Double Whammy, Part II: EEOC Stance and ACA Final Regulations Impose New Burdens on Wellness Programs

By Russell Chapman

A recently released Equal Employment Opportunity Commission (EEOC) information letter (EEOC Letter), along with the new final wellness regulations under the Patient Protection and Affordable Care Act (ACA), present new challenges for employer-provided wellness programs.

The EEOC Letter, released in January 2013 and recently made publicly available under the Freedom of Information Act, provides that a disease management program administered under a group health plan is in fact a wellness program and is subject to the Americans with Disabilities Act (ADA). Thus, an employer may in some circumstances be required to provide participants in such a disease management program with a "reasonable accommodation" in order to take full advantage of the benefits offered under the plan.

Meanwhile, the final wellness regulations under the ACA, published on June 3, 2013 and effective with the first plan or policy year beginning on or after January 1, 2014, require wellness programs that base a wellness reward on meeting a condition related to a health factor based on a measurement, test, or screening (an "outcome-based" wellness program) to offer a participant who does not meet the standard a "reasonable alternative standard." This requirement applies whether or not the participant can show that it would be unreasonably difficult or medically inadvisable, due to a medical condition, to satisfy the standard. The requirements for "participation based" and "activity-only" wellness programs, as defined in the final regulations, remain mostly unchanged from the proposed regulations, with some modifications.

The EEOC January 2013 Information Letter

The EEOC Letter addressed a group health plan that waived its deductible for participation in a disease management program or adherence to a doctor-prescribed exercise and medication program, and included a requirement that the participants undergo blood tests to determine that they were taking medications as prescribed as part of the...
physician-prescribed disease treatment program. Failure to comply resulted in the employee’s disenrollment from the disease-management program and automatic enrollment in the employer’s “standard” plan, a high-deductible group health plan.

The EEOC took the position that the disease management program was a wellness program because – though the program did not require participants to complete a health risk assessment – the EEOC “assumed” a participant would be required to disclose to the program the existence of the chronic disease in order to be eligible for the disease-management program. This of course would be a requirement for any disease management, large case management, or similar utilization review program of a group health plan. For example, one must actually have diabetes in order to be eligible for a disease management program providing benefits for treatment aimed at controlling diabetes, just as one must have appendicitis in order to receive benefits for an appendectomy under any group health plan. Similarly, disclosure to the group health plan of the existence of certain medical conditions is a common feature of pre-treatment approval and other utilization review procedures that have become common in most group health plans and policies since the 1980s. The EEOC Letter, without discussion or analysis, summarily pronounces these procedures “disability-related inquiries” under the ADA.2

This, the EEOC reasoned, brought the program into the realm of a wellness program because, as the EEOC assumed, “a condition of participation is that employees disclose that they have qualifying health conditions, which would be a disability-related inquiry, and that other disability-related inquiries or medical examinations would be required to determine continued eligibility for any incentive offered.3

Second, as has been its practice for several years, the EEOC would not comment on whether the program was “voluntary” for purposes of whether the “disability-related inquiries” in the program were exempt from the ADA’s prohibition on such inquiries.4

Third, since in the EEOC’s view the program was a wellness program, and made “disability-related inquiries” of participants, the EEOC concluded that the program would be required to provide reasonable accommodation under the ADA to any participant who could not comply with the requirements due to a disability.

Finally, assuming the disease-management program was voluntary and provided reasonable accommodation to persons who could not meet the requirements because of a disability, the EEOC determined that the program would not be deemed involuntary because a non-compliant participant was disenrolled from the program and enrolled instead in the high-deductible plan available to all other participants. That is, the non-compliant participants could be effectively transferred from the disease management program to the employer’s “standard” plan. Thus, the EEOC effectively acknowledged that ineligibility as a sanction for non-compliance with a wellness program (assuming the program is voluntary and conforms to the ADA’s reasonable accommodation requirements) would not violate the ADA as long as the individual was automatically enrolled in the employer’s “standard” plan.

Conspicuously absent from the EEOC’s discussion was any mention of the ADA’s general exemption for adherence to the terms of a bona fide employee benefit plan,5 which was the subject of last year’s Eleventh Circuit ruling in Seff v. Broward County.6

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2 Id.
3 Id. The application by the EEOC of the term “wellness program” to a disease management program arguably is at variance with the ACA’s, and the Final ACA Regulations’, definition of that term, both of which define the term “wellness program” as a program of health promotion or disease prevention offered by an employer. See PHSA § 2705(j); Treas. Reg. § 54.4980-1(f); DOL Reg. § 2570.902(f); and HHS Reg. § 146.121(f). Rather than promoting health or preventing disease, disease management programs manage and treat existing disease. Note that even if a disease management program were a wellness program, under the Final ACA Regulations discussed infra, because a disease management program does not require a medical outcome for the receipt of benefits, but only cooperation with a given treatment program, it would arguably be a “participatory” wellness program, and not an “outcome-based” wellness program. However, the DOL has informally taken the position that a disease management program in which participants must show that they have a certain disease in order to participate, and must further cooperate with the treatment program in order to obtain a lowered premium rate, is in fact a health-contingent wellness program. See, ABA Joint Committee on Employee Benefits. Questions for the DOL, Q/A-15 (May 3, 2006) (as visited July 30, 2013) (cooperation with disease management program to avoid “punitive” higher premium charge is a health-related status wellness program). Query whether this position by the DOL and the EEOC ignores the “benign discrimination” provision of the regulations, which permits favorable treatment of an individual based on the presence of an adverse health factor. See, e.g., Treas. Reg. § 54.4980-1(g). Arguably, such a program comes under the heading of “benign discrimination,” because rather than base a reward on meeting a standard related to a health factor, the existence of the chronic condition is an initial eligibility factor for obtaining enhanced benefits. Similarly, if the participant in a disease management program must cooperate with a treatment program in order to maintain eligibility for the program, if that is a wellness program, it would be a participatory program, not a health-contingent one, since the participant is not required to achieve any level of health in order to maintain eligibility.
5 ADA § 12201(c). The EEOC’s statement that a “reasonable accommodation” standard applies to a wellness program that is part of a group health plan clearly demonstrates that the EEOC is choosing to disregard the very existence of ADA Section 12201(c).
The introduction of a “reasonable accommodation” standard into group health plans generally, and into disease management programs specifically, many of which require the participant to cooperate with their personal physician’s treatment plan in order to maintain eligibility for the program, would present a significant obstacle to the delivery of benefits under such plans. It would introduce a disruptive reasonable accommodation “interactive dialogue” process into benefit determinations, and would interfere with benefit plan claims and appeal procedures. The ADA’s customary procedures for reaching reasonable accommodation of disabilities in the workplace are inappropriate in the group health plan context and incompatible with carefully designed ERISA and ACA claims, appeals and benefit delivery procedures. These factors support the underlying justification for the ADA’s exemption of employee benefit plans meeting the requirements of ADA Section 12201(c).

The ACA Wellness Statute and Final Regulations

**Background: HIPAA and the 2006 Regulations**

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), among other things, amended the Internal Revenue Code of 1986, as amended (the Code), the Employee Retirement Income Security Act of 1974, as amended (ERISA), and the Public Health Services Act (PHSA), by prohibiting a health plan and a health insurance issuer offering group health insurance coverage (a “group health plan”) from discriminating with regard to eligibility, premiums or contributions on the basis of certain health status-related factors. For this purpose, a “health status-related factor” includes an individual’s health status, medical condition (including both physical and mental illnesses), claims experience, medical history, genetic information, and receipt of health care.7

HIPAA provided an exception to the nondiscrimination requirement for a group health plan that established, under regulations, "premium discounts or rebates or modifying otherwise applicable copayments or deductibles in return for adherence to programs of health promotion and disease prevention."8 In 2006, the Treasury Department, EBSA, and the Department of Health and Human Services (HHS) (collectively, the "Departments") jointly issued final regulations under the HIPAA wellness program exception (the "HIPAA wellness regulations").9

The HIPAA wellness regulations generally divided wellness programs into two categories. The first type of wellness program was one conditioning a reward on a requirement not related to a health factor, that is, a “participation only” requirement. An example would be a requirement that the participant attend periodic wellness seminars or complete a health risk assessment questionnaire in order to obtain the wellness reward. Under the 2006 HIPAA wellness regulations, such a participation-based wellness program need only be offered to all similarly-situated individuals in order to avoid liability under HIPAA’s nondiscrimination rule.

The second type of wellness program under the 2006 HIPAA regulations is one in which, to obtain a reward under the program, the individual must meet a requirement related to a health factor, such as a requirement that the individual participate in an exercise program at a prescribed level, remain tobacco-free, maintain a total blood cholesterol level below 200, or a body-mass index (BMI) of 30 or lower.

Under the HIPAA wellness regulations, effective generally through the end of plan years beginning in 2013, such a health factor-based wellness program must meet the following requirements:

- As with a participation-based wellness program, the health factor-based wellness program must be available to all “similarly situated” employees. This requirement is generally met by offering the program on the same terms to a group of employees designated by function, location, business unit, corporate unit, organization, or similar business-related criteria.
- Participants must have the opportunity to qualify for the program at least annually.

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7 ERISA § 702.
8 Code § 9802(b)(2)(B); and ERISA § 702(b)(2)(B).
9 71 FR 75014. Effective for plan or policy years beginning on or after January 1, 2014, these regulations have been amended and replaced by the final ACA wellness regulations, discussed below. The final ACA wellness regulations now cover the nondiscrimination requirements under both HIPAA, which was not amended by the ACA, and the ACA’s new, separate nondiscrimination requirement, added to the PHSA (42 U.S.C. § 300gg), and incorporated into ERISA § 715, added by the ACA. See 78 FR at 33160, n. 8.
• If it is determined that, due to a medical condition, it is unreasonably difficult or medically inadvisable for the participant to meet
the health factor-based standard, the plan must offer a “reasonable alternative standard” that is worked out between the plan and
the individual on a case-by-case basis. The plan may require the individual requesting a reasonable alternative standard to provide
verification from the individual’s physician that it would be unreasonably difficult or medically inadvisable, due to a medical condition,
to meet the health factor-based standard.

The reasonable alternative standard for meeting the wellness program that is related to a health factor (i.e., remain tobacco-free)
does not have to be determined in advance or set out in the plan itself, but may be arrived at through individual interaction with the
participant. The HIPAA regulations include a safe harbor notice of the reasonable alternative standard:

If it is unreasonably difficult due to a medical condition for you to achieve the standards for the reward under this program, or
if it is medically inadvisable for you to attempt to achieve the standards for the reward under this program, call us at [insert
telephone number] and we will work with you to develop another way to qualify for the reward.

If the administrator rejects the participant’s proposed alternative standard as not being reasonable and denies the wellness
reward, then this decision is treated as an adverse benefit determination under the July 2011 amendments to the ACA external
review regulations. Thus, the adverse internal review decision under a health factor-based wellness program is subject to external
independent review for non-grandfathered group health plans subject to those requirements.

• Terms of the wellness incentive requirement must be disclosed in all plan materials describing the program.

• The financial incentive may not exceed 20% of the total cost of coverage (i.e., the combined employee and employer contribution).

The ACA Wellness Amendment

Without repealing the existing HIPAA nondiscrimination provision, the ACA amended ERISA, the Code and the PHSA to prohibit group health
plans and insurers offering health coverage in the group and individual markets from discriminating in eligibility, premium determinations or
benefits on the basis of a health status-related factor. The ACA’s prohibition against discrimination on the basis of a health status-related
factor adds one such factor to the list of prohibited categories currently existing under the HIPAA nondiscrimination rule, namely, “any other
health status-related factor determined appropriate by the Secretary of HHS.”

The ACA effectively codified the existing 2006 HIPAA wellness regulations with some modifications. These modifications, apart from an
increase in the available wellness reward, are relatively minor, and appear to preserve the spirit and intent of the 2006 HIPAA regulations.

The ACA divides wellness programs into two categories: programs that do not base any condition on receiving a reward on a standard related
to a health factor, and those that do. The regulations refer to the first type of program as a “participatory” wellness program, and the second
as an “outcome-based” wellness program.

The ACA provides that if a participatory wellness program is made available to all “similarly situated” employees, then Section 2705 of the
PHSA will not be violated. The statute then provides the following list of participatory wellness programs that will not be subject to the
wellness requirements: (1) reimbursement for fitness center membership; (2) a “diagnostic testing program” that does not base any part of
the reward on the outcome of the test; (3) a smoking cessation program where the wellness reward is provided whether or not the individual
quits smoking; and (4) a wellness reward for attendance at a periodic health education seminar.

10 PHSA § 2705 is codified at 42 U.S.C. § 300gg-4. References in this discussion will be to the PHSA. The PHSA requirements are incorporated into Code Section 9802 and ERISA § 702 through parallel regulations. In this discussion, a “health status-related factor” will be referred to as a “health factor.”
11 PHSA § 2705(a)(9). The ACA also transferred existing HIPAA and GINA requirements in existing PHSA § 2702 to the newly created PHSA § 2705.
12 PHSA § 2705(j).
13 PHSA § 2705(j)(1)(B).
14 PHSA § 2705(j)(1)(C).
15 PHSA § 2705(j)(1)(B) and (j)(2).
16 PHSA § 2705(j)(2)(A) – (E). Section 2705(j)(2)(C) includes providing a waiver of copayment or deductible for certain preventive care. These services, to the extent required under
PHSA Section 2713 and the regulations, must be covered without any cost sharing by a group health plan or covered issuer.
The ACA wellness statute provides that an outcome-based wellness program "shall not violate" Section 2705 of the PHSA if the following requirements are met:

1. The reward for all outcome-based wellness programs does not exceed 30% of the cost of coverage, taking into account both employer and employee contributions, applied to the coverage tier of the group of individuals (employee, employee plus spouse, or employee plus family) eligible to participate, and participating in, the wellness program. This maximum may be increased under regulations to 50%. The "reward" may be either a discount or a surcharge based on compliance with the program.\(^\text{17}\)

2. The program is "reasonably designed" to promote health or prevent disease. To meet this requirement, the program must: (A) have a "reasonable chance of improving the health of, or preventing disease in" the participating individual, (B) not be "overly burdensome", (C) not be a subterfuge for discriminating on the basis of a health factor, and (D) not be "highly suspect" in its methods.\(^\text{18}\)

3. Eligible individuals have the opportunity to obtain the wellness reward at least annually.\(^\text{19}\)

4. The "full reward" is made available to all "similarly situated individuals." For this purpose, the program must allow for a "reasonable alternative standard" or a waiver of the standard for obtaining the reward for any individual for whom it is unreasonably difficult due to a medical condition, or medically inadvisable, to attempt to satisfy the health factor-based standard. If reasonable under the circumstances, the plan may seek verification from the participant’s physician that one of the two standards for the reasonable alternative standard or waiver is present.\(^\text{20}\)

5. All plan materials describing the wellness program must disclose the availability of a reasonable alternative standard or possibility of a waiver. The disclosure is not required to set forth the actual terms of the reasonable alternative standard.\(^\text{21}\)

The statutory framework is fairly simple and straightforward, and in most instances mirrors the 2006 HIPAA wellness regulations’ requirements. A few provisions are worth noting. First, the sole requirement under the statute for a participation-based wellness program is that it be made available to all "similarly situated employees." The statute does not otherwise define this phrase.

The existing Departments of Labor (DOL), Treasury and Health and Human Services (HHS) (the “Departments”) regulations define a group of "similarly situated employees" as a grouping of employees based on a bona fide employment-based classification consistent with the employer’s usual business practice. Whether an employment-based classification is bona fide is determined on the basis of all the relevant facts and circumstances. Relevant facts and circumstances include whether the employer uses the classification for purposes independent of qualification for health coverage (for example, determining eligibility for other employee benefits or determining other terms of employment). Examples of classifications listed in the regulations that, based on all the relevant facts and circumstances, may be bona fide include full-time versus part-time status, geographic location, membership in a collective bargaining unit, date of hire, length of service, current employee versus former employee status, and occupation.\(^\text{22}\)

Another difference between the ACA’s statutory wellness provision and the 2006 regulations is the addition of the proviso “if reasonable under the circumstances” in determining when a plan may seek verification from the participant’s physician that the health factor-based requirement would be unreasonably difficult due to a medical condition, or medically inadvisable, to attain.

\(^{17}\) PHSA § 2705(i)(3)(A).

\(^{18}\) Id., § 2705(i)(3)(B).

\(^{19}\) Id., § 2705(i)(3)(C).

\(^{20}\) Id., § 2705(i)(3)(D).

\(^{21}\) Id., § 2705(i)(3)(E).

\(^{22}\) DOL Reg. § 2590.702(d); Treas. Reg. § 54.9802-1(d) and HHS Reg. § 146.121(d). Note, however, that the creation of classifications of employees directed at individual employees based on the existence of a health factor is not a bona fide group of "similarly situated" employees or individuals for purposes of the nondiscrimination requirement. Thus far, these regulatory provisions have not been amended, but they may have been abrogated for some purposes, such as community rating, or selecting groups of employees for purposes determining measurement periods for crediting hours and determining full-time status under the employer (“play or pay”) mandate, under the ACA. For example, the January 2013 employer mandate regulations provided that an employer could provide different measurement and stability periods for purposes of determining “full-time” employee status under the employer mandate rules (IRC Sec. 4980H) as including only (a) collectively bargained employees and non-collectively bargained employees, (b) each group of collectively bargained employees covered by a separate collective bargaining agreement, (c) salaried employees and hourly employees, and (d) employees whose primary places of employment are in different States. Prop. Treas. Reg. § 54.4980H-3 (c)(1)(v) (Jan. 2, 2013, 78 F.R. at 243). Therefore, caution is advised in applying the “similarly situated” definition in other contexts under the ACA. However, the current definition of “similarly situated individual” appears to continue to have validity in the context of the health-factor nondiscrimination rules.
The ACA Final Wellness Regulations

The ACA Final Wellness Regulations ("Final ACA Regulations") amend and add to existing regulations previously published by the Treasury Department, EBSA, and HHS. The three sets of Final ACA Regulations are identical in wording. These regulations are intended to amend and replace the current 2006 HIPAA wellness regulations effective for plan years beginning on or after January 1, 2014. According to the Departments, compliance with the ACA wellness provision and the Final ACA Regulations constitutes an affirmative defense to a claim that the plan or issuer violated the ACA’s prohibition against discrimination on the basis of a health factor.

In structure, the Final ACA Regulations divide wellness programs into two main categories, "participatory wellness programs" and "health-contingent wellness programs." Health-contingent wellness programs are further subdivided into two categories not suggested by the statutory language: "activity-only wellness programs" and "outcome-based wellness programs."

Definitions and Preliminary Issues

What is a "wellness program"?

As under the 2006 HIPAA regulations, a wellness program is any program of health promotion or disease prevention. There is no requirement that the wellness program be a part of a group health plan, but the context of the regulations is that the wellness program will be a part of, or that the group health plan will be administered with reference to, the wellness program, because the regulations and the ACA statutory provision are applicable solely in the context of a group health plan that would otherwise discriminate on the basis of a health factor.

What is a "participatory wellness program"?

As with the statutory provisions of the ACA, the Final ACA Regulations define a participatory wellness program as wellness program in which none of the conditions for obtaining the wellness reward require the individual to satisfy a condition related to a health factor. Examples include payment for the cost of a health club membership, a diagnostic testing program in which no part of the reward is based on the outcome of any test, a program waiving cost-sharing for certain preventive care, or attending wellness classes.

What is a "health-contingent wellness program"?

A health-contingent wellness program is a wellness program in which to attain the reward, the participant must satisfy a standard related to a health factor (such as maintaining a healthy weight, blood pressure, blood sugar, etc.), or a standard requiring the individual to "undertake more" than other similarly situated individuals in order to attain the reward. Health-contingent programs are subdivided into "activity-only" wellness programs and "outcome-based" programs.

What is an "activity-only wellness program"?

An activity-only wellness program is a type of health-contingent wellness program in which the individual is required to undertake some form of physical activity, such as a diet or exercise program, in order to obtain the wellness reward. Under the Final ACA Regulations, an activity-only
wellness program may require a participant to demonstrate that, due to a medical condition, it would be unreasonably difficult or medically
inadvisable to complete the otherwise applicable standard in order to utilize a reasonable alternative standard to obtain the wellness reward.

What is an "outcome-based wellness program"?

An outcome-based program is the second type of health-contingent wellness program. An outcome-based program conditions receipt of
the wellness reward on attaining or maintain a specified health outcome, such as maintaining a healthy weight or blood cholesterol level as
determined by a biometric screening, or abstaining from tobacco use. 37

Under the Final ACA Regulations, outcome-based programs which initially determine whether the participant is in compliance with the wellness
standard on a "measurement, test or screening", such as a biometric screen or HRA questionnaire, must automatically offer the participant
a reasonable alternative standard or waive the requirement. 38 The automatically-offered reasonable alternative standard may be either a
participatory program or an activity only program, or it may be an outcome-based standard set at a more attainable level than the original
standard, with additional time afforded to attain the incremental standard. 39 This automatic reasonable alternative standard requirement is
examined in greater detail below. 40

What is a "reward"?

Under the HIPAA regulations, the concept of a "reward" seemed to create confusion. Is a "reward" a discount, a rebate, a credit against a
cost sharing requirement, or can it also be the avoidance of a penalty? The Final ACA Regulations clear up any misconceptions along these
lines by providing that the "reward" under a wellness program may encompass either a discount, rebate, credit toward a deductible, or the
avoidance of a penalty, such as a surcharge.

Do the Final ACA Regulations Apply to Grandfathered Plans?

The Final ACA Regulations omit a provision found in the effective date section of the proposed regulations that limited the application of the
ACA's wellness provision to non-grandfathered plans under the ACA. Therefore, the Final ACA Regulations apply to both grandfathered and
non-grandfathered group health plans. 41 However, the Final ACA Regulations do not answer the question of whether a wellness reward that
is structured as a surcharge on an existing premium or cost of coverage level for noncompliance with the program may cause a grandfathered
plan to lose its grandfathered status under the ACA. Therefore, plan sponsors should exercise caution in designing newly-created wellness
programs that will apply to a grandfathered plan.

Participatory Wellness Programs

There is little change under the Final ACA Regulations from the 2006 HIPAA wellness regulations in the case of a wellness program that does
not require the individual to meet a requirement related to a health factor in order to attain a reward. The Final ACA Regulations define a
participatory program as one in which no part of the reward is based on the individual’s being required to satisfy a standard related to a health
factor. 42 Examples of a participatory program include: (1) a requirement that the participant undergo a health screen (a “diagnostic testing

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37 Id., § 54.4980-1(f)(1)(v).
38 For ease of reference, this discussion will refer to this "measurement, test or screening" as simply a "test", which the participant either passes or fails. For example, if the test is a
biometric screen in the form of a finger-stick blood draw requiring the participant to have a total serum cholesterol level at or below 200, the participant passes the test with a total
serum cholesterol level at 180, but fails the test at a total serum cholesterol level of 225.
39 This "automatic reasonable alternative standard" requirement for outcome-based programs is the most controversial change wrought in the wellness regulations under the ACA.
The requirement appeared in the proposed regulations, and resulted a great deal of negative comment, notably that the "automatic reasonable alternative standard" requirement
effectively deprived an outcome-based program of ever requiring a participant to actually achieve the healthy weight, blood pressure or other requirement.
40 An outcome-based wellness program may not require the participant to demonstrate that that, due to a medical condition, it would be unreasonably difficult or medically
inadvisable to complete the otherwise applicable standard in order to utilize a reasonable alternative standard, unless the automatic reasonable alternative standard offered is
itself an activity-only wellness program. See infra, n. 67 and accompanying text. But cf., 42 U.S.C. § 300gg-4(j)(3), which makes no such division of programs which base a reward
on "satisfying a standard that is related to a health status factor" into "activity-only" or "outcome-based" programs, and provides that such a program "shall not violate" the
nondiscrimination provision if the requirements of Subparagraphs (A) through (E) of Paragraph (3) are met. One of these requirements is, without qualification: "If reasonable under
the circumstances, the plan or issuer may seek verification, such as a statement from an individual’s physician, that a health status factor makes it unreasonably difficult or medically
inadvisable for the individual to satisfy or attempt to satisfy the otherwise applicable standard." 42 U.S.C. § 300gg-4(j)(3)(D)(ii).
41 See, 78 FR at 33167, and Treas. Reg. § 54.4915-2715.
to wellness programs. However, as discussed below, the Final ACA Regulations disclaim any effect on other laws, such as Title VII, the Americans with Disabilities Act (ADA) or Genetic Information Nondiscrimination Act (GINA), as they may apply to wellness programs.

Requirements Common to Health Factor-Based Wellness Programs

As defined under the Final ACA Regulations, the two types of health factor-based programs, activity-only programs and outcome-based programs, have two requirements in common.45

Annual Qualification

Both activity-only programs and outcome-based programs must allow participants the opportunity to qualify for the wellness reward at least once each year.46

Size of Reward

Under either program, the maximum wellness award that may be offered is 30% (the "applicable percentage") of the total cost of coverage (including both employer and employee contributions) under the group health plan that includes the wellness program.47

The rules for determining the aggregate cost of coverage to which the applicable percentage will apply are similar to those found under the 2006 HIPAA wellness regulations. If only the employee is eligible to participate in the program, then the applicable percentage applies to aggregate cost of the employee-only tier of coverage. If covered spouses or other dependents are eligible for the wellness program, the applicable percentage is applied to the aggregate cost of the coverage tier in which the individuals are participating, such as employee-only, employee plus spouse, or employee plus family.

In the case of a health-contingent wellness program targeting tobacco use and cessation, the applicable percentage is increased to 50%, as authorized by the ACA wellness statute discussed previously. Because a participation-only wellness program effectively does not limit — at least where the ACA is concerned — the level of reward that may be offered to a participant, and a non-tobacco-based health contingent wellness program is limited generally to 30%, the interaction of the applicable percentage to these different types of programs may create confusion.

Where a health-contingent wellness program includes a requirement relating to cessation or reduction of tobacco use, and a separate requirement not relating to tobacco use, the health-contingent program that is unrelated to tobacco use is tested separately regarding the 30% limit; however, the reward for the wellness requirement aimed at limiting tobacco use is not tested separately. Rather, the combined reward for meeting any non-tobacco related requirements under the program, together with those relating to tobacco use, may not exceed the 50% limit.48

43 Id.
44 Id., § 54.4980-1(f)(2). Presumably, the definition of "similarly situated individual" for this purpose remains as discussed above under the existing regulations. See, e.g., id. at § 54.4980-1(d), and note 22 and accompanying text, infra.
45 These requirements are repeated verbatim in the respective regulations’ sections describing activity-only and outcome-based programs, and are therefore discussed separately here since they are identical with regard to each type of program. See Treas. Reg. § 54.4980-1(f)(3)(i) and (ii), (f)(4)(i) and (ii), and (f)(5).
46 Id., § 54.4980-1(f)(3)(i) and (f)(4)(i).
47 Id., § 54.4980-1(f)(3)(ii), (f)(4)(ii), and (f)(5).
48 Id., § 54.4980-1(f)(5), Example 3(ii). Note that the Final ACA Regulations refer only to programs intended to "prevent or reduce tobacco use" in connection with the higher applicable percentage limit. Not discussed is whether the enhanced applicable percentage would apply to programs aimed at forms of nicotine delivery other than tobacco use, such as e-cigarettes. According to reports, e-cigarettes are not a tobacco product; the nicotine they provide may be extracted from tobacco or chemically synthesized, but it is not tobacco as such. WebMD.com, http://www.webmd.com/smoking-cessation/features/ecigarettes-under-fire, accessed July 26, 2013. See also American Medical Association, Council on Science and Public Health, Use of Electronic Cigarettes in Smoking Cessation Programs (2010), http://www.ama-assn.org/resources/doc/csaph/10csaph6ft.pdf (accessed July 26, 2013). The AMA report generally takes a dim view of e-cigarettes, but does note that they eliminate about 600 ingredients, more than 40 recognized carcinogens, and other toxins otherwise found in ordinary cigarette smoke. Nicotine may also be delivered without the use of tobacco through nicotine water, wafers, candy, gum, inhalers or other products. Eriksen M, Mackay J, Ross H., The Tobacco Atlas, Fourth Ed. Atlanta, GA: American Cancer Society; New York, NY: World Lung Foundation; 2012, also available at www.TobaccoAtlas.org.
Additional Requirements

Both activity-only wellness programs and outcome-based wellness programs must comply with the "Reasonable Design" and "Uniform Availability" requirements under the Final ACA Regulations, but these requirements differ markedly from one type to the next. Therefore, they are discussed separately below.

Requirements for Activity-Only Wellness Programs

As discussed, the typical activity-only wellness program requires the participant to engage in some sort of stated or measurable physical activity, such as adhering to a specified diet or exercise program. Under the Final ACA Regulations, in addition to the annual qualification requirement and limits on the size of the wellness reward, an activity-only program must meet the Reasonable Design and Uniform Availability requirements.

Reasonable Design

The regulations do not elaborate further on this requirement in the case of an activity-only program, and merely repeat the statutory language. An activity-only program meets the "reasonable design" standard if, based on all the facts and circumstances, it (i) has a reasonable chance of improving the health of, or preventing disease in, participants, (ii) is not overly burdensome, (iii) is not a subterfuge for discriminating based on a health factor, and (iv) is not highly suspect in the method chosen to promote health or prevent disease. 49

Uniform Availability and Reasonable Alternative Standard

The uniform availability and reasonable alternative standard requirements, with one notable exception, do not stray very far from the requirements of a health factor-based wellness program under the 2006 HIPAA wellness regulations. 50

Generally, under the 2006 HIPAA Regulations, an activity-only wellness program is available to all similarly situated individuals only during such time as a reasonable alternative to the otherwise applicable activity-based standard is made available to any participant for whom it would be (i) unreasonable difficult due to a medical condition, or (ii) medically inadvisable, to attempt to satisfy the activity-based standard set out in the program. 51 The reasonable alternative standard does not have to be determined in advance, but must be provided to any person described in the preceding sentence, and whether the reasonable alternative standard has been offered is based on a facts and circumstances determination. 52

Certain requirements may apply to the alternative standard proposed to determine whether it is reasonable. First, the plan may not require the participant to locate and pay the costs associated with the proposed alternative. For example, if the proposed reasonable alternative standard is an educational program, the plan must locate, or assist the participant in locating, the program, and must pay the costs of the program. If the proposed alternative is a diet program, the plan must pay any membership fees, but is not required to pay the cost of food. 53 The regulations note that payment for a reasonable alternative standard involving medical expenses will be subject to the usual cost-sharing provisions of the plan. 54 However, see below for a discussion of whether this employer-must-pay requirement may also apply in such situations.

Second, the alternative standard may not impose unreasonable time commitments, such as a requirement to attend a daily one-hour health class. 55

Third, at the participant’s request, the plan must accommodate the recommendations of the participant’s personal physician as to the medical appropriateness of the proposed alternative standard, and any subsequent changes to the alternative that the physician may recommend later. In effect, the participant’s personal physician may make changes to the alternative standard at any time. The regulations do not appear to

49 Id., § 54.4980-1(f)(3)(iii).
52 Id., § 54.4980-1(f)(3)(iv)(B) and (C).
53 Id., § 54.4980-1(f)(3)(iv)(C). The regulation does not articulate a rule in connection with this example, but the rule that might be inferred from these examples is that any expense associated the reasonable alternative standard that the participant would not have otherwise incurred (membership fees) must be paid by the plan, while any expense the participant would have incurred in any event (food) may remain the responsibility of the participant.
place any limitation on the number of times or the circumstances under which the participant’s physician may make such a recommendation, nor is there a "reasonableness" standard associated with this requirement.56

Fourth, to the extent a reasonable alternative standard is itself an activity-only wellness program (for example, a walking program substituted for a running program), the alternative program is subject to the requirements for activity-based programs as if it were the initial wellness standard.57

Verification of Need for Reasonable Alternative Standard

An activity-based wellness program, and only and activity-based wellness program, may, if reasonable in the circumstances, seek verification from the participant’s personal physician that the participant is eligible for the reasonable alternative standard, but only "if it is reasonable to determine that medical judgment is required to evaluate the validity of the request."58 Thus, if it is obvious that a reasonable alternative standard is required, such as a running program where the participant is wheelchair-bound or otherwise clearly physically impaired, then the plan would not be permitted to seek verification from the participant’s physician of the need for a reasonable alternative standard.59 As noted above, the "if reasonable in the circumstances" proviso did not exist under the 2006 HIPAA wellness regulations pertaining to the reasonable alternative standard, but was added in the ACA wellness statutory provision.

Notice of Availability of Reasonable Alternative Standard

An activity-based wellness program must disclose in all plan materials the availability a reasonable alternative standard, including a statement that the recommendations of the participant’s personal physician will be accommodated. The exact form of the alternative standard need not be set out in the notice. The regulations provide a model notice for use by activity-based wellness programs.60

Requirements for Outcome-Based Wellness Programs

As noted, an outcome-based wellness program is one in which the participant must actually meet a stated health outcome in order to qualify for the reward. Under the ACA Final Regulations, the initial requirements for an outcome-based program are the same as those for an activity-only program. The program must provide an opportunity to qualify for the reward at least annually,61 and the limitations concerning the amount of the reward are the same as for activity-based programs, as discussed above.62

Uniform Availability and Reasonable Alternative Standard – the "Never-Ending Cycle"

The Final ACA Regulations, however, radically depart from the 2006 HIPAA regulations and the statutory language of the ACA with respect to outcome-based wellness programs. The Departments interpret the statutory requirement that the wellness reward be uniformly available to all similarly-situated employees to require that, where initial determination of compliance with the outcome-based standard is based on a measurement, test or screening, the plan must automatically offer the participant a reasonable alternative standard or waive the otherwise applicable outcome-based standard.63

For example, if the wellness requirement is to maintain a healthy blood pressure level as determined by the results of a blood pressure screening, then the wellness program must automatically offer the participant a reasonable alternative standard to any participant whose blood pressure exceeds the stated level. The alternative might consist of attending health classes (i.e., a participatory wellness program) or a diet or exercise program (i.e., an activity-only wellness program). If an activity-only wellness program is offered as a reasonable alternative standard to the otherwise applicable outcome-based program, the activity-only wellness standard must itself meet the requirements for an activity-only wellness program.

59 See also the discussion regarding the EEOC’s January 18, 2013 Information Letter, which suggests that the plan would be obliged to follow the ADA’s reasonable accommodation procedures in such a case.
61 Id., § 54.4980-1(f)(4)(1).
62 Id., § 54.4980-1(f)(4)(2).
The automatic reasonable alternative standard requirement for outcome-based wellness programs follows the same general pattern as for activity-only wellness programs. That is, the exact alternative does not have to be set out in advance, and the input of the participant’s personal physician must be accommodated on the subject of medical appropriateness of the alternative. The regulations describe the alternative developed by accommodating the participant’s physician’s recommendation as a “second reasonable alternative standard.”

The alternative standard offered by the program may be a participatory-program standard, such as attending a class, or it may be a further outcome-based standard, such as a diet or exercise program. The rules regarding these standards apply when offered as an alternative to a participant who has not met the initial outcome-based standard, as if the participatory- or outcome-based standard were the initial standard. In the case of an outcome-based program offered as an alternative to the initial outcome-based standard, the second standard may not offer a different level of the same standard without providing additional time to meet that second standard.

For example, if the initial outcome-based standard is to maintain a BMI of 30 or below, and the participant measures a BMI of 40 on a health screen, the plan may offer, as a reasonable alternative to the initial standard, a requirement to maintain a BMI of some incremental reduction in BMI, to reduce the BMI level by 10%, or to achieve some other reasonable standard. In this case, the plan must allow a reasonable amount of additional time for the participant to meet the incremental alternative standard; the regulations offer an example of one year.

The requirements under the Final ACA Regulations will create new burdens on employers, and, arguably, reduce the effectiveness of wellness programs. For example, under current rules, a wellness program can require a participant to refrain from tobacco use to receive the wellness reward under the program. However, the Final ACA Regulations make it clear that such a program is considered an outcome-based program, and the participant who indicates he or she is a tobacco user on a health risk assessment questionnaire must be automatically offered a reasonable alternative standard (such as participating in a smoking cessation program) which must be arranged and paid for by the plan. A participant may, therefore, indefinitely go through successive tobacco-cessation programs without ever actually being required to cease such use in order to obtain the wellness reward.

The regulations create confusion as to participation-based alternative standards by suggesting that a participation-based standard offered as an alternative to an outcome-based standard will in fact be treated more strictly than an initial participation-based standard. In one example provided in the regulations, a program requires participants to maintain a cholesterol level of 200 or below. If a participant fails a test for the required blood cholesterol level, the plan could allow the participant to work with the participant’s physician to develop a cholesterol treatment plan, including medication and scheduled follow-up physician visits. Arguably, such an alternative would be a participation-based program because it does not require a specified health outcome, nor does it require physical activity such as running or an exercise program. In effect, the alternative in the example would be a disease management program, since it would, under the regulations, have to be paid for by the plan, subject to existing cost-sharing rules. However, the regulations go on to state that the plan must accommodate further changes and suggestions by the participant’s physician as if the alternative were an activity-based or outcome-based program. Thus, the Final ACA Regulations appear to confuse the very concepts and definitions set out in the regulations themselves.

Indeed, the example that follows confirms that a program in which the plan’s medical provider (rather than the participant’s physician) worked out the cholesterol reduction program would not comply with the regulations, and would in fact be in violation of the ACA, if the plan "does not provide an opportunity for the participant’s personal physician to modify the action plan if it is medically inappropriate" or if the plan "does not accommodate the recommendations of the participant’s personal physician with regard to medical appropriateness[]." Thus, the plan must permit the participant’s personal physician to modify the treatment plan at any time.

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68 Note that the alternative standard may be subject to the usual cost-sharing provisions of the plan if it consists of medical treatment. See n. 54, supra.

69 Id., § 54.4980-1(f)(4)(iv)(v)(Ex.6). "The plan cannot cease to provide a reasonable alternative standard merely because the participant did not stop smoking after participating in a smoking cessation program." It is ironic that under this language, a person who previously abstained completely from even occasional tobacco use under pre-ACA wellness programs could start smoking and still receive the wellness reward by resorting to the automatic reasonable alternative standard required by the final regulations.


71 Id., § 54.4980-1(f)(4)(iv)(v)(Ex. 2 and 3. The regulations are silent on the extent to which the treatment or medications recommended by the participant’s physician in his or her action plan must be covered under the plan regardless of the plan’s otherwise applicable terms, nor do the regulations provide any procedure or means of challenging the participant’s
Verification of Need for Alternative Not Permitted for Outcome-Based Standard

The Final ACA Regulations take the position that in the case of an outcome-based program, it is not reasonable to require verification that, due to a medical condition, it would be unreasonably difficult or medically inadvisable for the participant to meet the initial outcome-based standard. However, if the reasonable alternative standard is itself an activity-based program, and the “second reasonable alternative standard” (that is, the standard recommended by the participant’s physician) is an alternative to that program, then the program may seek such verification.

Notice of Availability of Reasonable Alternative Standard

The notice requirement of a reasonable alternative standard for an outcome-based program requires the additional disclosure that, if the participant does not satisfy the initial outcome-based standard, the plan must make available a reasonable alternative standard to qualify for the reward (and, if applicable, the possibility of waiver of the otherwise applicable standard). This notice must include contact information for the plan representative responsible for working out the alternative, and a statement that the recommendations of the participant’s personal physician will be accommodated. Sample language is provided in the regulations that meets this notice requirement stating that the plan materials may “merely mention that such a program is available” without setting out the details of the program.

No Rescission Available For Misstatements Regarding Tobacco Use

In the Preamble to the Final ACA Regulations, the Departments state that an issuer covered by the “fair health insurance premiums” provisions of the ACA may not rescind coverage of a participant who misrepresents his or her tobacco use status on a form required by the wellness program in order to receive the wellness program reward. Generally, the fair health insurance premium requirements apply to insurers providing health coverage in the individual and small group markets. The regulations base this position on the theory that Section 2701 of the PHS Act amended by the ACA provides a right of “recoupment” to a plan in the individual or small group market in the case of a participant who makes a misrepresentation which results in a lowered premium payment, and that this right of recoupment renders any misrepresentation regarding tobacco use “no longer material”. The preamble indicates that the “recoupment” right applies only to health insurance subject to the “fair health insurance premium” requirement, that is, to group insurance in the individual or small group market. It generally does not apply to an insured plan in the large group market or a self-insured group health plan.

Penalties for Violating the ACA/HIPAA Wellness Regulations

Violation of the prohibition against discrimination on the basis of a health factor under a group health plan, now contained in the ACA, HIPAA and the Code, may result in multiple penalties for the plan sponsor.

Excise Tax: The ACA’s market reform provisions, included in its amendments to the PHS Act, were incorporated into the Code through Code Section 9815, which makes the excise tax imposed by Code Section 4980D applicable to violations of part A of title XXVII of the PHS Act, as

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Id., § 54.4980-1(f)(4)(iv). InSight is published by Littler Mendelson in order to review the latest developments in employment law. InSight is designed to provide accurate and informative information and should not be considered legal advice.
amended by the ACA. The excise tax for violations of Code Section 4980D is $100 per day for each individual to whom the violations relate during the "noncompliance period." The noncompliance period begins on the first day of the violation and continues until it is "corrected." For this purpose, "correction" means correcting the violation retroactively to the extent possible, by putting the participant in at least as good a financial position as the participant would have occupied had the violation not occurred.

If a de minimis violation is not corrected before a notice of income tax examination is issued, then a minimum tax of $2,500 applies for each affected individual. If the violation is not de minimis, then the minimum excise tax will be $15,000 per affected individual.

The excise tax may be waived if the IRS determines that the plan sponsor did not know, and in the exercise of reasonable diligence could not have known, of the existence of the violation. Also, the tax will not apply if the violation was due to reasonable cause and not willful neglect (unintentional), and is corrected within 30 days of its discovery.

If the violation is unintentional, the maximum excise tax for the violations will be the lesser of 10% of the employer’s health plan expenditures for the preceding tax year, or $500,000. Note that the effect of the provision is that there is no limit to the amount of excise tax that may be imposed for a violation that is knowing and willful.

In the case of a single-employer plan, the excise tax is payable by the sponsoring employer, and in the case of a multiemployer plan, the excise tax is payable by the plan. Certain small, fully insured plans sponsored by employers with at least two but not more than 50 employees on most business days, are exempt from the tax. Of course, affiliated employers are combined for purposes of this determination.

The ACA added an affirmative reporting obligation in connection with all taxes reportable under Code Section 4980D, which is filed on IRS Form 8928. Therefore, plan sponsors who do not timely file a report of the taxes due may face interest and non-filer penalties in addition to the tax itself. Note that because the excise tax under Code Section 4980D is not reported on the plan sponsor’s regular corporate tax return (or information returns in the case of church or tax exempt organization), the filing of that return does not trigger the running of the statute of limitations for assessment of the Section 4980D excise tax. Therefore, plan sponsors may wish to consider filing a "zero" return on Form 8928 each year. For a taxable corporation, the Form 8928 is generally due at the same time as the plan sponsor’s corporate Federal income tax return.

ERISA Civil Enforcement: In addition, the DOL may enforce the requirements of the ACA through ERISA, in addition to potential civil actions by participants and beneficiaries.

HHS Enforcement for Nonfederal Governmental Plans: Nonfederal governmental plans are subject to HHS penalties that are similar to the excise tax imposed by Code Section 4980D.

**Effective Date**

The Final ACA Regulations will be effective as of the first plan year (or with respect to an insurer, the first policy year) beginning on or after January 1, 2014.

**Conclusion**

The advent of the EEOC’s January 2013 Information Letter and the Final ACA Regulations on nondiscriminatory wellness programs will, once again, require employers to examine carefully their wellness programs and make considered choices in their design and administration. The EEOC Letter in some respects has broader implications than the ACA Regulations. The EEOC appears to be making a broader attack on such programs, and in fact appears to be attempting to expand the ADA’s reach to the administration of such common group health programs as large case management, chronic and serious disease management, and other care and cost management programs. In this scenario, even

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77 Some employers may feel some trepidation at this suggestion, believing that the "zero" return may increase the plan sponsor’s likelihood of being audited by the IRS. This concern is not without foundation, but perhaps employers acting through their trade associations to act in concert in filing such returns each year en masse may help achieve safety in numbers.

78 Instructions to IRS Form 8928.

"benign discrimination" in wellness programs, in which favorable benefits are provided on the basis of the existence of a health factor, are threatened with the imposition of the ADA's "interactive dialogue" toward reaching a "reasonable accommodation" with a health plan participant.

Meanwhile, the EEOC for all intents and purposes appears to pretend that the EEOC's exemption of bona fide employee benefit plans under ADA Sec. 12201(c) simply does not exist, setting up such programs for possible legal disputes.

The Final ACA Regulations also offer new challenges. Health plans will welcome the higher rewards, to 30% from 20% of coverage costs, that may be offered for compliance with activity-only and outcome-based wellness programs, and the increase to 50% of such costs for programs targeting tobacco cessation. On the other hand, despite the claim in the Preamble to the Final ACA Regulations that the new automatic reasonable alternative standard requirement for outcome-based wellness programs will not be caught in a "never-ending cycle of reasonable alternative standards being required to be provided by plans and issuers," the final regulations in fact require exactly that. For example, in the case of an outcome-based wellness program based on tobacco use, the plan must continue to provide a reasonable alternative standard in successive years even if the participant never ceases tobacco use. This cannot be described other than as a never-ending cycle of reasonable alternative standards.

**What Employers Should Do Now**

All employers who sponsor wellness programs should review their programs to address the following issues to come into compliance with the final regulations by the first plan year beginning on or after January 1, 2014:

- Is the wellness program part of a group health plan?
- Does the wellness program condition the wellness reward on meeting a requirement that is related to a health factor?
- Is the wellness requirement an activity-based or outcome-based requirement?
- If outcome-based, is the program prepared to comply with the automatic reasonable alternative standard requirement?

*Russell D. Chapman* is Of Counsel in Littler Mendelson's Dallas office. If you would like further information, please contact your Littler attorney at 1.888.Littler or info@littler.com, or Mr. Chapman at rchapman@littler.com.

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78 FR at 33166.

"The plan cannot cease to provide a reasonable alternative standard merely because the participant did not stop smoking after participating in a smoking cessation program." Treas. Reg. § 54.4980-1 (f)(4)(vi) Ex. 7(ii).