

IMPLEMENTING A COMPLIANT WELLNESS PROGRAM

Nancy Farnam

248.530.6333

nfarnam@clarkhill.com

kgauthier@clarkhill.com

Kristi Gauthier

480.684.1300

CLARK HILL

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

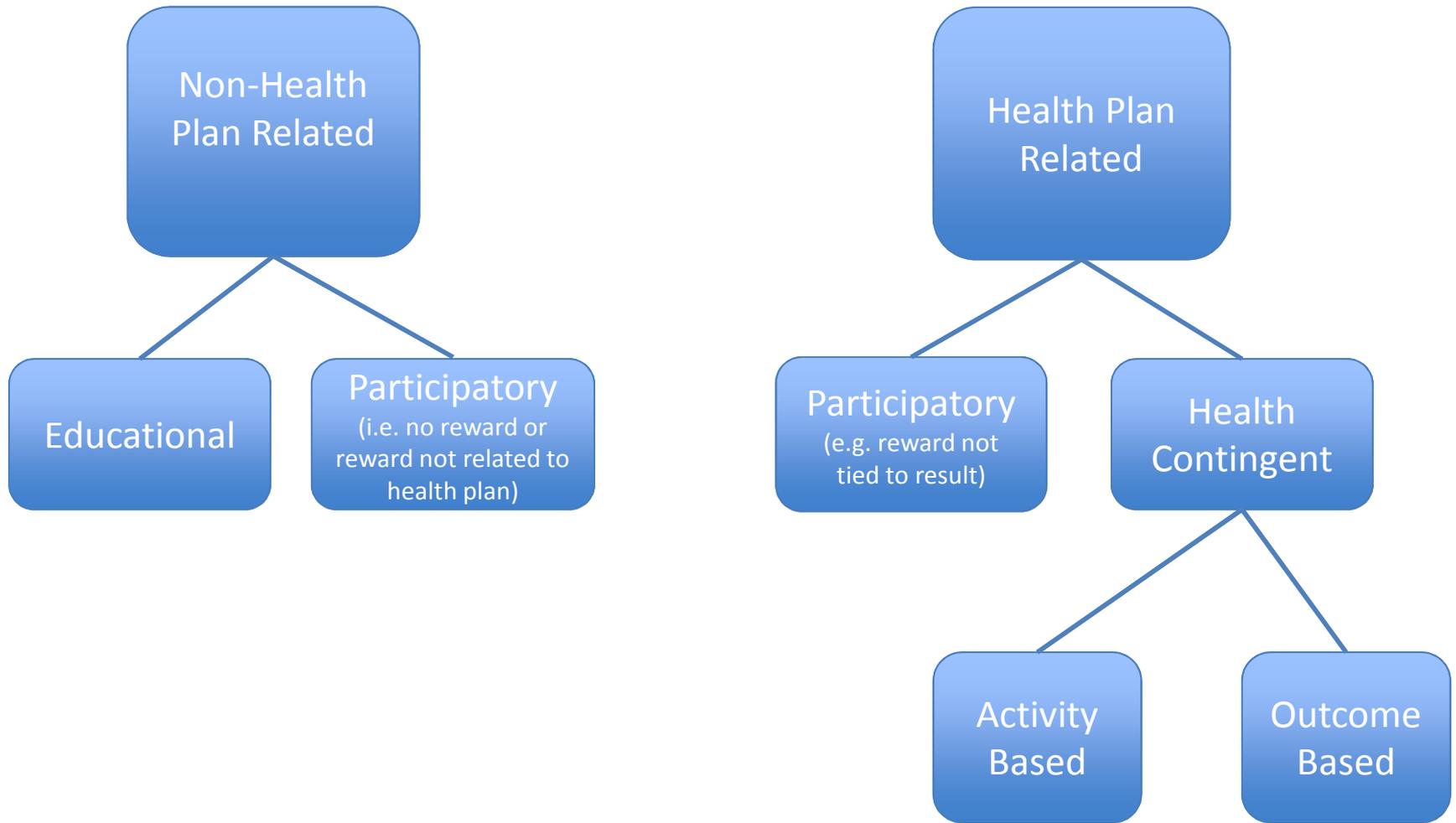
OVERVIEW

- What is a wellness program?
 - No specific definition; comes 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



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. 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 benefit plan
- Proposed amendments published April 2015
- Seeks to harmonize HIPAA and ACA rules with ADA requirements that medical inquiries or medical examinations must be voluntary

AMERICANS WITH DISABILITIES ACT (ADA)

- New regulations:
 - 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)

- 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)

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

AMERICANS WITH DISABILITIES ACT (ADA)

- Voluntariness
 - May not require employees to participate
 - Deny health coverage for non-participation
 - Limit health coverage or benefits for non-participation except as specifically allowed
 - 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

COMPLIANCE WITH OTHER LAWS...

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

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
- ERISA
 - Does program an employer sponsored welfare benefit plan providing medical benefits?
 - ERISA reporting and disclosure obligations

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

THANK YOU



Kristi R. Gauthier, Esq.
14850 N. Scottsdale Road, Suite 500
Scottsdale, AZ 85254
(P) 480.684.1300
(F) 480.684.1190
(E) kgauthier@clarkhill.com



Nancy L. Farnam, Esq.
151 S. Old Woodward, Suite 200
Birmingham, MI 48009
(P) 248.530.6333
(F) 248.988.2304
(E) nfarnam@clarkhill.com

LEGAL DISCLAIMER

Note: This document is not intended to give legal advice. It is comprised of general information. Employers facing specific issues should seek the assistance of an attorney.

CLARK HILL