Published on *The National Law Review* https://natlawreview.com

Final Wellness Program Rules: New Requirements Will Likely Require Changes to Outcome-Based Programs

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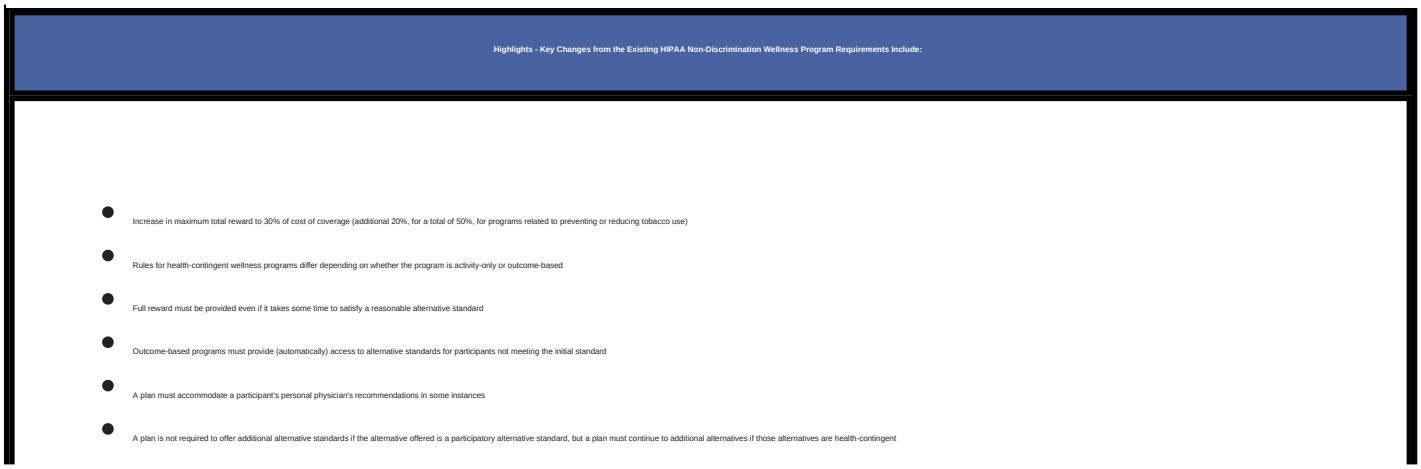
The Department of Health and Human Services, Department of Labor (DOL), and Department of the Treasury (collectively, the Departments) recently released final regulations clarifying and amending standards for nondiscriminatory wellness programs to reflect changes to existing provisions made by the Patient Protection and Affordable Care Act of 2010. The final regulations (2014 Final Rules) apply to all group health plans (including grandfathered plans) and group health insurance coverage for plan years beginning on or after January 1, 2014.

HIPAA Prohibits Discrimination Based on a Health Factor

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) generally prohibits group health plans and group health insurance issuers from discriminating against individual participants and beneficiaries based on a health factor. Health factors include health status, medical condition, claims experience, receipt of health care, medical history, genetic information, evidence of insurability, and disability. However, wellness programs designed to promote health or prevent disease, including those that offer rewards to employees for participating, are excepted from the HIPAA nondiscrimination provisions if they meet certain conditions.



Simplified model language for notice about the availability of reasonable alternative standards

Wellness Programs Exception

The 2014 Final Rules build upon rules issued by the Departments in 2006 related to the wellness program exception (2006 Rules) and proposed rules issued by the Departments in November 2012 (Drinker Biddle's previous alert on the proposed regulations is availablehere). The 2014 Final Rules maintain the two distinct categories of programs established under the 2006 Rules: participatory wellness programs and health-contingent wellness programs. Significantly, the 2014 Final Rules divide healthcontingent wellness programs into two types: activityonly programs and outcome-based programs.

Participatory Wellness Programs

Participatory wellness programs (previously called participation only programs under the 2006 Rules) do not require an individual to satisfy a standard related to a health factor as a condition for obtaining a reward. For example, an employer may reimburse the membership cost of a fitness center, provide a reward to participate in diagnostic testing that is not outcome-based, or provide a deductible or copayment waiver to encourage preventive care, such as prenatal care or well-baby visits. Participatory programs are exempt from the HIPAA nondiscrimination provisions as long as participation in the program is made available to all similarly situated individuals, regardless of health status. There are no limits for financial incentives allowed for participatory programs. The 2014 Final Rules are consistent with the 2006 Rules for participatory programs.

Drinker Biddle Comment: *Keep in mind that different rules apply to whether a reward provided is taxable income to the participant. Even if the program is participatory (and therefore not subject to the five requirements for health-contingent programs described below), the reward offered may be taxable income under federal and/or state law. A common example is reimbursement of fitness center membership fees.*

Health-Contingent Wellness Programs

Health-contingent wellness programs (previously called standard-based programs under the 2006 Rules) require individuals to satisfy a standard related to a health factor as a condition for obtaining a reward. Under the 2014 Final Rules, a "reward" includes both an incentive in the form of a reward (*e.g.*, premium discount, waiver of costsharing amount, an additional benefit or any financial or other incentive) and an incentive in the form of avoiding a penalty (*e.g.*, the absence of a premium surcharge or other financial or nonfinancial disincentive). Some popular rewards are reduced premiums, employer contributions to a health flexible spending account or health savings account, cash, and gift cards. In the 2014 Final Rules, health-contingent programs are further divided into activity-only programs and outcome-based programs:

- **Activity-only programs** require individuals to complete an activity related to a health factor to obtain the reward, but the activity need not result in a specific health outcome. For example, the employer may provide a reward for a walking, diet, or

exercise program.

- **Outcome-based programs** require individuals to attain or maintain a specific health outcome in order to obtain the reward. For example, an employer could provide a reward for not smoking, for obtaining a certain result on a biometric screening, or for maintaining a certain body mass index (BMI).

Each health-contingent program must meet five requirements to be exempt from HIPAA nondiscrimination provisions. The chart below identifies the requirements and to what extent the rules differ for activity-only programs vs. outcome-based programs.

	Requirement	Any Differences?
1	Frequency of Opportunity to Qualify	No
2	Size of Reward	No
3	Reasonable Design	Yes
4	Uniform Availability and Reasonable Alternative Standards	Yes
5	Notice of Availability of Reasonable Alternative Standards	Yes

1. Frequency of Opportunity to Qualify

The program must give eligible individuals an opportunity to qualify for the reward at least once per year.

2. Size of Reward

The 2014 Final Rules increase the total reward that may be offered for all wellness programs under a plan from 20% to 30% of the total cost of employee-only coverage under the plan (including both employee and employer contributions). If dependents participate in the wellness programs, the total cost of coverage considered is the coverage in which the employee and dependent(s) are enrolled. Further, if the program is designed to prevent or reduce tobacco use, the maximum reward is 50% of the cost of coverage.

Drinker Biddle Comment: *The maximum reward applies to all wellness programs in place under one plan. Therefore, if a plan offers both a tobacco-reduction program and an additional health-contingent program, the maximum reward for both programs may not exceed 50% of the cost of coverage. Within that 50%, the health-contingent program not related to tobacco use may not exceed 30% of the cost of coverage.*

3. Reasonable Design

Health-contingent programs must be reasonably designed to promote health or prevent

disease, whether activity-only or outcome-based. A program is reasonably designed if it:

- Has a reasonable chance of improving the health of, or preventing disease in, participating individuals;
- 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.

This determination is based on all relevant facts and circumstances.

Drinker Biddle Comment: *Wellness programs are not required to be accredited or based on particular evidencebased clinical standards, but such practices are encouraged as a best practice by the Departments because they may increase the likelihood of wellness program success.*

- **Activity-only programs:** In order to be reasonably designed, activity-only wellness programs must take into account each factor set out above in light of all relevant facts and circumstances.
- **Outcome-based programs** In addition to the facts and circumstances determination, in order to be reasonably designed, an outcome-based wellness program must provide a reasonable alternative standard to qualify for the reward for all individuals who do not meet the initial standard that is related to a health factor.

4. Reasonable Alternative Standard and Uniform Availability

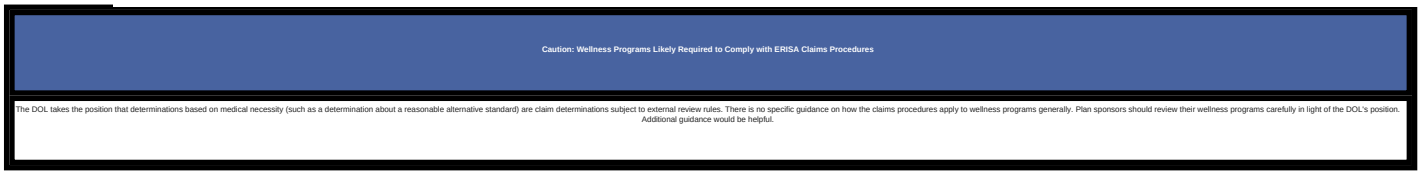
Special Rules for Activity-only and Outcome-based programs

- **Activity-only programs:** The 2014 Final Rules related to reasonable alternative standards offered by activity-only programs essentially follow the 2006 Rules, but now limit those rules to activityonly programs. Under these rules, a reward is not available to all similarly situated individuals unless the program allows a reasonable alternative standard (or waiver of the applicable standard) for any individual for whom it is either unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard or medically inadvisable to attempt to satisfy the otherwise applicable standard. It is permissible for a plan to require verification (such as a statement from the individual's personal physician) that the individual has such a medical condition, but only if it is reasonable under the circumstances. The 2014 Final Rules specify that it would be reasonable to require such verification if medical judgment is required to evaluate the validity of a request for a reasonable alternative standard.
- **Outcome-based programs** The 2014 Final Rules related to reasonable alternative standards offered by outcome-based programs are significantly changed from the

2006 Rules. If an individual does not meet a plan's target standards for outcome-based programs based on a measurement, test, or screening related to a health factor, the individual must be provided with a reasonable alternative standard, regardless of any medical condition or other health status, to ensure that outcomebased initial standards are not a subterfuge for discrimination or underwriting based on a health factor.

If a reasonable alternative standard is, itself, an outcome-based program, it must also satisfy the requirements of the 2014 Final Rules, including offering another reasonable alternative standard, which makes maintaining an outcome-based program more difficult due to the potential for a never-ending cycle of reasonable alternative standards. However, certain special rules apply to prevent such a never-ending cycle. First, the reasonable alternative standard cannot be a requirement to meet a different level of the same standard without additional time to comply that takes into account the individual's circumstances. For example, if the initial standard is to achieve a BMI less than 30, the reasonable alternative standard cannot be to achieve a BMI less than 31 on that same date. A permissible reasonable alternative standard in this case would be to reduce the individual's BMI by a small amount or percentage over a realistic period of time, such as within a year. Second, an individual must be given the opportunity to comply with the recommendations of the individual's personal physician as a second reasonable alternative standard to meeting the reasonable alternative standard defined by the plan, but only if the physician joins in the request.

Under outcome-based programs, it is not reasonable to require verification that a health factor makes it unreasonably difficult or it is medically inadvisable for the individual to satisfy the otherwise applicable standard. However, if the reasonable alternative standard to an outcomebased program is an activity-only program, then the plan may seek such verification, if reasonable under the circumstances, with respect to the activity-only portion of the program.



Drinker Biddle Comment: *Prior to the 2014 Final Rules, many plan sponsors began to make their wellness programs more stringent in the hopes of ensuring that individuals would actually become healthier. Such efforts may still be possible, but plan sponsors should structure such programs carefully to ensure consistency with the new restrictions on outcome-based programs.*

Facts and Circumstances Determine Whether an Alternative Standard is ReasonableThe determination of whether a plan has provided a reasonable alternative standard is based on the facts and circumstances. The 2014 Final Rules provide that the following factors, among others, should be taken into account in determining whether a plan

has provided a reasonable alternative standard:

- If the reasonable alternative standard is completion of an educational program, the plan must make the educational program available or assist the employee in finding such a program, and may not require an individual to pay for the cost of the program.
- The time commitment required must be reasonable.
- If the reasonable alternative standard is a diet program, the plan is not required to pay for the cost of food but must pay any membership or participation fee.
- If an individual's personal physician states that any plan standard (including the recommendations of the plan's medical professional) is not medically appropriate for that individual, the plan must provide a reasonable alternative standard that accommodates the recommendations of the individual's personal physician with regard to medical appropriateness. Plans may impose standard cost sharing for medical items and services furnished in accordance with the physician's recommendations.

Drinker Biddle Comment: *If a plan offers more than one reasonable alternative standard, the 2014 Final Rules do not address the extent to which all alternatives made available must be paid for by the plan. For example, if an individual has high cholesterol and can only receive the reward by participating in a coaching program, is it enough that the plan provides a free video program even though in-person coaching is an additional charge? Similarly, it is unclear the extent to which supplies or materials related to the alternative must be paid for by the plan, other than in the specific examples listed. Additional guidance on these issues would be helpful.*

Timing and Form Requirements for Reasonable Alternative Standards Specific requirements for a reasonable alternative standard depend upon whether the alternative is a participatory or health-contingent wellness program. If the alternative is, itself, a participatory wellness program, no other alternative need be offered during that year. To the extent that a reasonable alternative standard is, itself, a health-contingent wellness program, it must satisfy the requirements in the 2014 Final Rules for either activityonly or outcome-based programs. For health-contingent alternatives, plans must continue to offer a reasonable alternative standard, whether it is the same or different, and cannot limit the number of times a reasonable alternative standard is offered. For example, if a plan offers a walking program as a reasonable alternative to a running program, the walking program is an activity-only program and therefore the plan must also provide a reasonable alternative for individuals for whom it is unreasonably difficult due to a medical condition to complete the walking program. If the reasonable alternative standard is, itself, an outcome-based program, it must adhere to special rules as previously described.

Drinker Biddle Comment: *The Departments noted that overcoming a tobacco addiction or meeting other health outcomes (e.g., weight loss) may require a cycle of failure and renewed effort.*

Plans may always waive the otherwise applicable standard instead of providing a reasonable

alternative standard. Additionally, plans do not need to establish a particular reasonable alternative standard in advance of an individual's specific request for one, as long as one is provided upon request. Reasonable alternative standards may be provided for a class of individuals or on an individual-by-individual basis.

Full Reward Must Be Provided To All Similarly Situated Individuals

The full reward under either an activity-only or an outcome-based program must be available to all similarly situated individuals. Individuals who qualify by satisfying a reasonable alternative standard must be provided the same, full reward that is provided to individuals who qualify by satisfying the otherwise applicable standard. This same, full reward must be provided even if an individual takes some time to request, establish, and satisfy a reasonable alternative standard. For example, if a calendar year plan offers a premium discount and an individual satisfies a reasonable alternative standard on April 1, the plan must still provide the premium discounts for January, February, and March.

Plans may determine how to provide the portion of the reward for the period before the alternative was satisfied (*e.g.*, a lump sum payment for the retroactive period or pro rata over the remainder of the year) as long as the method is reasonable and the individual receives the full reward. If the alternative standard is not satisfied until the end of the year, the plan may provide a retroactive payment for that year within a reasonable time after the end of the year, but may not provide pro rata payments over the following year.

Drinker Biddle Comment: *Plan sponsors should be cautious about providing a Year 1 reward in Year 2, and should consider, in particular, the IRS rules relating to deferral of compensation. Additional guidance from the Departments would be helpful.*

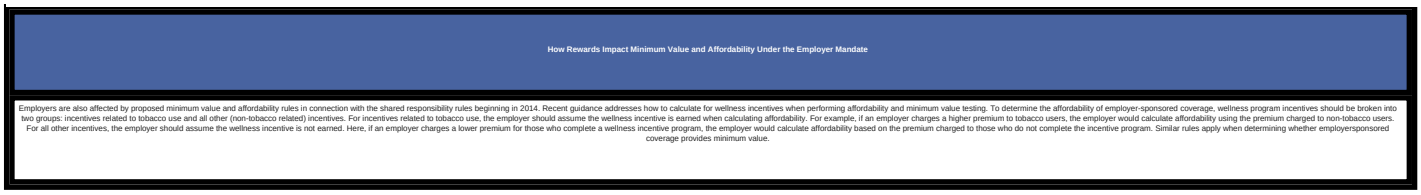
5. Notice of Availability of Reasonable Alternative Standard

The plan must disclose the availability of a reasonable alternative standard to qualify for the reward (and, if applicable, the possibility of waiver of the otherwise applicable standard) in all plan materials describing the terms of all health-contingent wellness programs (*e.g.*, summary plan descriptions and open enrollment materials). This disclosure must include contact information for obtaining the alternative. Additionally, in a change from the 2006 rules, the disclosure must also include a statement that recommendations of an individual's personal physician will be accommodated. For outcome-based wellness programs, a similar notice must be included in any communication that any individual did not satisfy an outcome-based standard. If plan materials only mention the existence of the program, without describing specific terms, disclosure is not required. The following sample language satisfies the requirement:

"Your health plan is committed to helping you achieve your best health. Rewards for participating in a wellness program are available to all employees. If you think you might be unable to meet a standard for a reward under this wellness program, you might qualify for an opportunity to earn the same reward by different means. Contact us at [insert contact information] and we will work with you (and if you wish, your doctor) to find a wellness program with the same reward that is right for you in light of your health status."

Drinker Biddle Comment: *The new sample language is intended to be simpler to understand and to increase the likelihood that those who qualify for an alternative standard will contact their plan to*

request one.



Other Compliance Issues

This is a good time for employers to consider their wellness programs in light of new standards under the 2014 Final Rules. Additionally, employers are advised to consider compliance of their wellness programs with various other laws impacting wellness programs, including the Genetic Information Nondiscrimination Act of 2008, the Family and Medical Leave Act, the Americans with Disabilities Act of 1990, as amended, federal and state tax laws, ERISA's fiduciary provisions, HIPAA privacy rules, and continuation coverage rules under COBRA.

National Law Review, Volume III, Number 183