THE VOICE OF FOOD RETAIL

Feeding Families Enriching Lives

January 25, 2013

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

Re: Incentives for Nondiscriminatory Wellness Programs in Group Health Plans

RIN 0938-AR48

Dear Sir or Madam:

On November 26, 2012, the Employee Benefits Security Administration (EBSA), Internal Revenue Service (IRS) and Centers for Medicare and Medicaid Services (CMS) published a notice of proposed rulemaking entitled Incentives for Nondiscriminatory Wellness Programs in Group Health Plans ("Proposed Rule").[1] The Food Marketing Institute (FMI) appreciates the opportunity to comment on this important matter.

FMI conducts programs in public affairs, food safety, research, education and industry relations on behalf of its nearly 1,250 food retail and wholesale member companies in the United States and around the world. FMI's U.S. members operate more than 25,000 retail food stores and almost 22,000 pharmacies with a combined annual sales volume of nearly $650 billion. FMI's retail membership is composed of large multi-store chains, regional firms and independent operators. Its international membership includes 126 companies from more than 65 countries. FMI's nearly 330 associate members include the supplier partners of its retail and wholesale members. The supermarket industry employs approximately 3.5 million Americans on profit margins of approximately one percent, so policies involving employees' benefits can have profound impacts.

For many FMI members, wellness programs are a critical component to maintaining both employer and employee health care costs, while also providing a valuable benefit to workers. FMI submits comments on the effect of the Proposed Rule on employers'

[1] 77 Fed. Reg. 70620 (November 26, 2012).

ability to implement attainment incentives, to maintain health care costs, and to comply with the Affordable Care Act's employer shared responsibility provisions.

FMI has significant concerns about the Proposed Rule's impact on the ability of employers to implement attainment incentives. While the 2006 regulations permitted attainment incentives in all but the most narrow circumstances (i.e., where attempting to achieve the wellness standard was medically inadvisable or unreasonably difficult due to a medical condition), the Proposed Rule arguably requires alternatives whenever employees or plan participants fail to meet the standard, even if the standards were clearly outlined at the onset of the employee's voluntary participation in the program and if the reasons for failure have nothing to do with an employee's health and are entirely the product of an employee's decision to engage in behaviors contrary to those being encouraged through the use of wellness incentives. We believe that the Proposed Rule eliminates any meaningful ability to implement attainment incentives.

Reasonably Designed Requirement (Section 2590.702(f)(3)(iv)).

Section 2590.702(f)(3)(iv) of the Proposed Rule provides that in order for a program to be reasonably designed, where the initial standard for obtaining the reward is based on a measurement, test or screening that is related to a health factor, the program must make available to a participant who does not meet the initial standard a different, reasonable means of qualifying for the reward. We believe this provision can be read to mean that there is no prerequisite to the requirement to make this different, reasonable standard available, such as the participant having a medical condition that prevents him or her from achieving the standard, or that it is medically inadvisable for him or her to try to meet the standard. For this reason, we believe this proposed expansion of the "reasonably designed" requirement is at cross-purposes with and significantly exceeds the Congressional mandate found in the nondiscrimination provision of HIPAA, 29 USC § 1182, even as restated by ACA section 2705(j)(3)(B) (the "HIPAA nondiscrimination provision").

The HIPAA nondiscrimination provision seeks to prohibit certain discrimination under a group health plan. In general, with regard to eligibility to enroll and premium contribution, 29 USC § 1182 as restated by ACA section 2705(j)(3)(B) prohibits discrimination on the basis of certain health status-related factors. The 2006 nondiscrimination regulations implemented this legislative vision by requiring that reasonable alternatives be made available when a participant in a wellness program could not meet a condition for a reward that was related to a health factor because of the participants' medical condition or because it was medically inadvisable for the participant to attempt to do so. See section 2590.702(f)(2)(iv)(A)(1) and (2) of the Proposed Rule. Under 2590.702(f)(2)(iv) (A)(1), for example, the program must allow 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*. By contrast, the 2006 nondiscrimination regulations applied the reasonably designed standard very narrowly, expressly stating that it would be a simple standard to satisfy.

Specifically, section 2705(f)(3)(iv) of the Proposed Rule states, "[t]o 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. Section 2705(f)(4), Example 2, of the Proposed Rule confirms that the Departments anticipate applying this provision broadly to dilute or essentially eliminate the ability to implement attainment incentives:

> Example 2. (i) Facts. A group health plan offers a reward to individuals who achieve account 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.
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> (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.

The language emphasized above illustrates that the standards for applying the incentive under the program are undefined, and, more important, go well beyond prohibiting discrimination of the basis of a health status-related factor. The analysis in the Example

implies that the only way a wellness program would be "reasonably designed" under the new rules is if it considers all of the relevant facts and circumstances, even those unrelated to the participant's medical condition or whether it is medically inadvisable to attempt to meet the condition. At the least, employers should be allowed to require physician verification of an individual's need for a reasonable alternative standard.

Contrary to the promise that this standard would be easily satisfied, this expansion of the "reasonably designed" requirement significantly complicates wellness plan administration. Specifically, it would create for plan sponsors and issuers a nebulous standard that, in effect, mandates an individualized assessment of all of the facts and circumstances surrounding the reasons a person could not meet the standard for the reward, including those that are unrelated to a health status-related factor. As a result, the administrative burden of offering an incentive-based wellness program would nullify the cost-containment objectives and also outweigh any achieved benefits. This expansion, coupled with some of the other provisions of the Proposed Rule, would also make it significantly more risky for plan sponsors and issuers to actually apply a surcharge under these rules. This, in turn, likely will discourage employers from implementing, much less expanding, wellness incentives, thereby undermining the legislative goal of increasing the use of wellness incentives (as evidenced by Congress' expansion of the maximum amount of wellness incentives from 20% to 30% or 50% of the healthcare premium). Discouraging employer implementation of wellness programs obviously also would undermine Congress' additional hope that employers would innovate and experiment in wellness programs to determine what programs might help improve our healthcare systems.

The significance of these changes is evidence in the new sample language provided in 2012 Regulations section 2705(f)(3)(v)(B). Notably, the new sample statement eliminates the language informing participants that the condition for being entitled to have a reasonable alternative made available is that the standard is unreasonably difficult due to a medical condition or because it is medically inadvisable to attempt to achieve the standard for the reward under this program. Certainly, in the event the Department agrees with some or all of these and similar comments, and the 2012 Regulations are modified accordingly, the sample language would need to be modified to be consistent with those changes.

Definition of Health-Contingent Programs - (2012 Regulations section 2590.702(f)(2))

The proposed regulations appear to suggest that "health-contingent wellness programs" include those programs that require an individual to "do more" than a similarly situated individual based on a health factor in order to obtain the same reward. See 2012 Regulations section 2590.702(f)(2) and Preamble, page 10. This language contains

some ambiguities and might result in the sweeping into the health-contingent classification those programs that are generally considered to be participatory. This concern is amplified by the language in the Preamble, p. 6, that would classify programs as "health-contingent" if they require meeting targets for exercise in order to obtain a reward. See also Example 1 under 26 CFR 54.9802-1(f)(3)(ii)(B).

Many would consider a wellness program that provides a premium contribution reduction to participants that attend a nutrition classes at a local college or a free health education seminar to be a participatory program. See Preamble, page 6. However, for some participants it might be more difficult to participate than a similarly situated participant due to a physical disability, a fear about public places, or some other condition to attend the classes or the seminar. It is unclear whether the language in the preamble would cause such programs to be considered "health-contingent."

Likewise, in the case of participation in a nutrition program, a person's health condition (allergy, high blood pressure, celiac disease) might require the individual to be more selective than another with regard to the food options under the program. Note, however, that in some cases, the effects of the health condition on the ability to participate could be immaterial, but nonetheless create a compliance concern for plan sponsors and issuers.

In the case of exercise targets, an individual also may fail or have a more difficult time meeting such targets because of health conditions. However, it also is possible that the failure to meet the target is because the individual either is not as attentive as he or she should be to the benefits of regular exercise, has scheduling conflicts, does not like the form of exercise that qualifies for the reward, or a combination of these and other non-health related factors. In other words, if a person fails to meet a biometric screening, such as blood pressure or cholesterol level, it is very likely to be the result of a health status-related factor. However, if a person fails to walk a half mile over the course of a week, it may have nothing to do with a health status-related factor.

It is true that certain targets for exercise may raise distinctions between participants based on health status-related factors. For example, a participant with a heart condition might not be able to walk 1 mile per day because of that condition, or may have more difficulty doing so compared to an individual without such a condition. In those cases, where the participant reports the health factor that causes him or her to be unable to meet the program, the program should offer a reasonable alternative as required for health-contingent programs. However, for generally applicable exercise targets and other activities generally participatory in nature, the failure to meet those targets should not be assumed to be related to a health factor. The proposed regulations should be clarified to require a determination by the plan sponsor or issuer of those activities that are participatory and those that are truly health-contingent. This bifurcated treatment will allow plan sponsors and issuers to provide greater incentives to encourage exercise,

while ensuring appropriate protections for those participants who health factors cause them to be unable to meet a particular exercise target or similar requirement (or make it more difficult to do so).

Reasonable Alternatives – Guidance on When Incentive Can be Applied. (Preamble, page 16-17)

The proposed regulations reiterate and would expand on the idea that "overcoming an addition sometimes requires a cycle of failure and renewed effort." Preamble, p. 16-7. This approach to wellness programs essentially would require plan sponsors and issuers to provide limitless alternatives when the first or second alternative was not successful and effectively prohibit or significantly limit plan sponsors and issuers from imposing a surcharge or removing a reward in cases of repeated failure of individuals to meet the program objectives outlined when the individual voluntarily enrolled in the program. The preamble to the 2006 regulations has addressed this issue with respect to tobacco cessation, however, the proposed rules apparently would expand this requirement to apply in any instance where addiction is an obstacle to achieving a standard under the program, including weight loss. This kind of open ended obligation to make reasonable alternatives available carries obvious negative implications for plan sponsors and issuers.

In order for the programs to work and for the incentives to drive results, participants have to believe that there is a real possibility that absent a change in their behavior that produces results, the incentives (rewards, surcharges, etc.) will be applied to them. If made final, the proposed regulations either (i) would so water down the ability of plan sponsors and issuers to apply the incentives, which Congress clearly intended to be applied as evidenced by its increasing the amount of the incentives, that the chances that wellness programs can drive healthier behaviors and outcomes is diminished substantially, or (ii) expose plan sponsors and issuers to significant litigation risk, causing them to be over cautious in applying a surcharge or removing a reward, likely eliminating any benefit incentives could derive.

Assume a program that is exclusively a tobacco prevention program. Under the 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 premium surcharge that satisfies the 50% limitation under (f)(3)(ii). One of the issues faced by many employers is that employees who engage in tobacco use will take part in the tobacco cessation program, which generally lasts about 8 weeks, and continue to use tobacco during and after the cessation program, knowing that the plan sponsor or issuer will have to keep coming up with alternative after alternative before it could apply the incentive. Neither the proposed regulations nor the 2006 regulations provide any guidance as to when a reasonable number of alternatives has been provided. This lack of guidance will leave

plan sponsors or issuers in a difficult situation of being unable to anticipate the costs of a proposed wellness program in terms of the costs of making additional alternatives available (see, e.g. Proposed Rule section 2590.702(f)(3)(iii)(B)(1)-(3), as well as in terms of the costs of litigation on the question of whether the plan sponsor or issuer should have provided more alternatives. Plan sponsors or issuers recognize that multiple attempts may be needed to address health conditions involving addiction. Plan sponsors and issuers also recognize that the effects of incentives/surcharges are undermined if, as a practical matter, they are not imposed.

We propose a balanced approach, one that allows plan sponsors and issuers to be able to gradually apply an incentive/surcharge with each new reasonable alternative that is offered to employees, except for the first two alternatives made available. So, for example, assume the incentive/surcharge under the program is $1,000. If a participant is a nicotine-addicted tobacco user and participates in a cessation program (first reasonable alternative) but fails to quit smoking, he would not be charged the surcharge if he agrees to participate in the alternative. The participant then tries hypnosis (second reasonable alternative), and still cannot kick the addiction. At this point, the tobacco user would be offered another reasonable alternative such as a prescription drug. At this point, however, a portion of the surcharge could be applied, such as 25% of the total incentive, or $250 in this example. The surcharge would increase incrementally (such as by 25% of the total incentive, or $250 each time) with until it reaches the $1,000 set forth in this example. While this would require an additional administrative burden on plan sponsors and issuers, it allows the plan sponsor and issuer to apply an incentive the program was designed to apply, while also taking into account the addiction that makes changing the behavior difficult.

Impact of Wellness Programs and the Incentives for Nondiscriminatory Wellness Programs in Group Health Plans Proposed Rule on implementation of the Affordable Care Act's employer requirements under Internal Revenue Code §4980H

FMI and its food retail and wholesale member companies have also been constructively engaged in addressing the implementation of the Affordable Care Act's employer requirements under Internal Revenue Code §4980H. As previously stated, for many FMI members, wellness programs are a critical component to maintaining both employer and employee health care costs, while also providing a valuable benefit to workers.

Adoption of FMI's aforementioned comments are critical to achieving these objectives but also for employers' compliance with IRC §4980H(b) requirements of offering coverage of at least minimal value and that is affordable to the employee under the Affordable Care Act.

With respect to forthcoming regulations and IRS Notice 2012-31 regarding certifying the Minimum Value of an Employer-Sponsored Health Plan, it is critically important that whatever means used for calculating minimum value must allow for incorporating wellness programs, in-house clinics (which may require lower cost-sharing for on-site prescriptions, diagnostic tests, etc.), and other approaches aimed at improving and maintaining employee health as a means to encouraging preventive health care utilization, improving health outcomes, and lowering health care cost growth. If the value of these benefits is not appropriately captured, many employers may be forced to scale back these important benefits.

With respect to determining whether employer-sponsored health coverage is affordable to the employee, FMI also believes that employers' spending on employee wellness programs, as well as employer contributions to Health Reimbursement Arrangements or Health Savings Accounts should be counted toward employers' premium contribution for the affordability test within IRC §4980H(b) and the safe-harbors outlined in the employer "shared responsibility" proposed regulations published in 78 Fed. Reg. 217 (January 2, 2013).

We believe that if EBSA, IRS and CMS follow the recommendations contained within these comments, barriers to implementing wellness incentives contained within the Proposed Rule will be removed allowing for further expansion of wellness incentives by employers reflective of the intent of Congress. In addition, incorporating the benefits provided by employers under wellness programs should be incorporated into the calculations for certifying whether employer-sponsored health coverage meets affordability and minimum value requirements under IRC §4980H(b). We appreciate your consideration of these comments.

Sincerely,

Erik R. Lieberman
Regulatory Counsel