IMPLEMENTING A COMPLIANT WELLNESS PROGRAM
AGENDA

- Overview of wellness programs
- Compliance with HIPAA and new Affordable Care Act requirements
  - Participatory v. health contingent programs
  - Reasonable alternative standards
- Compliance with other applicable laws (GINA, ADA, etc.)
- Penalties for non-compliance
OVERVIEW

- What is a wellness program?
  - No specific definition; come in all shapes and sizes
    - Educational seminars
    - Health club membership reimbursement
    - Office weight-loss “competitions”
    - Health questionnaires and/or biometric screenings
    - Disease management programs
    - Annual physical requirements
      - Many are offered in connection with a group health plan
      - May include incentives for participation
  
- Why offer a wellness program?
OVERVIEW

- General Rule: HIPAA Nondiscrimination rules prohibit discrimination based on health factors, except in two circumstances:
  - the discrimination is in favor of an individual with adverse health status
  - the wellness program meets the five requirements under the HIPAA wellness rules

- New final HIPAA wellness program rules effective 1/1/14 incorporate changes mandated by the Affordable Care Act

- Beyond HIPAA…many laws impact the design and management of a wellness program
TYPES OF WELLNESS PROGRAMS

Non-Health Plan Related

- Educational
- Participatory (i.e. no reward or reward not related to health plan)

Health Plan Related

- Health Contingent
  - Participatory (e.g. reward not tied to result)
  - Activity Based
  - Outcome Based
PARTICIPATORY V. HEALTH CONTINGENT PROGRAMS

Participatory Program:

- Reward not based on satisfying a health standard
- Key Test: Can an individual with a health condition be precluded from participating in the program?
- Not required to satisfy the HIPAA wellness program rules – but other laws may apply
- Must be available to all similarly situated individuals regardless of health status
- Examples:
  - Reimburse fitness center membership costs
  - Reward to participate in diagnostic testing, not based on outcomes
  - Reward for smoking cessation program, regardless of whether quit
  - Reward for attending no-cost health education seminar(s)
  - Reward to complete health risk assessments without further action required
PARTICIPATORY V. HEALTH CONTINGENT PROGRAMS

Health-Contingent Program:

- Requires an individual to satisfy a standard related to a health factor in order to obtain a reward
- Must comply with the HIPAA wellness program rules
- Affordable Care Act introduced two new subcategories of health-contingent wellness programs:
  - Activity-Based
  - Outcome-Based
PARTICIPATORY V. HEALTH CONTINGENT PROGRAMS

Activity-Based:

- Requires an individual to perform or complete an activity based on a health factor to obtain reward, but does not require an individual to attain or maintain a specific health outcome

- Examples:
  - Walking, diet or exercise programs where some individuals may be unable to or have difficulty participating due to a health factor such as asthma, pregnancy, recent surgery, etc.

- Note: Prior to new rules these types of programs were often considered to be participatory but now will be subject to the HIPAA wellness rules!

- Must provide a reasonable alternative for anyone for whom it is medically inadvisable to participate
PARTICIPATORY V. HEALTH CONTINGENT PROGRAMS

Outcome-Based:

- Requires an individual to attain or maintain a specific health outcome in order to obtain reward

- Examples:
  - Reward for not smoking
  - Reward for attaining certain results on biometric screening
  - Reward for favorable BMI, cholesterol levels, blood pressure, etc. while requiring those outside a healthy range to meet with a health coach to earn the reward

- Must provide a reasonable alternative for all individuals who don’t meet initial standard
HIPAA WELLNESS PLAN RULES

Five Requirements:
1. Annual Qualification: Must give individuals the opportunity to qualify for the reward at least once per year (same for activity and outcome based programs)

2. Limit on Amount of Reward: Reward for all health-contingent programs with respect to an individual may not exceed 30% of the cost for employee-only coverage under the plan (same for activity and outcome based programs)
   - Based on total costs (including employer and employee premium share)
   - If spouses and/or dependents may participate in wellness program, then based on total cost of coverage in which spouse and/or dependents are enrolled
   - Reward can be up to 50% for smoking cessation programs
   - “Reward” is defined to include both obtaining a reward (e.g. premium discount) or avoiding a penalty (e.g. absence of a premium surcharge)
   - Examples: 30% for BMI + 20% for tobacco use = permissible; 30% for BMI + 50% for tobacco use = not permissible
HIPAA WELLNESS PLAN RULES

3. Reasonable Design: Wellness program must be reasonably designed to promote health or prevent disease

   — Must have a “reasonable chance” of improving health or preventing disease

   — Must not be overly burdensome

   — Must not be subterfuge for discriminating based on a health factor

   — Must not be highly suspect in the method chosen to promote health or prevent disease

   — Determination based on all relevant facts and circumstances – using evidence-based clinical guidelines are encouraged as “best practices”
HIPAA WELLNESS PLAN RULES

4. Uniform Availability and Reasonable Alternative Standard: Wellness programs must provide reasonable alternatives to obtaining rewards
   — Reward must be available to all similarly situated employees – accomplished by providing a “reasonable alternative standard”
   — Different requirements for activity-based and outcome-based programs
   — More on this in a moment….

5. Notice of Availability of Reasonable Alternative Standard: Must disclose availability of reasonable alternative standard in all plan materials describing the wellness program
   — Must include contact information for obtaining reasonable alternative standard
   — Must include statement that the recommendations of an individual’s physician will be accommodated
   — For outcome-based programs, notice must also be included in any disclosure that an individual did not satisfy an initial outcome-based standard
HIPAA WELLNESS PLAN RULES

Model Language for Notice of Availability:

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

Activity-Based Programs:

- Plan must provide a reasonable alternative standard (1) if it is medically inadvisable for the individual to attempt to satisfy the plan standard; or (2) if it is unreasonably difficult due to a medical condition for the individual to obtain the reward

- Not required to determine the alternative standard in advance of a request

- May decide to waive the medical standard altogether (rather than determine alternative)

- If reasonable under the circumstances the plan may require physician verification that alternative standard is needed

- Reasonable alternative standard may be participation-only, activity-only or outcome-based
REASONABLE ALTERNATIVE STANDARDS

Activity-Based Programs (continued):

- Whether reasonable alternative standard is “reasonable” is based on facts and circumstances including:
  - Whether required time commitment is reasonable
  - If includes an education program, must make program available or assist individual in finding such program and may not require individual to bear the cost of the program
  - If includes a diet program, must pay the cost of membership or participation fee (but not food)
  - If physician states a plan standard is not medically appropriate must provide an alternative standard that accommodates the physician’s recommendations
REASONABLE ALTERNATIVE STANDARDS

Outcome-Based Programs:

- Must provide a reasonable alternative standard for any individual who does not meet the initial standard based on a measurement, test, or screening that is related to a health factor

- Required **regardless of medical condition**!

- Cannot require physician verification

- Not required to determine the reasonable alternative standard in advance of request

- Reasonable alternative standard may be participation-only, activity-only or outcome-based

- Same “reasonableness” criteria as required for activity-based programs
REASONABLE ALTERNATIVE STANDARDS

Outcome-Based Programs (continued):

- If the reasonable alternative standard is an outcome-based program:
  - It must also comply with the rules for outcome-based programs the same as if it were the initial plan standard (e.g. the plan must provide a reasonable alternative to the reasonable alternative for anyone who fails the alternative standard!)
    - In order to prevent never-ending cycle of alternative standards, when the alternative is another outcome-based standard, the individual can request to just follow his/her doctor’s orders to satisfy the alternative and earn the reward
  - Cannot be a requirement to meet a different level of the same standard without additional time to comply and that take into account individual’s circumstances (e.g. if initial standard is a BMI < 30, the program cannot then require individual to achieve a BMI < 31 on the same date, but could have a small amount or percentage reduction over a realistic period of time)
REASONABLE ALTERNATIVE STANDARDS

- Rules for timing and payment of reward:
  - Must provide availability of reasonable alternative standard throughout the year
  - Individuals must be able to earn the same, full reward as those who met the initial standard, even if it takes more time – this may result in retroactive payment of rewards
  - Example: If a calendar year plan offers a health-contingent wellness program with a monthly premium discount and an individual who qualifies for a reasonable alternative standard satisfies that alternative on April 1st, the plan must provide the premium discounts retroactively for January – March to that individual
  - Plan has discretion on providing the reward (retroactive payments, pro rata payments for remainder of the year, within a “reasonable time” after end of plan year, etc.)
AMERICANS WITH DISABILITIES ACT (ADA)

- Employers cannot deny, on the basis of a disability, qualified individuals an equal opportunity to participate in, or receive benefits under, employer programs

- Generally prohibits employers from making medical inquiries or requiring medical examinations unless
  - Job-related and consistent with business necessity
  - Voluntary and part of an employee health program

- ADA applies to all wellness programs that include disability related questions or require participants to undergo medical examinations
AMERICANS WITH DISABILITIES ACT (ADA)

- Final regulations published May 16, 2016, effective for plan years beginning on or after January 1, 2017
  - Seeks to harmonize HIPAA and ACA rules with ADA requirements that medical inquiries or medical examinations must be voluntary
  - Explain what an employee health program is
  - Define what it means for an employee health program to be voluntary
  - Clarify that employer may offer limited incentives as part of a wellness program
AMERICANS WITH DISABILITIES ACT (ADA)

- Employee health program - programs must be reasonably designed to promote health or prevent disease
  - Reasonable chance of improving health or preventing disease
  - Programs can’t be overly burdensome or highly suspect in its method
# AMERICANS WITH DISABILITIES ACT (ADA)

<table>
<thead>
<tr>
<th>Reasonably Designed</th>
<th>Not Reasonably Designed</th>
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<tbody>
<tr>
<td>Conduct a health risk assessment or biometric screening for the purpose of alerting employees to health risks</td>
<td>Collect medical information on a health questionnaire without providing follow-up information or advice</td>
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<td>Use aggregate information from health risk assessment to design and offer health programs aimed at specific conditions that are prevalent in workforce</td>
<td>Establish a program where the main purpose is to shift costs from the employer to targeted employees based on their health</td>
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<td>Impose overly burdensome time for participation, require unreasonably intrusive procedures or place significant costs on employees</td>
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AMERICANS WITH DISABILITIES ACT (ADA)

- Voluntariness:
  - May not require employees to participate
  - May not deny health coverage for non-participation
  - May not limit health coverage or benefits for non-participation except as specifically allowed
  - May not take any other adverse action or retaliate against, interfere with, coerce, intimidate or threaten employees
AMERICANS WITH DISABILITIES ACT (ADA)

- Other requirements:
  - Employers must provide notice explaining what medical information will be obtained, how it will be used, who will receive it and how it will be kept confidential
  - Programs may offer incentives of up to 30 percent of cost of employee-only coverage
  - Programs must include reasonable accommodations
  - Employers may only receive information in aggregate format
AMERICANS WITH DISABILITIES ACT (ADA)

- Case law
  - Some cases at odds with EEOC guidance, relying on another provision under the ADA that permits employers to establish and administer the terms of a bona fide benefit plan that is based on underwriting risks, classifying risks or administering such risks
COMPLIANCE WITH OTHER LAWS…

- Genetic Information Nondiscrimination Act (GINA)
  - Title 1 bars the use of genetic information for group health plan underwriting purposes
  - Prohibits collecting genetic information for underwriting purposes or prior to or in connection with enrollment
  - “Underwriting” broadly defined to include rules for eligibility for benefits and determining premium or contribution amounts
  - “Genetic information” includes family medical history
  - Wellness programs providing rewards for completing health risk assessments should not request genetic information prior to or in connection with enrollment in the group health plan
COMPLIANCE WITH OTHER LAWS…

- Genetic Information Nondiscrimination Act (GINA)
  - Title II bars the use of genetic information for employment purposes; prohibits employers from requesting or requiring genetic information
  - Exception permits employer that offers health services as part of a voluntary wellness program to request genetic information if certain requirements are met
  - Program must be reasonably designed to promote health or prevent disease (similar to ADA requirement) and voluntary
  - Final regulations issued May 16, 2016 clarify that can offer incentive as part of health risk assessment for questions related to spouse’s past or current health status; limited to 30% of cost of employee only coverage
COMPLIANCE WITH OTHER LAWS...

- **Internal Revenue Code**
  - Cash or cash-equivalent rewards (e.g. gift cards) would be includable in an employee’s taxable income

- **ERISA**
  - Is program an employer sponsored welfare benefit plan providing medical benefits?
  - ERISA reporting and disclosure obligations
  - COBRA obligations
COMPLIANCE WITH OTHER LAWS…

- HIPAA Privacy
  - Does employer come in contact with protected health information from a group health plan?
  - Consider using HIPAA compliant third-party to manage the information for the wellness program
  - Business Associate Agreements in place with all vendors
PENALTIES FOR NONCOMPLIANCE

- HHS penalty of up to $100 per failure to comply (maximum of $25,000 per year)
- Self-reporting on Form 8928 with potential IRS penalty of up to $100 per day
- Potential Department of Labor (DOL) actions to enforce HIPAA and ACA requirements
- Potential compensatory and punitive damages for GINA violations, along with attorney’s fees and injunctive relief
- Additional penalties for state law and/or IRS tax violations
TIPS FOR SPONSORING A WELLNESS PROGRAM

- Understand your workforce
- Design a plan to achieve company objectives
- Work with legal counsel to navigate the legal requirements
- Establish written plan/policy documents
- Include rather than exclude
- Establish a “Wellness Champion” or “Wellness Committee” to oversee program
- Communicate with employees and seek their input
- Periodically assess the “success” of your program
QUESTIONS?

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THANK YOU

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