

## WELLNESS PROGRAMS UNDER FINAL HIPAA/PPACA, ADA, AND GINA REGULATIONS

Wellness programs come in many different shapes and sizes and may be called something other than wellness programs. These programs may provide very limited benefits such as educational health-related information, or they may be more extensive and involve biometric testing, individualized coaching, or even be part of a disease management program. Knowing what type of program you have is important because which federal laws apply (or do not apply) is largely determined by the type of program. Below, we provide an overview of four of the most important federal laws when administering wellness programs – the Patient Protection and Affordable Care Act (“PPACA”), the nondiscrimination provision of the Health Insurance Portability and Accountability Act (“HIPAA”), the Americans with Disabilities Act (“ADA”), and the Genetic Information Nondiscrimination Act (“GINA”). A few wellness programs will be subject to only one law; others may be subject to all four laws.

### HIPAA/PPACA

HIPAA/PPACA rules apply to all wellness programs that are health-plan related or that are themselves health programs and apply to all participants.

Type of Program	Definition & Examples	HIPAA/PPACA
<b>Participatory</b>	<p>Reward not based on health factor; reward based solely on participation in the program regardless of outcome. Examples:</p> <ul style="list-style-type: none"> <li>• Reimburse fitness center membership cost.</li> <li>• Reward for participating in smoking cessation program with no</li> </ul>	<p>Program must be available to all similarly situated individuals, regardless of health status and does not provide reward based on a health factor. No reward maximum under HIPAA/PPACA.</p> <p>Note that if program involves genetic information, disability-related inquires, or medical examinations, then you must also consider the reward maximum limits from GINA and the ADA. See below.</p>

Type of Program	Definition & Examples	HIPAA/PPACA
	<p>requirement to quit.</p> <ul style="list-style-type: none"> <li>Reward for completing health risk assessment that does not contain any disability-related inquiries.</li> <li>Reward to participate in diagnostic testing, reward not based on outcome.</li> <li>Reward to complete health risk assessment questionnaire that includes disability-related inquiries.</li> <li>Reward for participating in smoking cessation with no requirement to quit, but including nicotine testing.</li> </ul>	
<b>Health-contingent: activity-only</b>	<p>Reward is based on performing or completing an activity related to health factor; no requirement to meet or maintain specific health outcome. Examples:</p> <ul style="list-style-type: none"> <li>Exercise program where individuals are required to exercise 10 minutes three days a week.</li> <li>Diet program where individuals are required to track and reduce consumption of sugary soft drinks.</li> <li>Health risk assessment where individuals with certain health conditions are required to speak with a health coach to earn the</li> </ul>	<ul style="list-style-type: none"> <li><b>Frequency of opportunity to qualify:</b> Eligible individuals must be given at least an annual opportunity to qualify.</li> <li><b>Size of reward:</b> Total reward offered to an employee (and their dependents, if applicable) must not exceed 30% of the total cost of coverage, 50% if program is designed to prevent/reduce tobacco use. Note that if program involves genetic information, disability-related inquiries, or medical examinations, it is unclear what, if any, reward will be possible under a wellness program subject to GINA or the ADA. See below.</li> <li><b>Uniform availability and reasonable alternative standard:</b> The program must be available uniformly to all similarly situated individuals. Also, a reasonable alternative standard required to earn the same reward must be available (or waiver of the initial standard)</li> </ul>

Type of Program	Definition & Examples	HIPAA/PPACA
	reward.	<p>to an individual for whom it is either unreasonably difficult due to a medical condition, or medically inadvisable, to participate. If it is reasonable under the circumstances, verification (such as a statement from the individual's personal physician) may be requested by employer. In some cases the plan will need to accommodate the recommendations of the individual's personal physician for the reasonable alternative standard.</p> <ul style="list-style-type: none"> <li>• <b>Notice of availability of reasonable alternative standard: Plan materials describing</b> program must disclose the availability of the reasonable alternative standard to qualify for the reward (or the possibility of a waiver, if available).</li> </ul>
<b>Health-contingent: outcome-based</b>	<p>Reward is based on attaining or maintaining a specific health outcome. Examples:</p> <ul style="list-style-type: none"> <li>• Premium discount for not using tobacco.</li> <li>• Reward for certain result on biometric screening.</li> <li>• Reward for favorable BMI, while requiring those outside of the health range satisfy a different standard within a specified time frame.</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Frequency of opportunity to qualify:</b> Eligible individuals must be given at least an annual opportunity to qualify.</li> <li>• <b>Size of reward:</b> Total reward offered to an employee (and their dependents, if applicable) must not exceed 30% of the total cost of coverage, 50% if program is designed to prevent/reduce tobacco use. Note that if program involves genetic information, disability-related inquiries, or medical examinations, it is unclear what, if any, reward will be possible under a wellness program subject to GINA or the ADA. See below.</li> <li>• <b>Uniform availability and reasonable alternative standard:</b> The program must be available uniformly to all similarly situated individuals. Also, a reasonable alternative standard required to earn the same reward must be available (or waiver of the initial standard)</li> </ul>

Type of Program	Definition & Examples	HIPAA/PPACA
		<p>for any individual that does not meet the initial standard, regardless of the individual's medical condition or other health status. The employer cannot require verification from the individual's physician. If the underlying standard and the reasonable alternative are both outcome-based and if the alternative is to meet a different level of same standard, then the program must give the individual additional time to comply. If underlying standard and reasonable alternative are both outcome-based, then the individual must be allowed to request that the alternative is to comply with recommendation of his/her personal physician.</p> <ul style="list-style-type: none"> <li>• <b>Notice of availability of reasonable alternative standard:</b> Plan materials describing program must disclose the availability of the reasonable alternative standard to qualify for the reward (or the possibility of a waiver, if available).</li> </ul>

**Note:** In August 2017, the U.S. District Court for the District of Columbia ruled that the EEOC must reconsider its 2016 final wellness regulations implementing the requirements of the ADA and GINA. On December 20, 2017, Judge Bates of the U.S. District Court for the District of Columbia, issued a revised order in the wellness lawsuit brought by AARP against the EEOC. The revised order modifies the Court's August 22, 2017 ruling which found the EEOC's use of a 30% maximum penalty for wellness programs subject to the ADA and GINA to be arbitrary. The December order vacates, effective January 1, 2019, the wellness rules establishing the extent to which employers may penalize employees for failing to provide health information regarding themselves or their spouses without violating the ADA and GINA. In December 2018, the EEOC issued guidance removing the wellness incentives under the ADA and GINA regulations. The regulations otherwise remain in effect.

## ADA

ADA rules apply to all wellness programs that include disability-related inquiries or medical examinations such as biometric testing – including wellness programs that are not health plans or health-plan related. ADA rules only apply to employees.

Type of Program	Definition & Examples	ADA
Any wellness program with a disability-related inquiry or medical examination.	<p>Any question or series of questions that is likely to elicit information about an employee's disability ("disability-related inquiry"), or any procedure or test that seeks information about an individual's physical or mental impairments or health ("medical examination").</p> <p>Examples:</p> <ul style="list-style-type: none"> <li>• Health risk assessment that seeks disability-related information (e.g., Are you currently taking any medications?)</li> <li>• Biometric screening</li> <li>• Preventive care examination</li> <li>• A smoker surcharge that requires employees to be tested for nicotine use (in contrast, a program that merely asks employees whether they smoke is not covered by the ADA.)</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Program must be voluntary:</b> May not require participation or deny coverage under plan or any benefit package.</li> <li>• <b>Reasonable accommodation:</b> Required if needed to make program accessible to employees with a disability – such as sign language interpreter for deaf employee.</li> <li>• <b>Maximum reward:</b> In response to a court order, the EEOC issued guidance in December 2018 that removed a 30% maximum reward rules from its wellness regulations. Prior to the court's decision, the EEOC rules permitted a reward of up to 30% for the program to be considered voluntary. At this time it is unclear if any reward will be permissible for a wellness program subject to the ADA. Note that additional guidance is anticipated in 2019.</li> <li>• <b>Written notice:</b> Must provide notice indicating what medical information will be obtained, who will receive the information, how it will be used, how it will be kept confidential, restrictions on disclosure, and methods used to prevent improper disclosure.</li> </ul>

## GINA

GINA rules apply to all wellness programs that include genetic information – including wellness programs that are not health plans or health-plan related. Different rules apply depending on whether genetic information is requested for employees, spouses, or children.

Type of Program	Definition & Examples	GINA
<b>Any wellness program that requests genetic information.</b>	<p>“Genetic information” of an employee includes genetic tests, “family medical history,” and information about the manifestation of a disease or disorder in a family member. “Family” includes, but is not limited to, parents, spouses, siblings, children, and other ancestors, whether related by blood, marriage, or adoption. “Medical history” includes information about the manifestation of a disease or disorder in family members of an individual. Examples:</p> <ul style="list-style-type: none"> <li>• Genetic test offered to employee, spouse, or child</li> <li>• Health risk assessment that includes questions about personal medical history</li> </ul>	<p>Genetic information may not be collected prior to or in connection with enrollment or for purposes of underwriting. See <a href="#">Gallagher's Guide to Designing a Compliant Wellness Program</a> for more information. Employers may not offer incentives for individuals to provide “genetic information” except that employers may offer incentives when both employees and spouses are eligible to participate in wellness programs so long as certain conditions are met.</p> <p>As a limited exception, employers may offer limited incentives to employees and/or spouses to provide information regarding manifestation of a disease or disorder (i.e., personal medical history), if the following conditions and the limitations on collecting genetic information for purposes of underwriting or in connection with enrollment are met:</p> <ul style="list-style-type: none"> <li>• <b>Program must be voluntary:</b> May not require participation or deny coverage under plan or any benefit package.</li> <li>• <b>Maximum reward:</b> In response to a court order, the EEOC issued guidance in December 2018 that removed a 30% maximum reward rules from its wellness regulations. Prior to the court's decision, the EEOC rules</li> </ul>

Type of Program	Definition & Examples	GINA
		<p>permitted a reward of up to 30% for the program to be considered voluntary. At this time it is unclear if any reward will be permissible for either an employee or a spouse for a wellness program subject to GINA. No incentive is permitted for children. Note that plans subject to the HIPAA/PPACA nondiscrimination rules or the ADA must also comply with the reward maximum rules under those laws. Note that additional guidance is anticipated in 2019.</p> <ul style="list-style-type: none"> <li>• <b>No condition of participation or reward:</b> The employer may not condition participation or any reward on an individual's agreeing to the sale, exchange, transfer, or other disclosure of medical information in order to participate in the wellness program or receive a reward, or on the individual's waiving GINA protections.</li> <li>• <b>Written notice:</b> A notice must explain the restrictions on the disclosure of the information, state that individually identifiable genetic information is provided only to the individual receiving the services and the health care professionals or board certified genetic counselors involved in providing services, and that individually identifiable genetic information is only available for the purpose of providing health or genetic services and is not disclosed to the employer except in aggregate form.</li> </ul>

## ADDITIONAL REQUIREMENTS APPLICABLE TO WELLNESS PROGRAMS

Requirement	HIPAA/PPACA	ADA	GINA
<b>Reasonable Design</b>	<p>Program must be reasonably designed to promote health or prevent disease:</p> <p>Must provide a reasonable chance to improve health or prevent disease;</p> <p>Must not be overly burdensome;</p> <p>Must not be a subterfuge for discrimination based on health; and</p> <p>Must not be highly suspect in the method chosen to promote health or prevent disease.</p>	<p>Program must be reasonably designed to promote health or prevent disease:</p> <p>Must have a reasonable chance of improving health or preventing disease;</p> <p>Must not be overly burdensome;</p> <p>Must not be a subterfuge for violating the ADA or other laws prohibiting employment discrimination;</p> <p>Must not be highly suspect in the method chosen to promote health or prevent disease; and</p> <p>A program consisting of a measurement, test, screening, or collection of health-related information without providing follow-up information, or advice designed to improve the participant's health is not reasonably designed to promote health or prevent disease, unless the collected information actually is used to design a program that</p>	<p>Program must be reasonably designed to promote health or prevent disease:</p> <p>Must have a reasonable chance of improving health or preventing disease;</p> <p>Must not be overly burdensome;</p> <p>Must not be a subterfuge for violating GINA or other laws;</p> <p>Must not be highly suspect in the method chosen; and</p> <p>A program consisting of a measurement, test, screening, or collection of health-related information without providing follow-up information, or advice designed to improve the participant's health is not reasonably designed to promote health or prevent disease, unless the collected information actually is used to design a program that addresses at least a subset of conditions identified.</p>



Requirement	HIPAA/PPACA	ADA	GINA
		addresses at least a subset of conditions identified.	
<b>Confidentiality</b>	<p>Under HIPAA privacy rule, must protect PHI obtained by the program including:</p> <p>May not use for employment purposes or for another employer-sponsored plan.</p> <p>Employer may receive information in aggregate form. May receive individually identifiable information in limited circumstances with required employer certification that it will not use PHI for employment purposes or for other benefit plans to the group health plan.</p> <p>Breach notification required - "immediate" notice to affected individuals. Notice to HHS and in some cases, media.</p>	<p>Requirements similar to HIPAA with some differences:</p> <p>Generally may not disclose to employee's supervisor or manager.</p> <p>Individuals who handle medical information generally should not be responsible for making employment decisions.</p> <p>Breach notification required – "immediately" to affected employees. No separate requirement to notify EEOC or media.</p> <p>Participant may not be required to agree to the sale, exchange, sharing, transfer or other disclosure of medical information or waiver of confidentiality protections in order to participate or receive a reward.</p>	<p>Additional confidentiality requirements:</p> <p>Employers that possess genetic information must maintain that information in medical files that are separate from personnel files.</p> <p>The information must be treated as a confidential medical record with disclosure prohibited except in very limited circumstances.</p> <p>Confidentiality requirements apply to genetic information in both paper and electronic forms.</p> <p>Spouse must provide prior knowing, voluntary, and written authorization before information collected or tests performed.</p>
<b>No Adverse Action/Discrimination</b>	<p>Group health plans must not discriminate against participants and beneficiaries in premiums, benefits, or eligibility based on a</p>	<p>Employer must not take any adverse employment action or retaliate against, interfere with, coerce, intimidate, or threaten</p>	<p>Employer may not discriminate on the basis of genetic information when it comes to any aspect of employment, including hiring, firing,</p>

Requirement	HIPAA/PPACA	ADA	GINA
	health factor. An exception to the general rule allows premiums discounts or modifications to cost-sharing for compliant wellness programs.	employees who choose not to participate.	pay, job assignments, promotions, layoffs, training, fringe benefits, or any other term or condition of employment.

***Note: This is a high level overview of the wellness requirements under the final regulations for HIPAA, PPACA, ADA, and GINA as of January 2019. Wellness program are subject to additional federal laws such as COBRA, ERISA and nondiscrimination laws. All wellness programs should be reviewed by legal counsel prior to implementation.***

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*The intent of this analysis is to provide general information regarding the provisions of current federal laws and regulation. It does not necessarily fully address all your organization's specific issues. It should not be construed as, nor is it intended to provide, legal advice. Your organization's general counsel or an attorney who specializes in this practice area should address questions regarding specific issues.*