first ten approved States will be included in the wellness program demonstration project. Once ten States' demonstration projects have been approved, the application period will be closed until further notice.

## **V. Termination**

HHS, in consultation with DOL and the Treasury Department, reserves the right to rescind a State's approval to participate in the wellness program demonstration project, on a case-by-case basis, based on its determination that a State previously approved to participate in the wellness program demonstration project no longer meets the statutory requirements, as implemented in section III of this bulletin; or on the basis of policy considerations including identified trends of undue burdens for individuals insured in the individual market, cost shifting or discrimination. Prior to making such a determination, HHS will notify the State of the reason(s) that HHS is considering rescinding the State's approval and work closely with the State to resolve the applicable issue(s). If HHS, in consultation with DOL and the Treasury Department, decides to rescind a State's approval, HHS will notify the State in writing and provide instructions for terminating a State's demonstration project within a specified wind-down period.

## **VI. Appeal Process**

Within 15 calendar days of receipt of HHS's determination that a State's application does not qualify for the wellness program demonstration project or that a State previously approved to participate in the wellness program demonstration project no longer meets the requirements, a State may request HHS to undertake a secondary review of an application or a determination that the State's demonstration project no longer meets the application requirements by emailing the appeal request to [marketreform@cms.hhs.gov](mailto:marketreform@cms.hhs.gov). Additional evidence can be submitted with the request for review. If the secondary review upholds the initial determination, the State shall have no further rights to administrative appeal. After the first ten applications are approved, no appeals will be accepted with respect to applications that are not approved, except if the wellness program demonstration project is expanded to allow additional States to apply as described in section VIII.

## **VII. How to Submit an Application**

We strongly encourage States to engage with HHS early in the process of developing their application materials. A State may submit a wellness program demonstration project application to: [marketreform@cms.hhs.gov](mailto:marketreform@cms.hhs.gov). HHS, in consultation with DOL and the Treasury Department, will review each application and make a preliminary determination of whether it is complete or if additional information is needed within 60 days after it is submitted. Once an application is deemed complete, HHS, in consultation with DOL and the Treasury Department, will review the application and make a determination of approval or denial. Complete applications will be reviewed in the order they are received.



### **VIII. Future Opportunity for Additional States to Apply**

As provided by PHS Act section 2705(1)(2), HHS, in consultation with DOL and the Treasury Department, will evaluate the wellness program demonstration project. If HHS, in consultation with DOL and the Treasury Department, determines that the wellness program demonstration project is effective, the Departments may decide to expand the wellness program demonstration project and allow additional States to apply no sooner than three years from the date of this bulletin. Once a State's wellness program demonstration project is approved, that approval is valid unless and until HHS, in consultation with DOL and the Treasury Department, determines the State no longer meets the requirements as described in section III of this bulletin, or until the wellness program demonstration project is terminated.

#### **Where to get more information:**

Organizations that have any questions regarding the bulletin should contact HHS at [marketreform@cms.hhs.gov](mailto:marketreform@cms.hhs.gov) and include the organization's name as the subject of the email.