



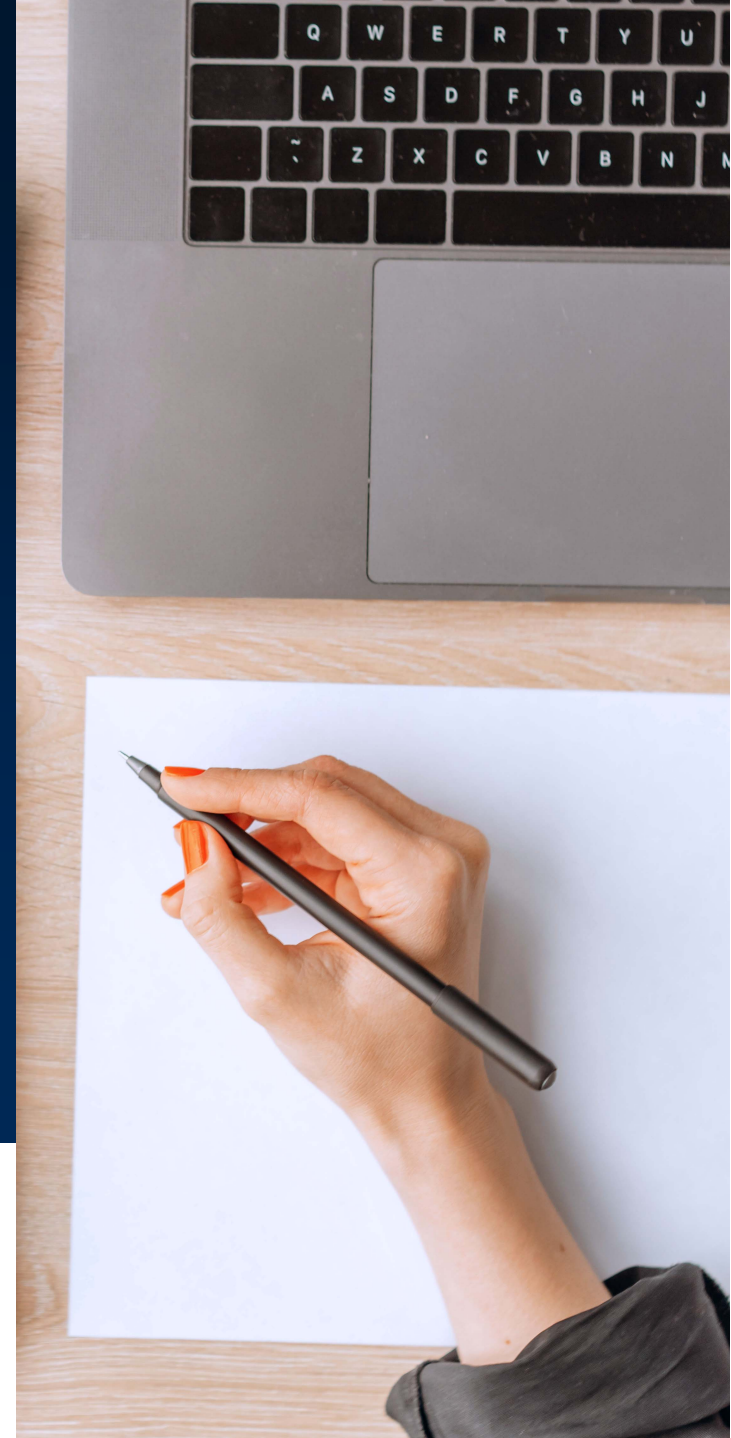
Wellness Programs: Compliance Considerations

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*Presented by the Regulatory and
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Today's Presenters



Christopher Bao
*Vice President,
Regulatory and Legislative Strategy*

Christopher and the Regulatory & Legislative Strategy team support Brown & Brown customers by reviewing and analyzing regulations that govern Employee Health and Welfare Benefit plans. These areas include HIPAA, the Affordable Care Act, ERISA and COBRA.



Kelly Polinski
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Kelly and the Population Health & Well-Being team support customers with strategies that enhance health and well-being. Their work includes analyzing health trends, designing well-being programs, and collaborating with partners to improve outcomes across mental, physical, and social health dimensions.

Presentation Agenda



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Wellness Program Overview

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Applicable Regulations Related to Incentives

- HIPAA
- ADA
- GINA

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Other Regulatory Considerations

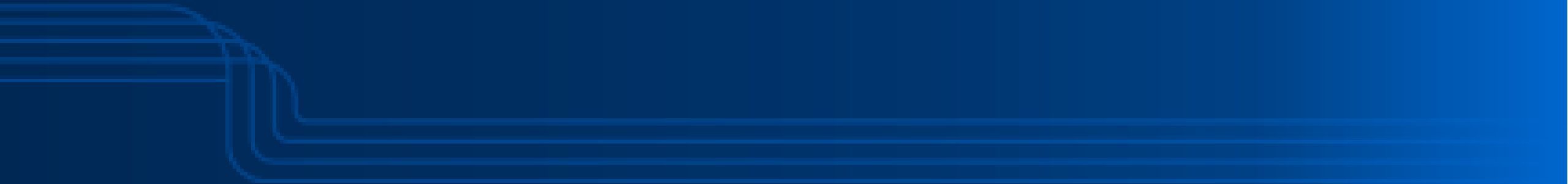
- COBRA
- Affordable Care Act (ACA) and Affordability
- ERISA
- Tax Considerations

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Wellness Program Litigation

01

Wellness Program Overview



Wellness Programs

Part of a Comprehensive Population Health Strategy

- Wellness programs can play an important role in supporting the health and well-being of an employee or member population.
- An effective population health approach is first informed by data analysis and then built using multiple levers, such as:
 - » Access to quality care,
 - » Preventive services,
 - » Chronic condition management,
 - » Mental health support, and
 - » Wellness programs



Generally: Wellness Programs

Definition of a Wellness Program

An employer-sponsored program that seeks to improve and promote health and fitness in the workplace. This typically includes premium discounts, but can also include cash rewards, paid gym memberships or other incentives to participate. Some wellness programs focus on assisting employees in diabetes management, promoting active lifestyles, smoking cessation, weight loss or attending a preventive health screening.

Related to Healthcare

Program focus is on health-based improvement/incentives.

Does Not Apply to Non-Healthcare Related Coverage

Our focus today, although the topic is important, is not oriented around financial well-being.

Related to Group Health Plans

We will be addressing incentives/rewards that are either related to a group health plan or are provided as part of a wellness program that is itself considered a group health plan.

Regulations Surrounding Wellness Programs



HIPAA

Prohibits discrimination among similarly situated individuals based on the presence or absence of a health factor in relation to eligibility, premiums or contributions. There is an exception for voluntary wellness programs that meet specific standards.



ADA

Prohibits employers from making disability-related inquiries or requiring medical examinations of their employees. There is an exception for voluntary wellness programs that maintain information according to confidentiality requirements and do not use the information to discriminate against an employee.

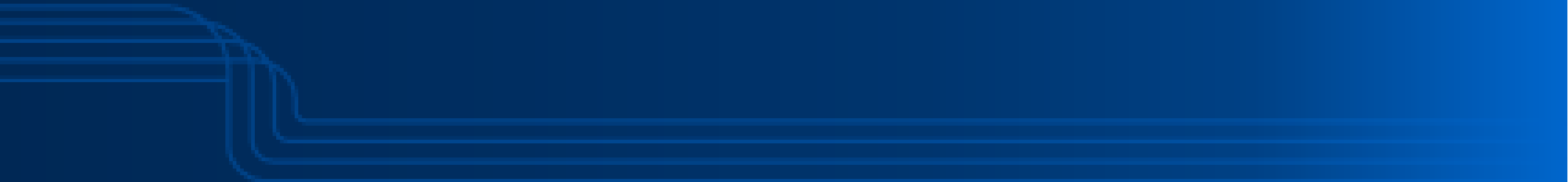


GINA

Prohibits employers from using or requesting genetic information of employees and employees' family members for underwriting purposes, or in the determination of employee contributions towards benefits. There is an exception for voluntary wellness programs that meet specific standards.

02

HIPAA & Wellness Programs



HIPAA: Wellness Programs



Not a Group Health Plan

Rewards not related to, or a part of, the group health plan.



Group Health Plan

- Affects healthcare premiums
- Is part of the group health plan
- Is itself a group health plan



It is also important because whether the wellness program is considered a “group health plan” determines if the plan is also subject to ERISA, COBRA and potentially other applicable laws.

Wellness Program Types Under HIPAA



Participatory

- A program that either does not provide an incentive; or
- Provides an incentive but the conditions to obtain the reward are not based on a health factor.



Health-Contingent

- A program that provides an incentive based on a health factor
- Two kinds of Health-Contingent Programs
 - **Activity-Based** – The reward is contingent on the completion of an activity
 - **Outcomes-Based** – The reward is contingent on a health outcome

HIPAA: Wellness Program Incentives/Surcharges



Reward/Incentive

- Providing a “benefit” to employees for participating/satisfying goal.



Surcharge

- A penalty for engaging in certain behaviors/having certain health outcomes.



While we will be using the term “rewards/incentives” for the remaining part of the presentation, the terms “reward” and “surcharge” can be used interchangeably.

Rewards can be provided in many forms, but the most common are a reduction to employee premium contributions or employer contributions to an HRA/HSA.

HIPAA: Participatory Wellness Incentives

Definition and Examples

Incentive/non-incentive only based upon participation in the wellness program, not related to a health factor and program is offered to all similarly situated individuals.

Examples of Participatory Wellness Programs

- Educational Seminars
- Gym Membership
- Tobacco Cessation Education
- Diagnostic Testing (without specific health standards)

Rewards and Incentives

A wellness program that only offers a reward/incentive for employees (and any family members) to participate in the program and does not require any health contingent goals to be met have the following reward/incentive limits:

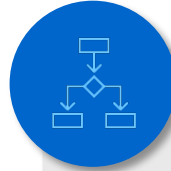
- **NO INCENTIVE LIMITS**

HIPAA: Health-Contingent Programs



Activity-Based

- Exercise/Diet Programs without required outcomes
- Flu Shots/Immunizations



Outcomes-Based

- Exercise/Diet Programs with required outcomes
- Tobacco free status (employee affidavit or with testing)
- Diagnostic Testing (with goals)



If rewards are based upon a health factor, HIPAA imposes certain standards on the wellness program for it to remain a “voluntary” and compliant wellness program under the HIPAA rules.

HIPAA: Health-Contingent Wellness Program Rules

Reasonably Designed

- Must be reasonably designed to promote health or prevent disease
- Has a reasonable chance at improving health/preventing disease
- Not overly burdensome
- Is not a disguised effort at discriminating against employees based upon a health factor
- The methods chosen to promote health/prevent disease are not highly suspect

Uniform Availability

- The full reward (100% of the reward) must be available to similarly situated participants (applies to both participatory and health-contingent wellness programs) regardless of date of completion

Frequency of Reward

- Eligible individuals must be able to qualify for the reward at least once per year

HIPAA: Health-Contingent Wellness Programs

Reasonable Alternative Standard (RAS)

Must be offered to those that are unable to satisfy the conditions of the Health-Contingent Wellness Program, and different than the ADA requirement of “reasonable accommodation” based upon disability.

Activity-Only Wellness Programs

- Must be provided to any individual where:
 - » It is unreasonably difficult due to a medical condition to participate in the activity; or
 - » It is medically inadvisable to attempt to participate in the activity.
- Health plan may seek verification of medical condition (e.g., doctor’s statement)

Outcomes-Based Wellness Programs

- Must be offered to all individuals, and cannot take into consideration medical condition
 - » Health plan cannot request verification (e.g., cannot request doctor’s statement)

HIPAA: Health-Contingent Programs



Non-Tobacco Related Incentive

- Up to 30% of the total premium cost of coverage for the “benefit package” available to those eligible for the wellness program.



Tobacco-Related Incentive

- Up to a total of 50% (all incentives combined) of the total premium cost of coverage for the “benefit package” available to those eligible.



Reward thresholds are based upon who is eligible to receive the wellness reward (employee only or employee and family members) and the total combined cost of coverage paid by both the employer and employee for the benefit plan they are enrolled in.

Caution: Integrated HRA.

HIPAA: Health-Contingent Programs



If the plan is subject to ERISA

- If the health plan is subject to ERISA and the wellness plan is considered a group health plan under ERISA, the wellness program is subject to ERISA and therefore those requirements would need to be met



Health-Contingent Wellness Programs

- Information about the availability of a RAS is required in all plan materials that describe the terms of the health-contingent wellness program
 - » Notice must include contact information for obtaining the RAS
 - » Recommendations of an individual's personal physician will be accommodated
- Notice of RAS is not required if plan materials limit information to mentioning a wellness program, in general, is available (and no other description of wellness program terms)

Extreme Weight-Loss Challenge



Program Design

HR rolls out a “Biggest Loser”-style challenge where employees must lose 10% of their body weight in 12 weeks to earn a cash reward.



What Went Wrong?

- Rapid weight loss targets can be unsafe
- The approach is suspect from a medical perspective
- It may encourage unhealthy behaviors rather than prevent disease



Why is This Risky?

- HIPAA requires programs to have a reasonable chance of improving health, not creating medical risk or incentivizing unsafe practices.

The Early Bird Bonus



Program Design

Employees who complete a biometric screening get a medical plan premium discount.

Those who do so by March receive the full \$500 discount.

Anyone who completes it later in the year only receives a \$250 discount.



What Went Wrong?

- Similarly situated employees receive different rewards
- Timing of when screening is completed determines reward value



Why is This Risky?

- HIPAA requires the full reward be available to all similarly situated individuals, regardless of when they complete the activity.

The Tobacco 'Wellness' Program



Program Design

An employer wellness program includes a tobacco surcharge but does not offer an alternative standard, coaching option, or cessation support.



What Went Wrong?

- The program penalizes a health status
- There's no meaningful path for employees to qualify for the reward

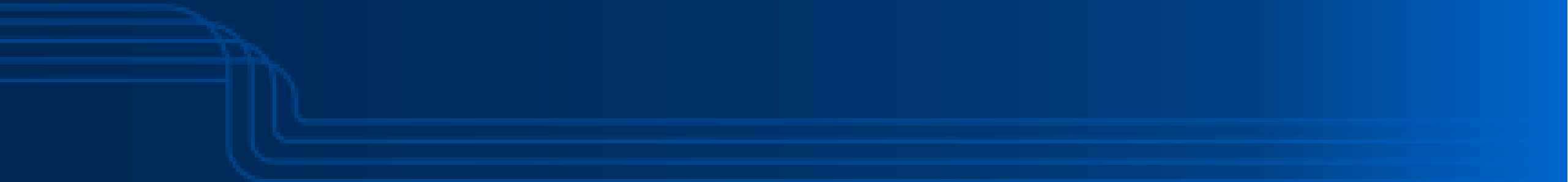


Why is This Risky?

- This looks like a disguised attempt to discriminate based on a health factor, which HIPAA explicitly prohibits.
- Does not offer a reasonable alternative standard as required under HIPAA.

02

ADA & GINA



ADA and GINA: Wellness Incentive Limits



Incentive Regulations Vacated

- Court found that EEOC wellness regulation rules could be “coercive” under the ADA/GINA rules. EEOC has not yet adopted final rules for a “voluntary” wellness program.



Class Action

- Class action lawsuit against an employer that imposed a \$25 per week (\$1,300 per year) penalty for employees who did not participate in wellness program. Significant settlement (excess of \$1M for employees).



Current Rules: Plan Sponsors should consider offering “de minimis” rewards/incentives for those activities/programs that may implicate ADA or GINA. If the reward is more than a “de minimis” amount, they could offer a separate health-contingent wellness incentive for a separate activity/program that is solely subject to the HIPAA rules. However, the sum of all rewards, including “de minimus” incentives, cannot exceed 30% of the cost of coverage (or 50% or less for tobacco-related incentives) under the HIPAA wellness program rules.

ADA: Wellness Programs



Subject to the ADA

Wellness program that includes a disability inquiry or medical examination.

Disability Inquiry

Question(s) that are likely to elicit information about a disability.

Medical Examination

A procedure/test that seeks information about an individual's physical/mental impairment/health.

ADA: Wellness Programs

ADA: Wellness Program Must Be Voluntary

Elements of a voluntary wellness program:

- Employees cannot be required to participate
- Employers cannot take any adverse employment action/retaliate against, interfere with, coerce, intimidate or threaten employees
- Employers must provide to employees a prescribed notice provided by the EEOC:
 - » <https://www.eeoc.gov/regulations/sample-notice-employer-sponsored-wellness-programs>
 - » Employees must receive notice prior to providing health information, and within enough time to properly decide whether they want to participate in the wellness program



ADA: Wellness Programs

Additional requirements for wellness programs under the ADA:

- **Reasonably Designed** – Must be designed to promote health or prevent disease
- **Reward/Incentive** – Unclear at this time (de minimis standard)
- **Reasonable Accommodation** – Although the EEOC has not adopted a requirement for a RAS, a reasonable accommodation must be provided to all employees with a disability so that they are offered the same benefits and privileges provided to employees without a disability
- **Gatekeeping Prohibited** – Cannot require participation as condition for eligibility under the group health plan

ADA: Wellness Programs

Examples of ADA Wellness Programs

The following examinations/inquiries are examples of wellness programs that could implicate application of the ADA rules:

- Health Risk Assessment (HRA)
- Blood pressure screening
- Testing for tobacco as part of a tobacco cessation program
- Range-of-motion tests for muscle strength and motor function
- Medical exams measuring heart rate or blood pressure
- Asking an employee whether they have (or ever had) a disability, how they became disabled or the severity of an employee's disability
- Asking for information related to an employee's disability

It's Voluntary... Except.... not



The Story

- A 3,000-employee manufacturer launches new wellness program to reduce healthcare costs with a Health Assessment + on-site biometric screening required
- \$1,200 premium discount for completion; higher premiums for non-participants
- Program labeled “voluntary,” but reinforced through manager follow-ups
- Some employees request opt-outs but are hit with higher premiums



What Went Wrong

- The financial difference is large enough to be considered coercive
- Employees are effectively forced to disclose disability-related information
- Managers are pulled into enforcement, blurring privacy lines
- There is no meaningful accommodation process



Why This Creates ADA Exposure

- Under the ADA, wellness programs that collect medical information must be voluntary.
- When declining participation results in significant financial consequences, the program crosses the line into coercion.

GINA: Wellness Programs



Subject to GINA

If a group health plan or employer requests information that is related to an employee's (or family member's) medical history or genetic information.

Title I

Group health plans are prohibited from collecting genetic information (e.g., family medical history) for underwriting purposes.

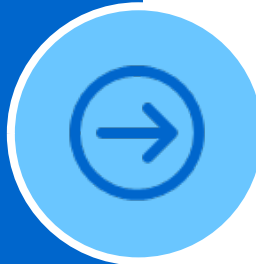
Title II

Genetic information or medical information can be requested, so long as it is "voluntary".

GINA: What Is Genetic Information?

Genetic Information:

- Information about the individual's genetic tests;
- The genetic tests of the individual's family member/spouse;
- The manifestation of disease or disorder in the individual's family member/spouse; and
- The individual's/spouse's request for genetic research, counseling and education.



Genetic Test:

- A test involving analysis of human DNA, RNA, chromosomes or metabolites that detect genotypes, mutations and chromosomal changes

GINA: Wellness Programs

Examples of GINA Wellness Programs:

- Analysis of human DNA, RNA, chromosomes; or
- Metabolites that detect genotypes, mutations and chromosomal changes
- Requests for individual's family medical history or spouse's medical history



Not Considered GINA Information:

- Body mass index
- Blood pressure
- Cholesterol
- Age
- Sex
- Tobacco use

GINA: Wellness Programs

Wellness programs require separate analysis under both GINA Title I and GINA Title II.

- GINA Title I Wellness Programs – Applies to GHPs or wellness programs that are part of a GHP
 - » “Underwriting purposes” includes eligibility for the plan and determination of/contribution towards premium
 - **Caution:** Health Assessments (HAs) that contain requests for family medical history or genetic information
 - Employees should not complete the HA prior to (or in connection with) enrollment in the health plan
 - No HA-based incentives, or tie incentives to an HA that does not request info related to GINA



GINA: Wellness Programs

- GINA Title II Wellness Programs – Only apply if the wellness program is not a GHP or is not part of a GHP
 - » Wellness program can request medical/GINA information, so long as it is “voluntary”
 - Reasonably Designed – Must be designed to promote health or prevent disease, and not highly suspect
 - Not Overly Burdensome
 - Non-Discriminatory – Is not a disguised effort to discriminate against employees for employment purposes based on GINA information
 - Authorization – Employer receives prior knowing/voluntary authorization
 - Non-Disclosure to Employer – The GINA information is not shared with anyone in the workplace, including those that make employment decisions (aggregate reporting is acceptable)
 - Reward/Incentive – **Amount of incentive/reward is unclear at this time (de minimis standard)**
 - If HRA that includes GINA questions, must provide language reasonably likely to be understood by individuals prior to taking the HRA that the reward/incentive is being presented to individuals regardless of whether they complete GINA questions
 - An employer may offer reward/incentive for genetic information of employee/spouse, but not of an employee’s child
 - Gatekeeping Prohibited – Cannot require participation as condition for eligibility under the GHP

Cancer Risk Survey



Program Design

An employer with high cancer claims costs launches a wellness initiative focused on cancer risk identification.

Employees can earn a \$750 premium discount for completing an online Cancer Risk Assessment.

The assessment includes questions such as:

- “Did either of your parents have cancer before age 50?”
- “Does cancer run in your family?”



What Went Wrong?

- Family cancer history is genetic information under GINA
- Employers cannot request or incentivize disclosure of genetic information
- The financial incentive makes the disclosure non-voluntary

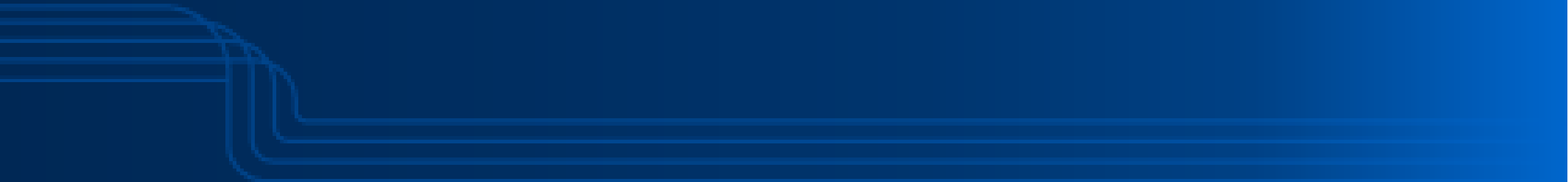


Why is This Risky?

- GINA is designed to prevent employers from identifying genetic cancer risk, even indirectly. Asking these questions crosses the line.

03

Other Regulatory Considerations



Wellness Programs: Family Member Incentives



Incentive for One Person

- Incentives may be provided separately for each member participating in the wellness program (e.g., one reward for employee participation in the wellness program, and a separate reward provided for a spouse's participation in the wellness program)



One or More Incentives Requiring Multiple Persons to Complete Wellness Program to Receive Reward

- A program that may only provide rewards/incentives if the employee **and** a family member complete a wellness activity/program, but no reward if only one person completes the activity or program, could be problematic
- Issues
 - » **Reasonably Designed** – Would it be reasonably designed to promote health/prevent disease if the reward is contingent upon completion by an employee's family member(s)?
 - » **Discrimination Based on Family Status** – Different treatment based upon family status?

ACA: Affordability of the Coverage

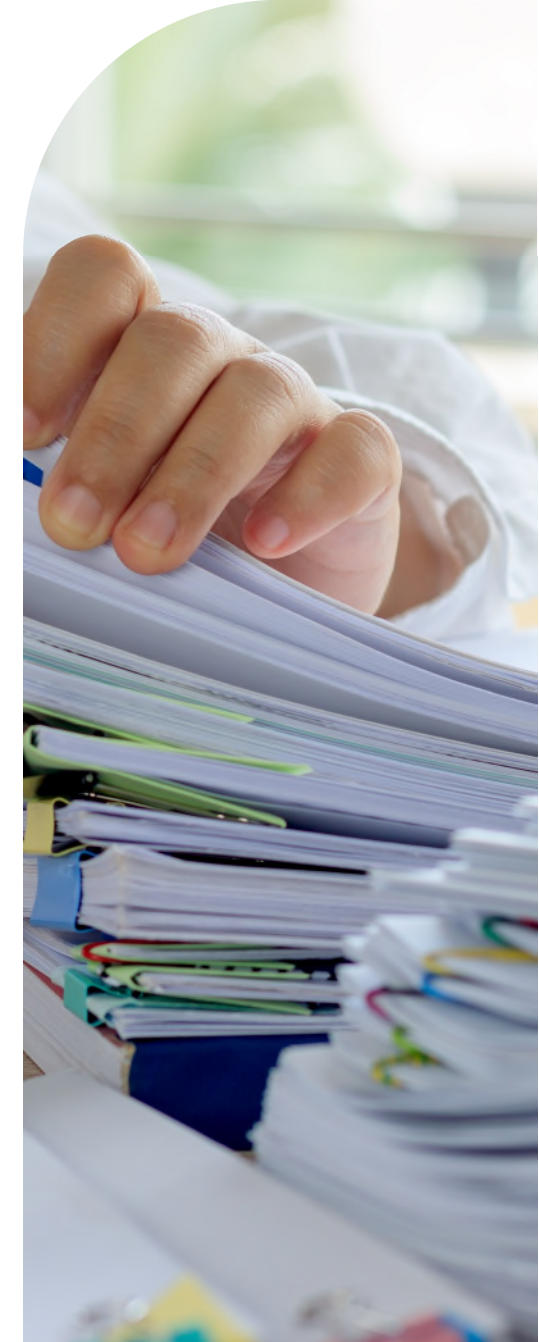
ACA: Coverage Affordability and Penalties

- If a plan is not considered “affordable” to a FT employee, the employer could be subject to penalties for failure to offer an affordable plan to an employee that purchases coverage in the Marketplace/Exchange and receives a premium tax credit

Wellness Program Incentives and Coverage Affordability Under the ACA

- A wellness program offering premium contribution incentives should ensure that the plan would be considered affordable under the ACA

Category	ACA Affordability Assumption	Program Example	Monthly Contribution Used for ACA Affordability Calculation
Non-Tobacco Related Premium Incentives (i.e., Wellness Incentive)	Employer must assume employees did not earn the wellness incentive	Employee-only monthly contribution is \$200, but employees who complete wellness requirements receive a \$50/month reduction	\$200
Tobacco-Related Premium Incentives	Employer must assume all employees are tobacco free	Employee-only monthly contribution is \$200, but employees who are tobacco free receive a \$50/month reduction	\$150



IRS: Taxability of Wellness Incentives

IRS: If Rewards/Incentives are Used Towards Healthcare

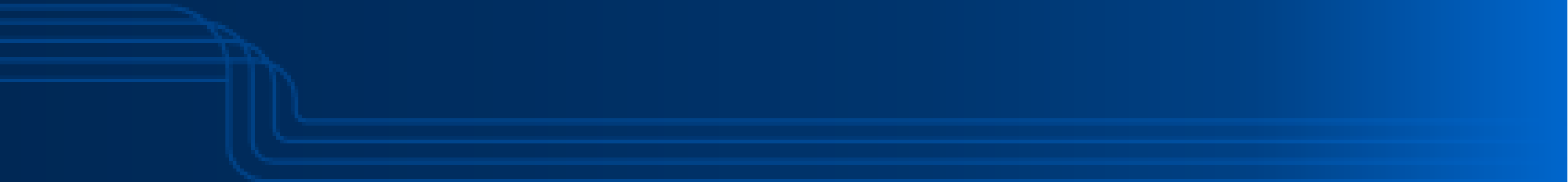
- If a plan contributes to an HSA, HRA or FSA or reimburses any healthcare-related out-of-pocket expenses, most likely these amounts can be provided to the participant without imputing income to the employee/participant

Wellness Program Incentives that are in the Form of Cash/Items

- A wellness program that offers cash or “cash-equivalent” rewards/incentives would be taxable to the employee/participant
 - » There is no “de minimis” exception to cash rewards/incentives (e.g., \$5 gift card must be imputed as income to the employee)
- Items
 - » **De minimis Items** – “de minimis” prize items are not taxable to participants (e.g., t-shirt that has a value of \$10 or less)
 - » **Non-de minimis Items** – An employer must impute income to the employee for any items that are not considered “de minimis” to the employee (e.g., iPad)

04

Wellness Program Litigation



Wellness Program Class Action Lawsuit

VOLUNTARY PROGRAMS?

Wellness Program Design

- Medical plan premium discount for taking a biometric test and meeting other health related criteria such as blood sugar, blood pressure, and cholesterol.
- Employees who participated in the wellness program automatically received a discount.
- Employees who did not elect to participate in the biometric screening received a premium increase of ~\$34 per week following the grace period.

Lawsuit Claim

- **Class action suit claimed the wellness program was not voluntary under the ADA rules.**
- While the employer filed a motion to dismiss the case, the court did not allow.
- The case has not yet been resolved.

Findings

- The court found that because there was a medical examination involved (i.e., biometric test) that the ADA rules applied. Due to ambiguity in the EEOC rule on what constitutes a “voluntary” wellness program under the ADA, the plaintiff’s claims had some merit, and a judge or jury needed to determine whether the program was voluntary.

Employer Takeaways

- If an employer requests or requires genetic information as part of a wellness program, the employer must receive knowing and voluntary written authorization from an individual before acquiring this information.
- When offering incentives for participation in wellness programs that could be subject to ADA, due to disability-related inquires or medical exams, or GINA should review the structure of these programs with their legal counsel.

Wellness Program Class Action Lawsuit

REASONABLE ALTERNATIVE STANDARD

Wellness Program Class Action Lawsuit

- An employer implemented a tobacco surcharge where employees using tobacco were required to pay an additional \$30 in premium per pay period (\$780 per year) for the employer's medical plan.
- The program did not include a reasonable alternative standard (e.g. tobacco cessation program) that would allow an employee to avoid the surcharge.

Lawsuit Claim

- The case alleges that the tobacco surcharge violates Employee Retirement Income Security Act (ERISA) regulations that prohibit employers from discriminating against plan participants that have health status related factors.

Findings

- The class action suit explains that the company should offer a reasonable alternative standard (such as a smoking cessation program) that would allow employee to avoid the entire fee upon completion of the program, to be compliant with ERISA.

Employer Takeaways

- Employers offering an outcomes based, health-contingent wellness program need to ensure that there is a reasonable alternative standard available to participants.
- Information about the availability of a RAS is required in all plan materials that describe the terms of such wellness program

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