Legal Issues in the Design and Implementation of Wellness Programs

Susan M. Nash
Joanna Kerpen
McDermott Will & Emery

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“Wellness Programs” – A Broad Label

- Wellness programs are typically designed to provide employees (and dependents if applicable) a benefit to promote health and disease prevention.
- To incentivize participation, discounts, rebates or prizes are offered to individuals who participate. Programs can take many forms:
  - Stand-alone or part of group health plan
  - Some designed to improve general overall health of employee population; others are disease management-oriented
  - Intended to help contain benefits costs
- Many offer rewards to employees who participate (or impose penalties on those who do not):
  - Cash or cash equivalents (e.g., gift cards)
  - Medical plan incentives (e.g., premium reductions / surcharges)
  - Noncash rewards (e.g., employee discounts or prizes)
Legal Landscape

- Patchwork of overlapping rules, including:
  - HIPAA wellness program rules
  - HIPAA privacy rules
  - Genetic Information Nondiscrimination Act of 2008 (GINA)
  - Americans with Disabilities Act (ADA)
  - Internal Revenue Code Limitations

- Affordable Care Act increased permissible wellness-related financial rewards beginning in 2014
New Final HIPAA Wellness Program Rules

- Published on June 3, 2013
- Issued by Internal Revenue Service, Department of Labor and Centers for Medicare & Medicaid Services
- Generally apply to self-insured and fully-insured group health plans for plan years beginning on or after January 1, 2014 (grandfathered and non-grandfathered)
Background – HIPAA Wellness Program Rules

- HIPAA generally prohibits group health plans from discriminating with respect to eligibility, benefits, and premiums or contributions based on eight “health factors”
  - Health status, medical condition (physical or mental), claim experience, receipt of health care, medical history, genetic information, evidence of insurability and disability
  - For example, plans generally may not require a participant to pay a premium or contribution that is greater than that for a similarly-situated participant based on a health factor

- HIPAA wellness program rules are an exception to this general prohibition on discrimination
  - Plans are permitted to vary benefits and premiums or contributions in connection with programs of health promotion or disease prevention (i.e., wellness programs) that meet specific requirements
Types of Wellness Programs

- Final rules retain two main categories of wellness programs:
  - Participatory
  - Health contingent
- **New rule:** Health contingent wellness programs are divided into two subcategories
  - Activity-only
  - Outcome-based
- Compliance requirements vary significantly based on type of program
Participatory Wellness Programs

- Either:
  - Do not provide a reward; or
  - Do not include any conditions for obtaining a reward that are based on an individual satisfying a standard that is related to a health factor

- Examples:
  - A program that reimburses all or a portion of the cost of membership in a fitness center
  - A program that provides a reward for taking a series of biometric tests (without regard to the results) or completing a health risk assessment (without any further action required with regard to any issues identified)

- Must be made available to all similarly situated individuals, regardless of health status
- Not required to meet the Five Factor Test
Health Contingent Wellness Programs
Activity-Only

- An individual is required to perform or complete an activity related to a health factor in order to obtain a reward
- Activity-only wellness programs do not require an individual to attain or maintain a specific health outcome
- Examples:
  - Walking programs
  - Diet programs
  - Exercise programs
- Some individuals may be unable to participate in an activity-only wellness program due to a health factor – must be offered reasonable alternative standard to qualify for the reward
- Must meet the Five Factor Test
Health Contingent Wellness Programs
Outcome-Based

- An individual must attain or maintain a specific health outcome to obtain a reward
- Program generally has two tiers:
  - Tier 1 – test or screening to determine if initial standard is met
  - Tier 2 – required follow-up wellness activities for those who do not meet or attain healthy standard from Tier 1 in order to obtain same reward as those who met Tier 1 initial standard
- Examples:
  - Program tests for BMI, cholesterol, or blood pressure in a particular range; provides reward to individuals who meet initial healthy standard; requires those who do not to take additional steps to obtain same reward
  - Program provides premium or contribution discount to non-smokers; requires smokers to complete tobacco cessation program or other additional steps to obtain same reward
- Must meet the Five Factor Test
Health Contingent Wellness Programs
Five Factor Test

- Size of reward: The reward may not exceed 30% of the cost of coverage (employer + employee) – or up to 50% for tobacco cessation programs (increased from 20% prior to 2014)
- Reasonable design: The program must be reasonably designed to promote health or prevent disease
- Frequency of opportunity to qualify: The program must give eligible individuals the opportunity to qualify for the reward at least once a year
- Uniform availability and reasonable alternative: The reward must be made available to all similarly situated individuals (including making available a reasonable alternative standard)
- Notice: The plan must disclose in all plan materials describing the terms of the program the availability of other means of qualifying for the reward or the possibility of waiver of the otherwise applicable standard
Health Contingent Wellness Programs

- Must offer a “reasonable alternative standard”
  - Activity-only wellness programs
    - A reasonable alternative standard for obtaining the reward (or waiver of the requirement) must be provided for any individual for whom it is either unreasonably difficult due to a medical condition to meet the otherwise applicable standard, or for whom it is medically inadvisable to attempt to satisfy the otherwise applicable standard
    - Plan can seek reasonable verification, such as statement from individual’s personal physician
  - Outcome-based wellness programs
    - A reasonable alternative standard for obtaining the reward (or waiver of the requirement) must be provided to any individual who does not meet the initial standard, regardless of any medical condition or other health status factor
Health Contingent Wellness Programs

- Notice of availability of reasonable alternative standard
  - Plan must disclose the availability of a reasonable alternative standard to qualify for the reward and possibility of waiver
  - Must include contact information for obtaining alternative and a statement that recommendations of an individual’s personal physician will be accommodated
  - For outcome based-wellness programs, this notice must also be included in any disclosure that an individual did not satisfy an initial outcome-based standard
  - Sample language now includes a statement that recommendations of an individual’s personal physician will be accommodated
Example – Health Contingent Wellness Programs, Activity-Only

- A group health plan provides a reward to individuals who participate in a walking program. If it is unreasonably difficult due to a medical condition for an individual to participate (or if it is medically inadvisable for an individual to attempt to participate), the plan will waive the walking program requirement and provide the reward. All materials describing the terms of the walking program disclose the availability of the waiver.
Examples – Health Contingent Wellness Programs, Outcome-Based

- BMI Screening: A group health plan provides a reward to participants who have a body mass index (BMI) that is 26 or lower, determined shortly before the beginning of the year. Any participant who does not meet the target BMI is given the same discount if the participant complies with an exercise program that consists of walking 150 minutes a week. Any participant for whom it is unreasonably difficult due to a medical condition to comply with this walking program (and any participant for whom it is medically inadvisable to attempt to comply with the walking program) during the year is given the same discount if the participant satisfies an alternative standard that is reasonable taking into consideration the participant’s medical situation, is not unreasonably burdensome or impractical to comply with, and is otherwise reasonably designed based on all the relevant facts and circumstances. All plan materials describing the terms of the wellness program include the following statement: “Fitness is Easy! Start Walking! Your health plan cares about your health. If you are considered overweight because you have a BMI of over 26, our Start Walking program will help you lose weight and feel better. We will help you enroll. (**If your doctor says that walking isn’t right for you, that’s okay too. We will work with you (and, if you wish, your own doctor) to develop a wellness program that is.)” Participant A is unable to achieve a BMI that is 26 or lower within the plan’s timeframe and receives notification that complies with the wellness final rules. It is unreasonably difficult due to a medical condition for A to comply with the walking program. A proposes a program based on the recommendations of A’s physician. The plan agrees to make the same discount available to A that is available to other participants in the BMI program or the alternative walking program, but only if A actually follows the physician’s recommendations.
Examples – Health Contingent Wellness Programs, Outcome-Based

- Tobacco Use Surcharge with Smoking Cessation Alternative: In conjunction with an annual open enrollment period, a group health plan provides a premium differential based on tobacco use, determined using a health risk assessment. The following statement is included in all plan materials describing the tobacco premium differential: “Stop smoking today! We can help! If you are a smoker, we offer a smoking cessation program. If you complete the program, you can avoid this surcharge.” The plan accommodates participants who smoke by helping them enroll in a smoking cessation program that requires participation at a time and place that are not unreasonably burdensome or impractical for participants, and that is otherwise reasonably designed based on all the relevant facts and circumstances, and discloses contact information and the individual’s option to involve his or her personal physician. The plan pays for the cost of participation in the smoking cessation program. Any participant can avoid the surcharge for the plan year by participating in the program, regardless of whether the participant stops smoking, but the plan can require a participant who wants to avoid the surcharge in a subsequent year to complete the smoking cessation program again.
Action Items for 2014

- Need to review proposed wellness program design for compliance with new HIPAA rules
  - Evaluate type of program under new rules
    - Applicable requirements depend on categorization
  - Confirm size of reward meets requirements
  - Consider reasonable alternative standards
  - Ensure that open enrollment materials and any other communications about the program include required disclosures; consider use of sample language provided in regulations
HIPAA Privacy Rule Overview

- The HIPAA Privacy Rule establishes standards for the use and disclosure of protected health information (PHI) by covered entities.
- A group health plan is a covered entity, an employer is not a covered entity per se.
- A group health plan includes a health insurance issuer, group health plan, Medicaid, Medicare issuer, individual health plans, employee welfare benefit plan, etc.
- A wellness program may be a HIPAA covered entity, part of another HIPAA covered entity or not be covered by HIPAA at all.
HIPAA Privacy as it applies to Wellness Programs

- Determine if the Wellness Program fits HIPAA’s definition of a group health plan subject to ERISA or the catch all definition of “health plan”
- HIPAA Privacy may or may not apply to the wellness program
- DOL Wellness Guidance - February 14, 2008 the DOL released Field Assistance Bulletin (FAB) 2008-02 (“FAB”)
Assuming HIPAA Privacy applies to the Wellness Program

- If the wellness program is part of an ERISA covered medical plan, then it will be covered by the HIPAA privacy policies, procedures and privacy notice that cover the medical plan.
- If the wellness program is a stand alone ERISA covered plan or it falls within the catch all definition of “health plan” it will need to be added to the medical plan’s HIPAA policies and procedures, or have its own.
Assuming HIPAA Privacy applies to the Wellness Program

- HIPAA generally requires covered entities to obtain signed authorizations from individuals who participate in wellness programs (unless it is a disease management program)
  - Authorization necessary
- HIPAA requires compliance with the minimum necessary rule
  - Permits a covered entity to use and request the minimum amount of information necessary to complete the task at hand
- HIPAA requires that any information obtained through a wellness program be secured and protected
Assuming HIPAA Privacy applies to the Wellness Program

- HIPAA limits the type and purpose of disclosure of PHI from a covered entity to a non-covered entity (i.e. the wellness plan to the company)
- A covered entity is not permitted to disclose PHI to an employer unless the plan documents and privacy notice provide for such disclosure
  - Exception for summary health information, eligibility and enrollment information to obtain premium bids, modify, amend or terminate the plan
  - Exception for pre-placement physicals, drug tests, and fitness-for-duty examinations
HIPAA Privacy Disclosure to Wellness Vendors

- Business associates under HIPAA are not covered entities but are directly subject to many of the HIPAA rules and requirements
- A wellness vendor will typically be a business associate under HIPAA
  - Before disclosing PHI to a business associate, a covered entity should require a business associate to enter into a HIPAA compliant business associate agreement
  - This agreement will state the parameters of how the business associate may use and disclose the participant’s PHI, and the consequences for failing to abide by those limitations
Communications about a Product or Service?

- Most Likely, communications about products or services meet the HIPAA definition of marketing – defined as a communication to an individual about a product or service that encourages the individual to purchase or use it.

- General rule is that marketing is not permitted without obtaining a signed authorization from an individual.
  - Authorization necessary.
HIPAA Marketing

- Exceptions:
  - Communications between a plan and participants for plan administration purposes
  - Communications describing participating providers in a network
  - Communications describing services offered by a provider of benefits offered under a health plan
  - Case management, care coordination, recommendation of alternative treatment, therapies or providers
  - A health plan can communicate about health-related products and services available to plan enrollees and members that add value, but are not part of benefit plan – may not be discount or pass-through of items available to public at large

- These exceptions do not apply if covered entity receives financial remuneration in exchange for making the communication
HIPAA Marketing

- **Additional Exceptions:**
  - A health care provider can provide refill reminders or otherwise communicate with an individual about a drug or biologic that is currently being prescribed for the individual (provided that any financial remuneration received by the covered entity in exchange for making the communication is reasonably related to the covered entity’s cost of making the communication)
  - Face-to-face communication with the individual
  - Promotional gifts of nominal value
Suggestions for Addressing HIPAA’s Privacy Rules

- Disclose to participants how their PHI obtained through the wellness program will be used and disclosed
- Include wellness program in existing privacy documents or create stand alone documents
- Update and distribute HIPAA privacy notices that contain use and disclosure with respect to wellness programs
- Limit disclosure to the employer unless an exception or documents and privacy notice are amended
Suggestions for Addressing HIPAA’s Privacy Rules

- Enter into business associate agreements with wellness vendors
- Include privacy language in contracts with other covered entities
- Determine when and if a signed authorization is necessary
- Comply with the minimum necessary requirements
- Consider HIPAA marketing prohibition and need for an individual’s authorization
Genetic Information Nondiscrimination Act of 2008 (GINA)

- Intended to prevent discrimination on the basis of genetic information in health insurance and employment
  - Prohibits discrimination in premiums
  - Limits genetic testing
GINA

- Limits the type of information that may be solicited from wellness program participants in a health risk assessment (HRA)
  - May not ask for genetic information
  - Genetic information includes family medical history
- When a question could be broad enough to be interpreted as requesting genetic information, the following language is suggested:
  - "In answering question __, or any questions that seem to request genetic information (or family history) you should not include any genetic information. 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."
Suggestions for GINA Compliance

- Review HRAs to ensure they do not request genetic information
- Review HRAs to ensure they do not request family medical history
- Include suggested safe harbor language
Americans with Disabilities Act (ADA)

- ADA does not prohibit employers or health insurers from implementing voluntary wellness programs aimed at promoting good health, disease prevention, medical examinations or health screening.
- ADA limits employers ability to ask “disability-related inquiries” – may impact type of questions asked on health risk assessments.
ADA

- The ADA prohibits an employer from denying benefits or providing different benefit terms or conditions based on an employee’s disability.
- Under ADA, medical examinations and inquiries in connection with wellness and disease management programs must be “voluntary” (i.e., no penalty)
  - If incentive is too large, program may not be considered “voluntary” and may be viewed as a penalty to those who cannot participate.
  - No safe harbor (e.g., HIPAA rules have 30%/50% threshold).
Suggestions for Complying with the Americans with Disabilities Act

▪ Tailor a program to fit into the ADA’s exception for a voluntary wellness program
▪ An employer may include voluntary medical histories as part of a health program as long as the employer neither requires participation or penalizes employees who do not participate
▪ From an employer’s perspective, medical records must be kept confidential and separate from employment records
▪ Wellness programs should be designed to accommodate those with disabilities
Suggestions for Complying with the Americans with Disabilities Act

- If wellness programs are provided in an area where disabled employees are unable to access, an alternative location should be used
  - Example, weight loss classes held on the third floor in a building that is not wheelchair accessible

- Do not structure incentives so that they appear to be a penalty to those who cannot comply
  - Example, health insurance discounts for those who agree to walk 3 times a week with no reasonable alternative for those who are unable to walk due to a medical condition
Internal Revenue Code Limitations

▪ Many wellness programs and incentives may have tax consequences
▪ Evaluate whether a wellness program is for medical care or general health and well-being
▪ Structure a program or incentive to achieve the company’s intended results
Internal Revenue Code Limitations

- Section 105(b) of the Internal Revenue Code generally provides that gross income does not include amounts received by an employee through accident or health insurance or otherwise if they are paid directly or indirectly to the employee to reimburse the employee for expenses incurred by the employee, his spouse or dependents for medical care, as defined under Code Section 213(d)

- Code Section 213(d) defines “medical care” to include amounts paid for the diagnosis, cure, mitigation, treatment or prevention of disease or for the purpose of affecting any structure or function of the body
  - Expenditures that are merely beneficial to the general health or well being of an individual are not expenditures for medical care
IRS Informal Guidance

- At an ABA Joint Committee on Employee Benefits meeting with IRS and Treasury Officials, (May 8-10, 2008) IRS officials stated that gift cards provided to employees by a third-party administrator of an employer's wellness program in exchange for participating in a health risk assessment were compensation from employment and should be reported on Form W-2 by the employer.
Evaluating Taxable vs. Non-Taxable Programs/Incentives

Non-Taxable Benefits

- The cost of a Health Risk Assessment
- In house use of a fitness facility
- At work health seminars or classes
- Vouchers for the on-site cafeteria
- Smoking cessation or weight loss programs based on a physician’s recommendation
Evaluating Taxable vs. Non-Taxable Programs/Incentives

Taxable Benefits

- Cash incentives over a specific dollar amount
- Large fitness equipment (i.e. treadmill or a bicycle)
- Vitamins or supplements without a physician diagnosis and recommendation
- Fitness memberships without a physician’s diagnosis and recommendation
Suggestions for Complying with the Internal Revenue Code

- Determine whether taxable versus non-taxable incentives are offered
- Fully disclose to employees whether a wellness program or incentive is taxable
QUESTIONS?