Wellness programs after the Affordable Care Act (Part II)

By Kate Ulrich Saracene and Darcie Falsioni

This alert is the second in a two-part series describing the compliance burdens for employer wellness programs. Part I of the series discussed the new wellness regulations under the Affordable Care Act, which are effective as of the first day of an employer’s plan year in 2014. Part II discusses compliance with the other laws that govern employer wellness programs.

Background

In 2013, the Departments of Treasury, Labor, and Health and Human Services (the “Departments”) finalized the Affordable Care Act (“ACA”) nondiscrimination rules for wellness programs offered in conjunction with Group Health Plans. The Departments noted at that time that the regulations do not address compliance with other laws, including other provisions of the Employee Retirement Income Security Act (“ERISA”), the Americans with Disabilities Act (“ADA”), Title VII of the Civil Rights Act of 1964 (“Title VII”), Internal Revenue Code (“Code”) Section 105(h)’s nondiscrimination provisions, the Genetic Information Nondiscrimination Act of 2008 (“GINA”), the Family and Medical Leave Act (“FMLA”), and state law. Nor did those regulations address implications for wellness programs regarding continuation coverage under the Consolidated Omnibus Budget Reconciliation Act (“COBRA”), privacy rules under the Health Insurance Portability and Accountability Act (“HIPAA”), wage and hour requirements under the Fair Labor Standards Act (“FLSA”), income tax provisions of the Code, or bargaining obligations under the National Labor Relations Act (“NLRA”). This alert explores how those other laws impact wellness programs.

Compliance with Other Laws

While the plan design of a wellness program is generally simple, employer wellness programs are subject to myriad federal laws, and, in some cases, state laws as well, which can make compliance rather difficult. To add to the confusion, the laws that apply to an employer wellness program vary depending on whether or not the wellness program is a “Group Health Plan,” as illustrated in the table below.
<table>
<thead>
<tr>
<th></th>
<th>GROUP HEALTH PLANS</th>
<th>NON-GROUP HEALTH PLANS</th>
</tr>
</thead>
<tbody>
<tr>
<td>ERISA</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>ACA</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>HIPAA</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>COBRA</td>
<td>√**</td>
<td></td>
</tr>
<tr>
<td>ADA</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>GINA</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>FLSA</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>IRC</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>NLRA</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>TITLE VII</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>State Laws</td>
<td>sometimes</td>
<td>√</td>
</tr>
</tbody>
</table>

*Church and governmental Group Health Plans are exempt from ERISA. They are always subject to state law.
**Church plans are also exempt from COBRA.

**Group Health Plan Status and the Employee Retirement Income Security Act (“ERISA”)**

ERISA is the primary law regulating private sector employee benefit plans, and imposes fiduciary and disclosure requirements on employer-sponsored plans. Employee benefit plans sponsored by churches or governmental employers are exempt from ERISA.

The threshold issue to determine whether ERISA (and a number of other federal laws) applies to a wellness program is whether the wellness program rises to the level of a “Group Health Plan.”

ERISA defines a Group Health Plan as “an employer-sponsored welfare benefit plan to the extent that the plan provides medical care (…including items and services paid for as medical care) to employees or their dependents directly or through insurance or otherwise.” “Medical care” includes amounts paid for:

- the diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body;
- amounts paid for transportation primarily for and essential to medical care referred to above; and
- amounts paid for insurance covering medical care described above.

The definition of Group Health Plan under the Code and under the ACA is substantially similar to that under ERISA.
Many common wellness program initiatives will cause a wellness plan to become a Group Health Plan subject to ERISA, including health risk assessments that provide advice and counseling, employer-paid immunizations (e.g., flu shots) and employer-paid biometric screenings (e.g., blood pressure screening, BMI, cholesterol, etc.). In addition, a wellness program can become a Group Health Plan by becoming linked to a Group Health Plan, such as by rewarding employees for participation in a wellness program with a medical plan premium discount, or lower cost-sharing (deductible, coinsurance, co-pays, etc.) under the employer's medical plan.

If a wellness program is a Group Health Plan, then it must comply with ERISA’s requirements, including the plan document, summary plan description, claims procedure and Form 5500 filing requirements. Typically, these requirements can be rather easily satisfied by incorporating the wellness program into an existing plan document for the employer’s medical plan, or by creating a separate plan document for the wellness program that incorporates by reference key provisions from the medical plan.

**Affordable Care Act (“ACA”)**

Under the ACA, Group Health Plans must satisfy certain requirements, such as:

- providing free preventive care for a mandatory list of services (unless the plan is grandfathered);
- providing coverage to qualified individuals participating in clinical trials for life threatening illnesses (unless the plan is grandfathered);
- providing expanded claims and appeals procedures, including the opportunity for third-party external review under certain circumstances (unless the plan is grandfathered);
- providing participants with a Summary of Benefits and Coverage describing the plan; and
- complying with the HIPAA/ACA nondiscrimination requirements and wellness program rules.

Thus, if a wellness program is a Group Health Plan, it is imperative that it be structured to either comply with, or be exempt from, these ACA requirements. Unless the wellness program satisfies the criteria for a grandfathered health plan, it will usually need to be restructured to comply.

It is generally unheard of for an employer to expand the scope of a stand-alone wellness program to include these additional ACA-mandated benefits. While this may be theoretically possible for self-funded medical plans, for employers with insured plans, it will likely be impossible to offer preventive care benefits to all employees without offering the other benefits available under the health insurance policy (although there is a market developing for so-called “skinny plans,” which provide only preventive health benefits, in order for large employers to inexpensively comply with the ACA’s requirements to offer Minimum Essential Coverage to all full-time employees).

Instead, employers generally take one of the two following paths to compliance:

- **Medical Plan Integration.** The first option is to incorporate the wellness program into the employer’s medical plan and to limit participation in the wellness program to those employees who are enrolled in the medical plan. By “integrating” your wellness program with an ACA-compliant medical plan in this manner, the ACA mandates are satisfied because they are provided through the integrated medical plan.

- **Employee Assistance Program (EAP) Integration.** Many employers, however, feel that wellness is a corporate value and are reluctant to limit wellness program participation to those individuals enrolled in the employer’s medical plan. For these employers, the only other option appears to
be to wrap the wellness program into the employer’s Employee Assistance Program (“EAP”).

New guidance issued by the Departments on “excepted benefits” (i.e., those benefit plans that are exempt from certain HIPAA and ACA mandates) provides that EAPs are excepted benefits if, among other things:

— the EAP does not provide “significant benefits in the nature of medical care”;
— the EAP benefits are not “coordinated with” the employer’s health plan (i.e., participants cannot be required to exhaust benefits under the EAP before using benefits under the other group health plan, participant eligibility for benefits under the EAP must not be dependent on participation in another group health plan, and benefits under the EAP must not be financed by another group health plan);
— there are no employee premiums or contributions; and
— there is no cost sharing.

The Departments left open the issue whether common wellness program features provide “significant benefits in the nature of medical care” that would remove wellness programs from the exception. Specifically, the Departments requested comments as to whether “a program that provides no more than 10 outpatient visits for mental health or substance use disorder counseling, an annual wellness checkup, immunizations, and diabetes counseling, with no inpatient care benefits, should be considered to provide significant benefits in the nature of medical care.” Until the Departments form a position, employers are left to use a reasonable, good faith interpretation of whether the benefits are “significant.” Where the employer determines that wellness program benefits are not “significant,” some simple plan documentation can incorporate the wellness program into the EAP to take advantage of its excepted benefit status.

**COBRA Continuation Coverage**

If a wellness program is a Group Health Plan, then COBRA continuation coverage applies. If an employer makes such a wellness program available to all employees regardless of enrollment in the health plan, then COBRA compliance will be a challenge for those employees who are not enrolled in the medical plan. Among other things, the employer must ensure that it sends the initial COBRA notice to all wellness program participants and not just those enrolled in the medical plan. Also, a COBRA election notice must be sent to all wellness program participants upon a “qualifying event” (e.g., termination of employment) to all “qualified beneficiaries” (e.g., eligible employees and eligible dependents”). The employer will need to administer COBRA continuation coverage from 18 to 36 months depending on the qualifying event. One particular challenge for the employer will be determining the “applicable premium” for COBRA. Moreover, if an employer offers immunizations or screenings on its premises (e.g., flu shots or biometric screenings), former employees may have to return to the workplace to receive their COBRA benefits.

**HIPAA Privacy and Security Rule**

A wellness program that is a Group Health Plan is subject to the HIPAA privacy and security rules. Thus, the governing plan document for the wellness program must contain specified HIPAA language, and HIPAA privacy and security policies must be in place. The wellness program must create a “firewall” between employees responsible for wellness program administration and other employer functions, and those employees handling protected health information must receive HIPAA training. Also, plans may be required to have a HIPAA Business Associate Agreement in place with the wellness program provider, and if any protected health information is stored or transmitted electronically in the employer’s computer systems, then the wellness program will also need a HIPAA security policy. Generally, employers whose health plans are fully insured are exempt from these requirements (as the insurer is a covered entity required to comply with
HIPAA), but the addition of a self-funded or self-administered wellness program could expose such employers to these additional HIPAA compliance headaches.

**Americans with Disabilities Act (“ADA”)**

The Americans with Disability Act (ADA) generally prohibits employers from discriminating against qualified individuals with disabilities and requires that such individuals be provided an equal opportunity to participate in, or receive benefits under, programs or activities sponsored by the employer. The ADA also requires employers to provide reasonable accommodations for employees with disabilities.

In the context of wellness programs, the ADA limits the circumstances where an employer may conduct physical examinations (e.g., biometric screenings like blood pressure and cholesterol to determine if an employee achieved a certain health outcome) or make medical inquiries (e.g., questions about current health status as part of a health risk assessment) of employees. Specifically, employers can conduct medical screenings and make inquiries only as part of an employee health program, and only where:

— participation is “voluntary,”
— information is maintained according to the ADA’s confidentiality requirements, and
— the information is not used to discriminate against an employee (e.g., employees with disabilities should not be required to complete additional requirements under a wellness program to receive benefits that are generally available to non-disabled individuals).

The Equal Employment Opportunity Commission (“EEOC”) has taken the position that a wellness program is voluntary “as long as an employer neither requires participation nor penalizes employees who do not participate.” So far, the EEOC has yet to issue regulations further defining “voluntariness,” but some of its opinion letters are informative. For example, in these opinion letters, the agency has indicated that participation in health questionnaires and screenings is not voluntary where it is a prerequisite for participation in an employer’s group health plan or for receiving reimbursements from a medical expense account such as a Health Reimbursement Account. The EEOC indicated these arrangements were problematic because individuals who did not participate would be “denied a benefit.” Thus, we know that participation in a wellness program cannot be a prerequisite for health plan coverage.

However, we do not have clear guidance on what amount of monetary incentive an employer can offer without violating the ADA. In one opinion letter, the EEOC suggested it was adopting the old HIPAA standards for determining whether monetary incentives affected voluntariness (i.e., that a wellness reward of 20% or less of the cost of health plan coverage would be permitted). The EEOC later rescinded that opinion letter, however, on the basis that the person requesting the guidance had not raised the question of what level of financial inducement to participate would be permissible under the ADA. The agency indicated that it was “continuing to examine what level, if any, of financial inducement to participate in a wellness program would be permissible under the ADA.” Subsequently, when specifically asked what level of financial inducement would be permitted, the EEOC stated that it “has not taken a position on whether and to what extent a reward amounts to a requirement to participate, or whether withholding the reward from non-participants constitutes a penalty, thus rendering the program involuntary.”

As a result, it is not entirely clear whether monetary incentives or surcharges are permitted, and there is some risk that offering any type of monetary incentives to participate in a wellness
program will violate the ADA. We think it is more likely, however, that the EEOC will ultimately adopt the standard for health contingent wellness programs described in our prior Part 1 alert, which permits participation incentives that are tied to health plan premiums, so long as the incentive is less than 30% of the applicable premium (or 50% in the case of tobacco cessation programs). That said, although participation-only wellness programs are not subject to the monetary limits on incentives under the wellness program nondiscrimination rules described in our Part I alert, we expect that the EEOC may take the position that employers will nevertheless need to comply with those percentage limits, even for participatory wellness programs, in order to avoid violating the ADA.

Regardless of the amount of the incentive, employers sponsoring a wellness or program should also be mindful of the ADA's reasonable accommodation obligations for employees with disabilities. For example, participation in a 5k run/walk might be difficult due to many disabilities, and disabled employees may need to be offered a reasonable alternative. In addition, if an employer requires employees to attend a class to receive a wellness incentive, the employer should consider whether a mobility-impaired employee can access the facility where the class is taking place. Also, a reasonable alternative standard may be required when an employee's disability prevents them from participating in a class or screening that is held while the employee is on disability leave.

As a result, we suggest adding language to wellness program communications that an employee may contact Human Resources to request a reasonable accommodation if they believe they are unable to fulfill a requirement due to disability. Human Resources can then engage in the ADA interactive process to offer the individual an alternative that they can satisfy, or consider whether to waive the requirement for that individual as a reasonable accommodation.

**Genetic Information Nondiscrimination Act ("GINA")**

GINA prohibits discrimination in employment, or under a Group Health Plan, on the basis of genetic information. GINA defines genetic information very broadly, and includes inquiries regarding family medical history, whether an employee has undergone genetic testing, and/or whether an employee has received genetic services.

Of most relevance for wellness programs, GINA created new requirements for health risk assessments, which are a common component of many wellness programs. Before GINA, many employers solicited family medical history information through a health risk assessment, because it is believed to be a good predictor of an individual’s health risks.

To add a layer of confusion, the rules are different for employers depending on whether the health risk assessment is part of a Group Health Plan, versus when it is offered independently by an employer.

**Requirements for Group Health Plans.**

Title I of GINA generally prohibits Group Health Plans from adjusting premium or contribution amounts on the basis of genetic information; requesting or requiring an individual (or a family member) to undergo genetic testing; or requesting, requiring, or purchasing genetic information for underwriting purposes.

Post-GINA, this means that Group Health Plans cannot request or collect any genetic information where: (1) a reward is offered for completion of a health risk assessment, or (2) where the health
risk assessment is conducted prior to or in connection with enrollment (including open enrollment)—both common features of wellness programs.

The easiest way for a Group Health Plan to comply with GINA is to simply not ask questions about genetics and family history. Thus, a wellness program that is a Group Health Plan could continue offering a reward for completion of a health risk assessment in connection with open enrollment if:

— the health risk assessment is voluntary and includes a disclaimer that it is completely voluntary;
— the health risk assessment does not specifically request or collect any genetic information; and
— if there are any open-ended questions that could invite disclosure of genetic information in response, the health risk assessment includes a disclaimer that employees should not provide any genetic information in their answer. For example, if the health risk assessment includes a question like “Have you had any lab tests this year?” or “Is there any other information about your health that would help us assess your risks?” the questions need to be accompanied by a statement such as “In answering these questions, you should not include any genetic information. That is, please do not include any family medical history or any information related to genetic testing, genetic services, genetic counseling, or genetic diseases for which you believe you may be at risk.”

Alternatively, a Group Health Plan could still request family medical history or other genetic information through a health risk assessment, but only if (1) the health risk assessment is conducted after enrollment has already taken place, (2) participation is voluntary, and (3) no reward is offered for its completion. Group Health Plans should consult with legal counsel before including questions regarding genetic information in a health risk assessment.

Requirements for Employer Programs that are not Group Health Plans.

Title II of GINA regulates employers and prohibits employers from discriminating against employees with respect to compensation, terms, conditions or privileges of employment on the basis of genetic information. Among other things, Title II (1) restricts employers from requesting, requiring, or purchasing genetic information; (2) requires that employers maintain employee genetic information as a confidential medical record; and (3) places strict limits on disclosure.

In many ways, GINA’s requirements for health risk assessments that are not part of a Group Health Plan are actually more complex. For employer health risk assessments that are not part of a Group Health Plan, GINA provides a limited ability to inquire about genetic information, if:

— the employee provides the genetic information voluntarily;
— the individual provides knowing, voluntary and written authorization;
— individually identifiable information is provided only to the individual (or family member receiving the genetic services) and the licensed health care professionals or board-certified genetic counselors providing the services; and
— the individually identifiable information is available only for purposes of the services and is not disclosed to the employer (or other covered entity) except in aggregate terms that do not disclose the identity of specific individuals.

Under the EEOC’s GINA regulations, genetic information is not provided voluntarily if the
individual is required to provide the information or penalized for not providing it. This generally means that employers cannot offer rewards for completing a health risk assessment. However, financial inducements can be offered for completing a health risk assessment that includes information about family medical history or other genetic information if the form:
- states that the inducement is available whether or not the individual answers the questions regarding genetic information,
- is written in a way that the individual is reasonably likely to understand it,
- describes the information that will be obtained and the general purposes for which it will be used, and
- describes the restrictions that will apply to disclosure of the genetic information.

For employers that offer disease management programs, if the employer offers a financial inducement to participate in the program to individuals who voluntarily provided genetic information that indicates an increased risk of developing a health condition, the same financial inducement also must be available to individuals who participate in the disease management program because their current health conditions or “lifestyle choices” put them at increased risk of developing a condition.

**Fair Labor Standards Act (“FLSA”)**
The FLSA is the federal law that, among other things, establishes rules regarding wage payment and overtime pay. Generally, covered, non-exempt employees must be paid for all hours worked at least the federal minimum wage rate and must be paid not less than time and one-half the employee’s regular rate for time worked over 40 hours in a workweek. Although the law is not entirely clear, time spent completing a health risk assessment or other wellness program activity could be regarded as compensable time under the FLSA. We recommend consulting with counsel if your wellness program has requirements that must be fulfilled outside of normal business hours (e.g., doctor visits or classes).

Furthermore, if a wellness program offers a cash incentive rather than a premium reduction, the cash incentive must be included when calculating employees’ “regular rate” for overtime purposes. For example, assume an employee receives $100 for participating in the wellness plan (i.e., essentially a $100 nondiscretionary bonus). If the employee works 2,000 hours during the year, he would be entitled to an additional $.025 per hour for overtime (i.e., \(\frac{100}{2,000}\)*.5) when the $100 reward is included in the regular rate. To avoid difficulties in calculating the regular rate, many employers provide a premium reduction rather than a cash incentive.

**Internal Revenue Code (“Code”)**
Reductions in Group Health Plan premiums, deductible or co-payments for wellness programs subject to ERISA are generally tax-free to employees. Other types of financial inducements typically associated with non-ERISA wellness plans are generally taxable (e.g., cash, gift cards, health club memberships, etc.). As a result, employers that offer financial inducements outside of the Group Health Plan must ensure that they withhold and report income on the incentives. In addition, wellness programs that are self-funded Group Health Plans must be tested to ensure that they not discriminate in favor of highly compensated employees.
National Labor Relations Act (“NLRA”)
The NLRA governs private sector employers’ duty to bargain with a union representing its employees. Unionized employers may have to negotiate with their union regarding introduction or amendment of wellness programs. Wellness programs are generally considered an employee benefit that would be considered a term or condition of employment, and unilateral action could constitute an unfair labor practice.

Title VII of the Civil Rights Act of 1964
Title VII prohibits employment discrimination based on race, color, religion, sex or national origin. Most frequently, employers are at risk for making gender-based distinctions in benefit plan design and should be mindful of these requirements when designing wellness programs.

Employers should also be cognizant of the need to make religious accommodations in certain circumstances. For example, if the wellness program provides a reward for receiving certain immunizations, then an employee with a religious objection to receiving the immunization may need to be provided with an alternative way to receive the same reward.

State Law
If a wellness program is subject to ERISA, then state law is generally preempted if the law “relates to” the terms of the wellness programs. Most, but not all state laws, will be preempted by ERISA. For example, state laws protecting smokers are likely preempted, because they often include specific provisions regarding benefit plans. On the other hand, state laws requiring wage payments are likely not preempted.

If a wellness plan is not subject to ERISA, then state law always applies. For example, government employers and church plans will have to comply with state laws in all instances. Employers should consult with counsel to ensure that their wellness programs do not violate state law.

Conclusion
Wellness programs can be used to make employees aware of health issues that might otherwise go undetected, which might result in significant savings to the employer in terms of lost productivity and the employer’s medical plan in terms of claims avoidance. Although the myriad laws impacting wellness programs may seem overwhelming, it is quite possible to design a compliant and cost-effective wellness program that has the potential for significant benefits to the employee and the employer. However, the significant legal complexity means that most employers will need to consult with experienced employment and benefits counsel to ensure that their wellness program designs and employment practices comply with both the new regulations and all other applicable laws.

For more information on the content of this alert, please contact your regular Nixon Peabody attorney or:

— Brian Kopp at bkopp@nixonpeabody.com or 585-263-1395
— Kate Ulrich Saracene at ksaracene@nixonpeabody.com or 585-263-1438
— Darcie Falsioni at dfalsioni@nixonpeabody.com or 585-263-1688
— Tonie Bitseff at tbitseff@nixonpeabody.com or 415-984-8294