FamiliesUSA
The Voice for Health Care Consumers

**VIA ELECTRONIC SUBMISSION**
January 25, 2013

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
Room N-5635, U.S. Department of Labor
200 Constitution Avenue NW
Washington, DC 20210
*Attention:* Wellness Programs

**RE: Incentives for Nondiscriminatory Wellness Programs in Group Health Plans NPRM**

Dear Ms. Turner and Ms. Baum,

Families USA is a nonprofit, nonpartisan consumer advocacy organization dedicated to the achievement of high-quality, affordable health coverage for all. We applaud the coordinated efforts of the Departments of Labor, Health and Human Services, and Treasury (the Departments) to update standards for wellness incentive programs, effective 2014, and appreciate the opportunity to provide comments on this proposed rule.

We want to thank the Departments for their responsiveness to consumer advocates' expressed concerns and recommendations regarding the potential for wellness incentives to be a subterfuge for discrimination under existing federal standards for wellness programs. We strongly support many of the new provisions and clarifications proposed in this rule regarding standards for health-contingent wellness programs, which address many previously expressed concerns.

We were particularly pleased that the proposed rule includes greater clarification as to what constitutes a reasonable alternative standard and explicitly ensures key consumer protections for individuals requesting an alternative. We also applaud the Departments' efforts to coordinate tobacco rating and wellness programs, as well as the proposed rule's approach that would require wellness programs to offer a different means of qualifying for an incentive to any individual who does not meet an initial health outcome. We strongly agree with the Departments that this proposed approach will reduce the risk of health-contingent wellness incentive programs being used as a subterfuge for discrimination and increase the likelihood that wellness programs help high-risk individuals improve their health.

In general, we strongly support the proposed approach in this rule and believe it is a significant step towards limiting the potential for wellness incentive programs to be used as a subterfuge for discrimination based on health status factor. We have additional recommendations in a number of areas of the proposed rule that we believe are necessary to clarify the intent of the proposed rule or to

strengthen the rule to better protect against discrimination in all types of wellness incentive programs, including participatory programs.

We offer the following recommendations in response to a number of areas of the proposed rule and the proposed rule's requests for comments.

***(f) Nondiscriminatory wellness programs – in general***

We want to thank the Departments for the clarification that an incentive governed under this rule can be structured as a reward or a penalty. This reflects the fact that there can be little to no difference between these two types of incentive structures, in terms of their effects on health care costs. As such, we agree that programs offering either incentive must comply with the same requirements. We strongly recommend that this language is maintained in the final rule.

***(f)(1) Participatory wellness programs defined***

Requirements for Participatory Wellness Programs

This proposed rule broadly defines participatory wellness programs to include both wellness programs that do not provide a reward and wellness programs that do provide a reward for completion of an activity that is not related to a health factor. Wellness programs that only offer employees the opportunity to use additional benefits (and offer to cover the cost of said benefits) but that do not provide any reward for completing certain activities (such as Examples (f)(1)(i) and (iii) ) do not pose a risk to individuals maintaining affordable health coverage and care. As such, we agree with the proposed rule that these types of programs should not have to meet any additional requirements to prove that they are available to all similarly situated individuals.

However, we believe additional protections are still needed for participatory wellness programs that vary individuals' health care costs, beyond helping pay for a program, based on their participation in wellness activities (such as the incentive programs in Examples (f)(1)(ii), (iv), (v), and (vi) ). Just as health-contingent wellness plans must take additional steps to demonstrate that they are equally available to all similarly situated individuals, we strongly believe participatory wellness programs that require individuals to participate in certain activities in order to obtain a health care-based incentive must also take additional steps to demonstrate that the required activities (and obtaining a health care-based incentive) are truly available to all similarly situated individuals.

We appreciate that Example (f)(1)(v) cites participation in a no-cost health seminar. We agree that any activity in which a person is required to participate, in order to obtain an incentive, should be made available at no cost to the individual. However, the regulatory language does not explicitly prohibit participatory programs from requiring individuals to cover a participation fee for a required activity. In

addition, it is still possible for wellness plans to only offer required activities offsite, during non-working hours. These program designs can make any health care-based incentive not truly "available" to employees who cannot afford the participation fee or who have personal obligations after work. Many participatory programs vary workers' health care costs based on their completion of online programs that can last months in duration. For workers without reliable and consistent computer and internet access, completion of these activities may be burdensome or impossible.

There are also some scenarios where participation in certain wellness program activities may be medically inadvisable for certain populations. For example, participatory wellness programs often ask people to complete educational programs and online self-tracking tools related to diet, exercise, and weight management. While not experts in this field, we have heard consumer concerns that these types of activities could actually trigger unhealthy behaviors for individuals with a history of eating and/or exercising disorders. Depending on their design, nutrition and dietary programs could also be medically inadvisable or not helpful for individuals who have unique dietary restrictions, such as individuals with chronic kidney disease. Similar to protections assured under health-contingent programs, individuals should not have to participate in medically inadvisable activities or medically disruptive activities in order to obtain affordable health coverage and care.

**The final rule should clarify that if a participatory program varies individuals' health care costs based on their participating in certain activities, beyond covering the cost of said activities, then it must meet the following additional requirements in order to be considered "available to all similarly situated individuals":**

- Any activities in which an individual is required to participate to obtain an incentive (including any alternative standard) must be offered at no cost to the participant. This is consistent with the proposed rule's requirements for a reasonable alternative standard that is an activity under a health-contingent program. The wellness program must also be designed to provide employees the *option* of completing incentive requirements in the workplace and on paid hours.
- The wellness program must furnish an individual with a reasonable alternative standard (or waiver) if he/she cannot participate in the program's required activities because: 1) It is medically difficult or inadvisable to participate in required activities, similar to protections assured for health-contingent programs now; 2) participation requirements are disruptive or duplicative to an individual's existing care plan, decided in conjunction with his/her personal health care provider; or 3) required activities are overly burdensome for an individual, taking into account his/her personal circumstances, including, but not limited to, child/elder care responsibilities, lack of transportation, lack of internet access, or multiple jobs. (For additional comments regarding overly burdensome programs, please see comments on page 13.)

Finally, we recommend that the final rule amend Example (f)(1)(iv) of the proposed rule. This example cites reimbursing the cost of participating in a tobacco cessation program or providing a reward for

participating in a tobacco cessation program. We agree that a program that simply offers to reimburse the cost of a tobacco cessation program for those that choose to participate should be considered a participatory program and should not have to meet any additional standards in order to comply with the requirement that it be available to all similarly situated individuals. However, we believe that if a program ties an additional reward to participation in a smoking cessation program, it should be considered a health-contingent program, as participation hinges on whether someone has a health-status factor (whether or not someone is a smoker). We recommend that the final rule remove the phrase, "or that otherwise provides a reward for participating in a smoking cessation program" from example (f)(1)(iv). (For additional recommendations regarding the definition of health-contingent wellness program, please see comments on page 5.)

Compliance with Additional Nondiscrimination Laws

We appreciate that the proposed rule makes reference to the Genetics Information Nondiscrimination Act (GINA). However, wellness incentive programs that request private health information can conflict with other important nondiscrimination laws. The Americans with Disabilities Act (ADA), as amended by the ADA Amendments Act, limits an employer's ability to make disability-related inquiries and to require medical examinations. Generally, the examination or inquiry must be made on a post-offer basis for employment and either be "job-related and consistent with business necessity," or a voluntary medical examination as "part of an employee health program available to employees at that work site."[1] Wellness plans and health risk assessments may be prohibited under the ADA's "no medical exams or inquiries" provision unless they are voluntary. The level of inducement, or more specifically the value of the incentive for taking the health risk assessment or undergoing a biometric screening, may affect whether the medical examination or inquiry is truly voluntary. We have concerns that incentives may be large enough that they are coercive and employees feel they have no choice but to provide private health information that, under the ADA, they have a right not to disclose. For example, employees may feel compelled to provide sensitive information that they fear could result in discrimination, such as information about a chronic illness or disability, in order to maintain affordable health coverage.

We understand that the scope of this proposed regulation does not include compliance with other nondiscrimination laws. However, additional guidance is needed to clarify what magnitude of incentive violates the "voluntary" requirement of the ADA. **We recommend that the final rule provides examples of how wellness incentives that are tied to completion of a health risk assessment or biometric screening can be implemented in a manner that ensures compliance with the ADA and GINA. We recommend that if a wellness incentive is tied to completion of a health risk assessment or biometric screening, it must give an individual who chooses not to complete the health risk assessment or biometric screening an alternative means of qualifying for the incentive in order to be in compliance with the "voluntary" requirements of the ADA.**

[1] *Americans with Disabilities Act of 1990*, Public Law 101-336 (July 26, 1990), as modified by *ADA Amendments Act of 2008*, Public Law 110-325 (September 25, 2008), Title 42, Chapter 126, Subchapter 1, Section 12112.

**At a minimum, we strongly recommend that the final regulatory language or preamble explicitly clarifies that compliance with this regulation does not ensure compliance with other nondiscrimination laws, including the ADA and GINA. Relevant agencies should develop additional guidance regarding ADA requirements for wellness incentives in the near future.**

***(f)(2) Health-contingent wellness programs defined:***

We appreciate the clarification within the preamble that a program that requires individuals to meet targets for exercise would be considered a health-contingent wellness program. In the past there has been confusion as to whether such a program would fall under the category of a participatory program or a health-contingent program. We strongly agree that a program that requires people to engage in physical activity should be considered a health-contingent program, as there are numerous medical- and disability- related factors that could prevent someone from meeting such requirements.

More broadly, we believe that any health-care based incentive program that requires participation in an activity in which ability to participate is contingent on a health status factor should be considered a health-contingent wellness program. This includes tobacco-cessation programs, programs that require participation in physical activity, or programs that require participation in a disease management program for individuals with a specific chronic condition. By nature, these programs are health-contingent because they are only relevant or feasible for individuals who have certain health status factors. Therefore, obtaining the incentive is tied to a health status factor.

To resolve any remaining confusion regarding what types of activity-based programs fall under the category of health-contingent wellness programs, **we recommend that the final rule explicitly states that any program that requires participation in an activity in which ability to participate is contingent on a health-status factor is considered a health-contingent wellness program. The final rule should include examples of these types of activity-based health-contingent wellness programs, including a fitness or exercise program, within the regulatory language.**

The proposed rule does not clearly define or limit the types of health factors to which health-contingent wellness programs can tie incentives. **It is critical that the final rule clarifies that wellness programs cannot use clear markers of medical illness, disability or largely preventable conditions, as this would violate nondiscrimination laws, as well as requirements that the program be reasonably designed and not a subterfuge for discrimination.** The Departments should monitor the health factors that health-contingent wellness programs use and periodically provide additional guidance on and examples of non-acceptable health factors, as necessary.

We also have concerns that the proposed rule includes high glucose levels as an example of a potential biometric measure that a health-contingent wellness program could use to determine initial eligibility for

an incentive. An individual's glucose levels can fluctuate throughout the day and are beyond the individual's control. Further, high glucose levels are the main marker of having diabetes, which is a disease and for the most part a non-modifiable condition. For these reasons, **we strongly recommend that the final rule removes any reference to glucose levels as an acceptable risk factor to determine eligibility for an incentive.**

Definition of Tobacco-Use

We applaud the Departments' efforts to coordinate tobacco rating and wellness incentive programs and to align definitions of tobacco use across these provisions. The preamble requests comments on definitions of tobacco use that should be used for the purpose of both tobacco rating and wellness incentive programs. We support the comments made by American Cancer Society, Cancer Action Network in response to the NPRM on Health Insurance Market Rules and Rate Review regarding this issue. We provided similar comments in response to that NPRM. We are concerned that any ambiguity in the definition of tobacco use could result in disputes for consumers that misunderstood the question or the consequence of an incorrect answer. **Thus, we recommend that screening for tobacco use should be limited to once a year, for the purpose of determining initial eligibility for a wellness incentive. If an individual is found not to use tobacco in that initial screen, he/she should not be screened again for tobacco use for a full year. If an individual is found to use tobacco in that initial screen, she/he should have the option to be rescreened for tobacco use at any time throughout the year in order to obtain an incentive. If an individual passes a subsequent tobacco-use screen he/she should be considered immediately eligible for the incentive for the remainder of that year. HHS should develop and test standard language for the question, which should ask about daily use over the last 30 days.**

**The final rule should also clarify that a misstatement by an individual regarding tobacco use is not grounds for the plan to rescind coverage and that if there has been a misrepresentation, the insurer can only collect a wellness tobacco surcharge that should have been paid during the relevant coverage year. It will be very difficult to determine the accuracy of a statement regarding past tobacco use and whether a misstatement was or was not intentional beyond that coverage year.**

***(f)(3) Requirements for health-contingent wellness programs:***

Frequency of opportunity to qualify:

We agree with the proposed rule that individuals should be given the opportunity to qualify for an incentive at least once per year. It is also paramount that there are limits on how frequently a plan can reassess whether someone still qualifies for an incentive after he/she is initially determined eligible. **We strongly recommend that the final rule clarifies that once an individual is determined eligible for**

**an incentive, he/she locks-in eligibility for that incentive for at least one full year with no reassessment.**

**To ensure individuals are given a fair opportunity to meet any requirements for an incentive, we also recommend that the final rule clarifies that an individual must be given at least one full year to meet any new incentive requirements. Individuals should be considered eligible for the full incentive, based on new requirements, in any lead up year.** This means that a wellness program should give people at least one year's notice of any changes to its wellness incentive requirements that will apply the following year. If a program is in its first year, no health-contingent wellness incentives should be used within that year unless people were given a full year's notice of those requirements prior to implementation of the program. New employees should be given a full year to meet health-contingent wellness program requirements and be considered eligible for an incentive in that initial year, regardless of meeting requirements.

Size of Reward

*Prorating Reward Across Family Members*

We appreciate the preamble's request for comments on whether a reward should be prorated across family members when an incentive is offered to dependents, in addition to workers, and one family member fails to obtain an incentive. **We strongly recommend that the combined maximum incentive for all eligible family members be based on 30 percent of the cost of the coverage option that covers only those family members eligible for the incentive.** For example, if a wellness incentive program is only available to workers and their spouses, but not other dependents, the combined maximum incentive for both a worker and spouse should not exceed 30 percent of the total premium for employee plus spouse coverage. In this scenario, even if the worker and spouse are enrolled in family coverage, the maximum allowed incentive should still be based on the cost of coverage that covers only those eligible for the incentive.

**We recommend that the maximum allowed incentive each family member can earn be pro-rated based on the portion of the premium attributable to that family member.** For example the worker's maximum incentive would be 30 percent of the cost for individual coverage**.** A spouse's maximum incentive would be based on 30 percent of the premium difference between employee plus spouse coverage and individual coverage. We suggest that the final rule include an example that illustrates how to calculate the maximum allowed incentive for each family member eligible to receive an incentive.

**We also strongly recommend that in situations where multiple family members can earn a wellness incentive that affects the cost-sharing requirements of a plan, like reducing deductibles or co-pays, that any incentive earned by a single family member be distributed in a way that reduces cost-sharing requirements uniformly for all family members included on the plan.** Health plan

terms and conditions can be complicated and difficult for many consumers to understand. Ensuring that all family members share the same cost-sharing responsibilities will minimize complexity and confusion for consumers.

*Full Participation by Spouses or other Dependents*

In general, we have concerns about programs that vary health-care costs for workers' dependents, as nonemployees are not traditionally in the workplace and therefore may not have adequate access to program supports and resources. Further, employers do not know the work obligations or other personal commitments of their employees' spouses or other dependents, which could affect their ability to participate in wellness programs. It is critical that wellness plans are restricted from applying any incentive to spouses or other dependents of employees unless they offer reasonably-designed wellness programs that are equally "available" to non-employees. This is in keeping with the intent of the statue, which allows for wellness incentives to be applied to spouses or other dependents only if they "may participate fully in the wellness program."

**We recommend that the final rule adds the following clarifications regarding standards wellness plans must meet in order to ensure that spouses or other dependents "may participate fully" in their wellness program:**

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- Nonemployees should not be required to participate in activities at the worksite or only be able to take advantage of a wellness program at another family member's worksite.
- Nonemployees should not be required to spend their own time or money to comply with a required activity that is offered onsite to employees.
- The program made available to non-employees should not have to be the exact same program offered to workers, but it must meet all standards the employee wellness program is required to meet under federal law.

Expanding employee wellness programs to family members of workers also raises significant privacy concerns. Employers should not be allowed to inquire into personal family affairs if a family member of an employee seeks an alternative to or waiver from a wellness incentive requirement. Employers should also not have access to information about which employees have family members who do not participate in or meet wellness program requirements. For these reasons it is critical that any employer that decides to expand a wellness program to family members of workers must have the program administered by a third party plan administrator.

Wellness plans that are made available to spouses raise additional privacy concerns because they could lead to an employee obtaining or inferring private information about a spouse's health that the spouse did not wish to share. **The final rule, or at least preamble, should clarify that wellness plans must have policies to mitigate the sharing of private information between family members.**

Applicable percentage

*Tobacco rating*

We applaud this proposed rule and the NPRM on Insurance Market Rules for coordinating tobacco rate-ups in the small group market with wellness programs so that the combined effect of both could never be more than a 50 percent increase; under the proposal, if wellness programs are offered, employees and their dependents could avoid tobacco rate-ups by participating in tobacco cessation wellness programs. It is essential that this provision be maintained. As we included in our comments on the Insurance Market Rules, we recommend that the rules clarify that tobacco rate-ups or tobacco-based wellness surcharges *must* be eliminated for people who participate in either wellness programs *or* other tobacco cessation programs/treatments in the small group market. We also recommend that the final rules clarify that an individual in the small group market should never be assessed two tobacco screenings or tobacco penalties, one through tobacco rating and one through a wellness program.

In addition, as individuals in the self-insured and large group market could now be assessed wellness surcharges equivalent to the maximum tobacco rating allowed in the small group market, **we strongly recommend that individuals in the group and self-insured market, in addition to the small group market, have the opportunity to avoid tobacco-based wellness surcharges if they participate in any tobacco cessation program (regardless of its association with the wellness program).**

*Wellness Incentives' Interactions with Affordability Provisions of the Affordable Care Act (ACA)*

We applaud the proposed rule for taking meaningful steps towards ensuring that achieving a wellness incentive is accessible to eligible individuals. We believe this rule, along with our proposed recommendations, will help limit the situations in which a person is unable to obtain an incentive. However, even with strengthened wellness plan requirements, there will still be instances where individuals are unable to meet wellness incentive requirements. Wellness incentives that vary employees' health insurance premiums or cost-sharing requirements have the potential to make health coverage and care significantly less affordable for those individuals who are unable to obtain the incentives.[2] As such, we have persisting concerns that if the cost of not earning an incentive is not accounted for in various affordability provisions under the ACA, health care-based wellness incentives could undermine one of the primary goals of the ACA- ensuring all individuals and families have access to an affordable, high-value coverage option.

The affordability provisions of concern include: the assessment of whether an employee's offer of employer-sponsored health coverage is affordable, based on whether an employee's required premium contribution is no more than 9.5 percent of his/her household income; the assessment of whether an

[2] Lydia Mitts, *Wellness Programs: Evaluating the Promises and Pitfalls,* (Washington: Families USA, June 2012), available online at, http://familiesusa2.org/assets/pdfs/health-reform/Wellness-Programs.pdf.

employer's offer of coverage is of minimum value, or has at least a 60 percent actuarial value; the requirement that annual per person deductibles for health plans in the small group market do not exceed $2000; and the assessment of whether an individual is exempt from the requirement to maintain health coverage because all available coverage options are unaffordable, defined as costing an individual more than 8 percent of his/her household income.

Also, while these proposed rules take meaningful steps towards limiting the potential for these programs to be used as a subterfuge for discrimination, we still have concerns that wellness incentives that make health coverage unaffordable exclusively for the least healthy employees could be used as a method to shed less healthy workers from employer-sponsored coverage. This becomes an even greater concern if the cost of not earning an incentive is not included in the assessment of whether an employer offers affordable and minimum value health coverage. If employers are not assessed a shared-responsibility penalty for not offering affordable, comprehensive health coverage to employees who do not meet wellness requirements, there will be little disincentive to designing wellness programs to shed the least healthy, most expensive workers from their health coverage.

**To address these concerns, we strongly recommend that the final rule or future regulations addressing how wellness incentives interact with affordability provisions of the ACA adopt the following recommendations:**

1. Determination of whether an employee's offer of employer-sponsored coverage is affordable, based on the 9.5 percent of income threshold, should always use the more expensive premium contribution that is associated with not earning a wellness incentive. If this results in coverage being unaffordable, that employee should have the option to receive premium tax credits to purchase coverage in the exchange, if otherwise eligible.
2. Determination of whether an employee's offer of employer-sponsored coverage is of minimum value should always use the least generous cost-sharing structure of the plan that is associated with not earning a wellness incentive. If this results in coverage not meeting minimum value, that employee should have the option to receive premium tax credits, if otherwise eligible.
3. An employer should be assessed a shared-responsibility penalty for any employee that receives premium tax credits because the offer of employer-sponsored coverage is unaffordable/not of minimum for individuals who do not earn a wellness incentive.
4. Additional deductible costs associated with not earning a wellness incentive should never result in anyone's total deductible exceeding thresholds under the ACA.
5. An individual should not be assessed an individual responsibility penalty for not having health coverage if all available coverage options are unaffordable, taking into consideration any wellness surcharges he/she would have been assessed.

**We strongly recommend that future rules addressing wellness incentives' application to affordability assessments of employer-sponsored coverage adopt the above recommendations 1-3,**

**in full. These set of recommendations work in harmony with one another to ensure that no individual is locked into unaffordable or low-value employer-sponsored health coverage because he or she cannot obtain a wellness incentive. They also most effectively restrict employers' ability to use wellness incentives as a tool to selectively shed their least healthy workers from their health coverage.**

**If these above recommendations are not adopted in full, at the very least, future rules on this issue must protect the right to an affordable health coverage option for employees who are unable to obtain a wellness incentive.** Employees whose offer of employer-sponsored coverage is made unaffordable or not of minimum value because they are unable to earn a wellness incentive should be able to receive premium tax credits, if otherwise eligible. This is regardless of whether employers are assessed a penalty for these individuals receiving premium tax credits. If employers are not assessed a penalty for employees that receive premium tax credits due to not earning wellness incentives, it will be paramount that strong monitoring and enforcement mechanisms are in place, including data reporting and public disclosure requirements for wellness plans, in order to monitor what types of employees are not obtaining wellness incentives (please see additional comments on data reporting on page 16). Plans that appear to be a subterfuge for discrimination, based on the types of employees who do not earn wellness incentives, should be investigated for compliance with these rules.

<u>Uniform Availability and Reasonable Alternative Standards:</u>

*Reasonable Alternative Standards*

We strongly support the clarifications made in this proposed rule regarding the requirements to offer a reasonable alternative standard. We agree that plans should be responsible for furnishing an alternative standard to eligible individuals and that plans should not be allowed to cease to provide a reasonable alternative standard to an individual just because that individual was not successful at modifying his/her behavior in previous attempts.

We also strongly support many of the proposed factors that should be taken into account when determining whether a plan has provided a reasonable alternative standard. In particular, we were extremely pleased that the proposed rule clarified that a plan is required to defer to the judgment of an individual's personal physician in designing an appropriate alternative standard. We also agree that individuals should not be required to pay a participation or membership fee for a program in which they are required to participate, as part of their alternative standard. The proposed rule explicitly prohibits plans from requiring an individual to pay for an alternative standard that is an educational program or diet program. We assume that the proposed rule's intent was to provide these two types of programs as illustrative examples of programs for which individuals should not be expected to pay, rather than an exhaustive list. **We strongly recommend that the final rule clarifies that plans cannot require**

**individuals to pay for the enrollment or participation fees for any alternative standard, including, but not limited to, educational, diet, exercise, or health coaching programs.**

We strongly agree with the proposed rule that individuals should be able to satisfy the requirements of a reasonable alternative standard by complying with their personal physicians' recommendations. An individual's personal physician has an intimate and holistic understanding of that individual's health problems and external factors that influence his/her health. As such, they are best-suited to develop effective and reasonable treatment plans for that individual.

However, we have concerns with the proposal that plans may "impose standard cost sharing under the plan or coverage for medical items and services furnished pursuant to the physician's recommendation." Section (f)(v)(4), Example 3 cites following a doctor's recommendations to take a medication and receive regular blood tests as an example of a reasonable alternative standard. Under the proposed rule, if the individual in Example 3 misses a prescription or blood test because they cannot afford to cover their out of pocket costs for those services and medications, he/she could end up being further penalized by a wellness incentive program. **We strongly recommend that if an individual is required to follow doctor recommendations that specifically prescribe a medication and/or regular exams or tests, that individual should be able to obtain these specific services and medications without any co-pays or other cost-sharing. This ensures that cost does not pose a barrier to individuals following their doctor's recommendations and meeting wellness requirements.**

**In response to the preamble's request for comments on whether additional rules or clarifications are needed with respect to the process for determining a reasonable alternative standard, we offer the following additional recommendations:**

- Section (f)(iii)(C) of the proposed rule allows a plan to request physician verification that an individual requires an alternative standard. The final rule should clarify that while a plan can request verification from an individual's personal physician that a medical condition makes it inadvisable or unreasonably difficult for that individual to satisfy a standard related to a health factor, the plan cannot request any private health information regarding the medical reason why that individual requires an alternative standard. The plan must accept simple physician attestation. Similarly, if an individual's personal physician believes a plan's recommendations are medically inappropriate, the plan cannot request information as to why the physician finds them inappropriate and must accept that physician's alternative recommendations. This clarification is critical to ensure that wellness programs never request private health information and that individuals never feel coerced into providing private information in order to obtain an alternative standard.
- The final rule should establish measureable timeliness standards by which a plan must complete an individual's request for an alternative standard. An individual must be considered eligible for the full wellness incentive until his/her request for an alternative standard is completed.

- Many wellness programs are administered by third party wellness vendors or health plans. However, in some situations a wellness incentive program may be administered by an employer's internal department responsible for employee benefits, such as an administrative or human resources department. Regardless of the party responsible for administering the program, it is paramount that there are strong privacy firewalls to ensure that any private health information that an individual discloses to a wellness program is not made available to his/her employer. The final rules should explicitly state that wellness programs must have policies in place to ensure all private health information and any requests for an alternative standard are not made available to employers in any non-aggregate or identifiable format.

Reasonable Design

We applaud the Departments for the proposed rule's new requirement that a plan must provide a different means of qualifying for an incentive to anyone who does not meet incentive requirements based on an initial measurement, test or screening. In the past, plans have been able to use wellness incentive programs to charge people more for health coverage if they failed to obtain certain health outcomes, without providing those individuals with any supports or assistance to address their health risk factors. As such, we strongly agree with the Departments that this requirement 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. We strongly recommend that this provision be maintained.

In order for this new requirement to achieve the above stated aim, we believe that wellness programs need to provide individuals with a different means of qualifying for a reward that is tailored to their personal circumstances and health. This will ensure that the alternative is feasible, from a practical standpoint, and effective at helping individuals improve their health. It will also help ensure that a program meets statutory requirements that it have a "reasonable chance of improving the health of…participating individuals" and that it "is not overly burdensome." We appreciate the Departments' invitation for comments on ways to ensure that employees will not be subject to an unreasonable "one-size-fits-all" approach to designing a different means of qualifying for the reward. **We offer the following specific recommendations to help ensure that individuals are provided a different means of qualifying for a reward that is personalized, reasonable, and not overly burdensome:**

- The final rule should provide a definition and examples of what constitutes an "overly burdensome" program. The definition of "overly burdensome" should take into account personal circumstances that could make it difficult for an individual to complete wellness activities that are held after work hours and away from the workplace. This includes elder/child care responsibilities, multiple jobs, and not having reliable transportation to a program site.

- The language in the final rule should explicitly state that in order for a program to be reasonably designed and not overly burdensome, any different means of qualifying for a reward must not be overly burdensome and must take into account an individual's personal circumstance.
- The final rule should stipulate that any individual who qualifies for a different means of qualifying for a reward must be provided the option of obtaining the reward by participating in a reasonably designed activity or complying with their personal physicians' recommendations. While plans may give individuals the option of obtaining a reward by achieving a less rigorous health metric, this cannot be the only different means made available to an individual.
- The final rule should clarify that if an individual selects a different means to obtain a reward that requires him/her to adhere to his/her personal doctor's recommendation, the plan must accept self-attestation of adherence as proof of compliance with this requirement. Plans should not interfere in doctor-patient relationships and should not have access to private information regarding an individual's health care.
- The final rule should extend the right to a different means of qualifying for a reward to individuals who cannot meet initial standards for obtaining a reward because the initial requirement is *participation* in a health-contingent activity that is overly burdensome for that individual, from a practical standpoint. For example, if a health-contingent wellness program requires individuals to participate in a fitness program held after work hours, individuals should have the right to a different means of qualifying for the incentive if that program is overly burdensome for practical reasons, such as after work obligations or lack of transportation to the fitness facility.
- The final rules should clarify that the requirements for a reasonable alternative standard provided to individuals who cannot meet health standards for medical reasons [set forth under section (f)(iii)(B)] also apply to any different means of qualifying for a reward provided to individuals who do not meet an initial health metric. This provision includes important protections, including that an alternative activity must be furnished by a plan and offered at no additional cost to the participant, and that deference must be given to an individual's personal physician in determining an appropriate alternative standard. These requirements should apply regardless of whether an individual receives an alternative standard because of a medical condition or because he/she has a health risk factor.

<u>Establishing Evidence-based Standards</u>

We applaud the Departments' efforts to strengthen the requirements for what constitutes a reasonably designed program in order to better protect against health-contingent wellness programs being a subterfuge for discrimination. However, we believe that additional evidence- or practice-based standards are still needed to ensure the reasonableness of the design of the wellness program that is offered in conjunction with a wellness incentive. If an employer decides to implement a health-contingent wellness incentive that varies health care costs, it should be required to offer a comprehensive wellness program that actually provides supports to improve health, especially in the life-style areas related to a health-contingent incentive. Practice-based standards recommend that a reasonably designed health-contingent wellness program should include the following components: strategic planning; cultural

support; programs for assessment and screening; behavior change interventions; engagement through communication and incentives; and evaluation.[3] Comprehensive wellness programs also should include changes to worksite polices and work environments to better support employees' health.

**We strongly recommend that the final rule states that a reasonably designed program must include a set of programs, resources, and worksite policies designed to promote health and prevent disease, if health-contingent incentives are included in its design. Wellness programs should also be required to annually evaluate their program. The final rule should make it explicitly clear that a reasonably designed program must consist of more than solely a health screening or test tied to a financial incentive and the opportunity to qualify for that incentive through a different means.**

**We also strongly recommend that the final rule states that, in order to be reasonably designed, a health-contingent wellness incentive tied to a health screening or test must be offered in conjunction with health coverage that includes coverage for evidence-based treatments for any screened risk factors.** For example, wellness incentive programs often tie obtaining an incentive to achieving a certain BMI score or other measure of weight. However, oftentimes the corresponding insurance does not include coverage of evidence-based services and medication that can help treat obesity and overweight. Any reasonably designed wellness program should ensure that participants have access to medical treatments that can help address the health risk factors targeted by the wellness program.

Notice of Availability of Other Means of Qualifying for Reward

We applaud the Departments' efforts to revise the sample language for the notice of availability of other means of qualifying for a reward, in order to better ensure individuals understand how to request a different means of qualifying for a reward. We also appreciate the proposed rule's invitation for comments regarding this proposed sample language. We believe additional information about consumers' rights within a wellness program and the various channels through which they may appeal a decision made by a wellness program must be included in this notice to ensure consumers have important information about their rights when requesting an alternative standard. We strongly recommend that the final rule requires notices to include the following information, explicitly stated:

- Reasons under which an employee may request an alternative standard;
- The name of the party responsible for completing a request for an alternative, in addition to contact information for requesting an alternative;
- The time within which a request for an alternative must be completed by that party;

[3] 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, "Joint Consensus Statement: Guidance for A Reasonably Designed, Employer-Sponsored Wellness Program Using Outcomes-Based Incentives," *Journal of Occupational and Environmental Medicine* 54, no. 7 (July 2012).

- The alternative channel for having a request reviewed if not completed within timeliness standards. The notice should include both name and contact information for the party that individuals should contact if their request is not completed in a timely manner;
- The documentation an individual needs to show proof of making a request for an alternative;
- Reasons under which an employee may request an external appeal of a decision made by a wellness program, including determinations of eligibility for an alternative means and determinations of initial eligibility for an incentive based on a health screening or test;
- Name and contact information for the party responsible for external appeals and for any available consumer assistance or health care ombudsman programs; and
- The DOL agency and contact information for submitting concerns or complaints regarding a wellness program. (Also see comments on Monitoring and Enforcement on page 17.)

Data Reporting:

Wellness programs have existed for a number of years, and they appear to be growing in numbers and diversity as a means of improving health and lowering long-term costs. Yet, as the Rand report sponsored by DOL clearly shows, there is a paucity of information regarding the impact of wellness programs in general and incentives in particular. Furthermore, an article recently published in Health Affairs shows the significant shortcomings in the existing studies and analysis of these programs.[4] In short, employers and insurers appear to be enthusiastically embracing an approach to improving health that is poorly understood and which may, in fact, provide ineffective services or establish barriers to meaningful health coverage through penalties or even discriminatory practices.

If we are to develop effective wellness programs and use the ACA statutory language wisely, there needs to be greater data reporting and public disclosure about these programs—their goals, how they are structured, what metrics are utilized, who does and does not participate, the incentives and their take-up, and the actual outcomes of these programs. **Wellness program vendors or administrators should provide employer or insurer sponsors with the basic data that could be used to conduct a proper evaluation. Basic data that should be reported and publicly disclosed includes whether employers offer health-contingent wellness programs, and, if they do:**

- Who the program is made available to (e.g., employees only or spouses and dependents, as well);
- Number of individuals eligible to participate in the wellness program;
- Form of any reward/penalty (e.g., adjustment to otherwise applicable premium contribution or cost sharing);
- Size of reward/penalty;

[4] Al Lewis and Vik Khanna, "Is It Time to Re-Examine Workplace Wellness 'Get Well Quick Schemes?'" *Health Affairs Blog*, January 16, 2013, available online at, http://healthaffairs.org/blog/2013/01/16/is-it-time-to-re-examine-workplace-wellness-get-well-quick-schemes/

- Frequency and timing of opportunities to earn reward;
- Description of health factor(s) or biometric standard(s) tied to earning the reward;
- Number of individuals who qualify (and number who fail to qualify) for the reward by meeting the health factor standard(s);
- Description of the alternative means offered;
- Number of individuals who request alternative means of qualifying for the reward;
- Number of individuals who qualify (and number who fail to qualify) for the reward via the alternative means; and
- Starting in second year, the number of individuals who qualify for the reward in a year who previously had failed to qualify, and the number of individuals who fail to qualify for a reward in a year who previously qualified (broken out by each wellness program standard if multiple standards are used).

Data should be collected in such a manner to allow for stratification based on eligible employees' demographics (e.g., age, gender), the health factor that gave rise to their eligibility (e.g., weight, tobacco use, cholesterol, etc), and their participation level (e.g., frequency of attendance, number of program attempts, etc.).

Monitoring and Enforcement:

In addition to establishing robust data reporting and public disclosure requirements, we believe additional steps are necessary to support adequate enforcement of this rule. **The Department of Labor (DOL) should develop a comprehensive monitoring and enforcement plan in order to evaluate wellness programs' compliance with this revised rule. We offer the following recommendations on potential methods DOL could adopt to monitor compliance:**

- The DOL should update its self-compliance tool for wellness programs included in the *Self-Compliance Tool for Part 7 of ERISA: HIPAA and other Health Care Related Provisions of ERISA*.[5] This manual should explicitly list all other relevant laws that could apply to wellness programs, including ADA, GINA and other civil rights laws. It should include references to additional guidance on how to comply with these laws.
- DOL should establish an agency responsible for collecting and responding to consumer concerns regarding specific wellness program designs. This agency should have a method for consumers to submit concerns both online and by phone. Wellness programs should be required to include this agency's contact information in its terms and conditions.

[5] Employee Benefits Security Administration, *Self Compliance Tool for Part 7 of ERISA: HIPAA and Other Health Care Related Provisions* (Washington: Department of Labor, October 2010 ) available online at, http://www.dol.gov/ebsa/pdf/cagappa.pdf

- DOL should conduct audits of wellness programs on a regular basis. While some audits may be random, DOL should also use the above mentioned data and consumer-submitted concerns to trigger audits of suspicious programs. DOL should conduct a higher volume of audits in the initial years of implementing this rule. It should use the results of these audits to publish additional compliance guidance that addresses common wellness program components that have been found to violate these rules.

In conclusion, we applaud the Departments' efforts to clarify the requirements for health-contingent wellness programs in order to better protect against these programs being used as a subterfuge for discrimination. We strongly support many of the provisions outlined in this proposed rule and encourage the Departments' to provide further clarification and amendments in the areas we have outlined in these comments. If you have any questions, please do not hesitate to contact Lydia Mitts at lmitts@familiesusa.org or 202-628-3030.

Sincerely,

Lydia Mitts
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Families USA