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BENEFITS BRIEF

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Agencies Issue Final HIPAA Wellness Program Rules under ACA

On June 3, 2013, the Departments of Health and Human Services, Labor, and Treasury issued final rules on "Incentives for Nondiscriminatory Wellness Programs in Group Health Plans." 78 Fed. Reg. 33158. The final rules update the existing HIPAA wellness rules, which can be found in the HIPAA nondiscrimination rules. 29 CFR 2590.702. The HIPAA nondiscrimination rules prohibit a group health plan from discriminating against an individual based on a health factor, except in two circumstances – if the discrimination is in favor of an individual with an adverse health status (called benign discrimination) or if under a wellness program that meets the requirements of the HIPAA wellness rules.

The new final HIPAA wellness rules are based on the same general framework as the existing HIPAA wellness rules and incorporate changes that were mandated by the Affordable Care Act (ACA), including increased limits on the amount of health-based wellness program rewards that a plan can offer or penalties it can impose. The final rules adopt many of the requirements set out in the proposed rules that were issued on November 26, 2012, but also include several significant changes.

The new wellness rules apply to group health plans and health insurance issuers providing group policies, including grandfathered plans. The new rules are applicable to plan or policy years starting on or after January 1, 2014.

Below we set out a step-by-step approach for group health plans to evaluate their wellness programs under the new final rules.

STEP 1: PARTICIPATORY OR HEALTH CONTINGENT?

Participatory Programs

As under the existing rules, plans first must determine whether their wellness program is Participatory or Health-Contingent. A program will be considered Participatory if none of the conditions to obtain a reward are based on an individual satisfying a health standard. Participatory programs are not required to meet the HIPAA wellness rule requirements (although they may have to meet other requirements, such as under the ADA, GINA, or ERISA).

PARTICIPATORY WELLNESS PROGRAMS **None of the Conditions to Obtain Reward Based on Individual Satisfying Standard Related to a Health Factor** ***Not Required to Meet 5 Requirements of HIPAA Wellness Rules***
Examples: • Reimburse fitness center membership cost • Reward to participate in diagnostic testing, not based on outcomes • Deductible or copayment waiver to encourage preventive care, such as prenatal care or well-baby visits • Reward or reimbursement for smoking cessation program, regardless of whether employee quits smoking • Reward for attending monthly, no-cost health education seminar • Reward to complete health risk assessment without further action required by employee (educational or otherwise) with regard to identified health issues

Health-Contingent Programs

Health-Contingent programs must meet the additional requirements of the HIPAA wellness rules in order to be in compliance with the HIPAA nondiscrimination rules. A wellness program is considered to be Health-Contingent if it requires an individual to satisfy a standard related to a health factor in order to obtain a reward.

The new final rules break this category down even more into Activity-Based and Outcome-Based, with different requirements for each depending on the type of program (see Step 2 below). Notably, exercise or walking programs, that many plans previously believed were Participatory, now appear to be Activity-Based programs under the "Health-Contingent" category so will be subject to the HIPAA wellness rules.

HEALTH-CONTINGENT WELLNESS PROGRAMS **Require Individual to Satisfy Standard Related to a Health Factor to Obtain Reward** ***Required to Meet 5 Requirements of HIPAA Wellness Rules***	
NEW! Activity-Based	**NEW! Outcome-Based**
Requires individual to perform or complete an activity related to health factor to obtain reward, but does not require individual to attain or maintain specific health outcome Examples: • Walking, diet, or exercise programs where some individuals may be unable to or have difficulty participating or completing due to a health factor, such as asthma, pregnancy, or recent surgery	Requires individual to attain or maintain specific health outcome in order to obtain reward Examples: • Reward for not smoking • Reward for attaining certain results on biometric screening • Biometric screening that tests for risk factors (e.g., high cholesterol, high glucose level) and provides reward to individuals within healthy range, while requiring individuals outside health range or at risk to take additional steps to obtain same reward, such as to meet with health coach

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STEP 2: IF HEALTH-CONTINGENT, MUST COMPLY WITH 5 REQUIREMENTS UNDER HIPAA WELLNESS RULES

If a wellness program is Health-Contingent (whether Activity-Based or Outcome-Based), it must meet the 5 requirements of the HIPAA wellness rules. The 5 requirements are structured similarly to the proposed rules, but with significant differences. Plans will need to break down each wellness program, determine its type, and run through the analysis below for each program.

#1 ANNUAL QUALIFICATION

As under the proposed rules, the wellness program must give individuals the opportunity to qualify for the reward at least once per year. The agencies said that this requirement is a "bright-line" standard for determining the minimum frequency of a reasonably designed program.

	HEALTH-CONTINGENT WELLNESS PROGRAMS	
	Activity-Based	**Outcome-Based**
#1 Annual Qualification	Must give individuals opportunity to qualify for the reward at least once per year	Same

#2 LIMIT ON AMOUNT OF REWARD

The reward for a Health-Contingent wellness program, together with the reward for other Health-Contingent wellness programs under the plan, must not exceed "the applicable percentage" of the cost of employee-only coverage under the plan. As under the proposed rules, the final rules allow a 30% limit for non-tobacco wellness program rewards plus an additional 20% for tobacco wellness programs (so up to 50% total if including tobacco programs). The regulations define "reward" to include both obtaining a reward, such as a premium discount, or avoiding a penalty, such as absence of a premium surcharge.

As in the current rules, the cost of coverage is based on the total amount of employer plus employee contributions for the benefit package under which the employee is receiving coverage. The final rules provide an example where the employee portion is $1,500 and employer portion is $4,500. The example says that the applicable percentage would be calculated based on the total cost of coverage of $6,000 ($1,500+$4,500). In addition, the cost is based on employee-only coverage unless any class of dependents may participate, in which case the reward may be based on the total cost of the coverage in which the employee and any dependents are enrolled.

In the Preamble to the rules, the agencies said that they considered whether to include requirements to allocate the reward among the employee and dependents, but instead, allow plans the flexibility to determine apportionment of the reward among family members, as long as the method is reasonable. The agencies said they may issue additional subregulatory guidance if questions persist.

	HEALTH-CONTINGENT WELLNESS PROGRAMS	
	Activity-Based	**Outcome-Based**
#2 Limit on Amount of Reward	**NEW! Non-Tobacco Programs** (e.g., BMI, cholesterol) – Limit is up to **30%** of cost of coverage **NEW! Tobacco Programs** – Limit is up to **50%** of cost of coverage **NEW! Limit on total reward is 50%** of cost of coverage Examples of Permitted Percentages: • 30% reward for BMI + 20% for tobacco use – Meets Limit • 10% reward for BMI + 40% for tobacco use – Meets Limit • 0% for BMI + 50% for tobacco use – Meets Limit • 30% for BMI + 50% for tobacco use – Not Allowed (only allowed up to 50% total when include tobacco)	Same

#3 REASONABLE DESIGN

As under the proposed rules, a wellness program must be reasonably designed to promote health or prevent disease. The final rules provide (similar to the proposed rules) that a program will meet this standard if it has a reasonable chance of improving health or preventing disease, is not overly burdensome, is not a subterfuge for discrimination based on a health factor, and is not highly suspect in the method chosen to promote health or prevent disease.

In the Preamble to the rules, the agencies said that whether a program is "reasonable" would be based on relevant facts and circumstances, but they were not adopting a "rigid set of pre-approved wellness program structures or guidelines." The agencies also did not adopt suggestions of requiring that wellness programs look to evidence-based clinical guidelines. The agencies did say that these types of guidelines would be encouraged as a "best practice."

	HEALTH-CONTINGENT WELLNESS PROGRAMS	
	Activity-Based	**Outcome-Based**
#3 Reasonable Design	• Must be reasonably designed to promote health or prevent disease • Program will satisfy standard if has reasonable chance of improving health or preventing disease, is not overly	Same (but additional rules related to Reasonable Alternative below)

	HEALTH-CONTINGENT WELLNESS PROGRAMS	
	Activity-Based	**Outcome-Based**
	burdensome, is not a subterfuge for discrimination based on a health factor, and is not highly suspect in the method chosen to promote health or prevent disease • Based on all relevant facts and circumstances	

#4 REASONABLE ALTERNATIVE

NEW! The major difference between the proposed and final rules is in how the reasonable alternative is structured. The current HIPAA wellness rules require a plan to provide a reasonable alternative method for individuals for whom it is unreasonably difficult or medically inadvisable to meet initial standard. The proposed rules expanded this requirement to apply to anyone who failed to meet the initial health standard, regardless of medical reason. The final rules adopt a hybrid approach, depending on the type of program:

- **Activity-Based programs must follow the "Medical Reasonable Alternative," similar to the current rules.**
- **Outcome-Based programs must follow the "Reasonable Alternative for All" approach, similar to the proposed rules.**

Reasonable Alternative – When Reward Is Paid

The agencies clarified in the Preamble to the final rules that individuals who are given an alternative must be able to earn the same, full reward as those who met the initial standard, even if it takes those under the alternative more time. In some cases, the agencies said this would mean that individuals would be entitled to retroactive payment of rewards. They provided an example under a calendar year wellness program where an individual does not satisfy an alternative until April and said that the individual must be given premium credits for January through March as well. The agencies said that the plan has the flexibility to determine how to provide the prior reward, such as retroactive payments or pro rata payments for the remainder of the year, as long as the method is reasonable and the individual receives the full amount of the reward. The Preamble also says that where an individual does not satisfy the alternative until the end of the year, the plan may provide retroactive payment for the reward "within a reasonable time after the end of the year," but may not provide pro rata payments over the next year, which would be "a year after the year to which the reward corresponds."

Reasonable Alternative – Type of Alternative

The agencies provided that plans have the flexibility to determine whether to provide the same alternative to an "entire class" of individuals or to provide on an "individual-by-individual" basis. As under the existing rules, plans do not have to determine the alternative in advance and may always waive the otherwise applicable standard and simply provide the reward to someone who does not meet the initial standard. In addition, the agencies allow the plan to require completion of a different reasonable alternative standard where someone does not meet the first

alternative, such as requiring a different alternative in Year 2 if an individual did not satisfy the alternative in Year 1. For example, the Preamble says that with respect to tobacco programs, the plan may require an educational seminar in Year 1 as the alternative standard, and if that does not work, can require a different alternative, such as nicotine replacement therapy, in Year 2. However, the agencies state that plans must continue to offer a reasonable alternative standard, whether the same or different, as long as the alternative continues to be a Health-Contingent standard (thus, it appears that the only way for a plan not to have to offer a further alternative would be ultimately to have a Participatory alternative standard.)

In addition, the final rules adopt guidelines for what would be a "reasonable" alternative. The guidelines are largely the same as those in the proposed rules with a new guideline that the "time commitment" required for the alternative also must be reasonable.

Reasonable Alternative – Doctor's Verification

The final rules removed the language from the proposed rules that suggested that if a person's condition was obvious (such as from prior claims), a doctor's verification was not permitted. Instead, the final rules provide that a doctor's verification only is permitted under the Activity-Based medical reasonable alternative. Requiring a doctor's verification would not be allowed under the Outcome-Based reasonable alternative approach, as this alternative is required to be available to anyone who fails the standard, so the agencies point out that there would be no need for a doctor's verification.

	HEALTH-CONTINGENT WELLNESS PROGRAMS	
	Activity-Based	**Outcome-Based**
#4 Reasonable Alternative	Medical Reasonable Alternative Only • Must provide alternative for individuals for whom it is unreasonably difficult due to a medical condition to satisfy standard or medically inadvisable to attempt to satisfy standard	**NEW!** Reasonable Alternative Required for All • Must provide alternative for "any individual" who does not meet the initial standard based on a measurement, test, or screening that is related to a health factor • Alternative required regardless of medical condition
Guidelines for Reasonable Alternative	Not required to determine alternative in advance, may determine upon request by individual. May decide to waive medical standard altogether (rather than determine alternative) **NEW!** Based on all facts and circumstances, with following guidelines: • If alternative is completion of educational program, plan must make program available or assist employee in finding program (instead of requiring individual	Same

	HEALTH-CONTINGENT WELLNESS PROGRAMS	
	Activity-Based	**Outcome-Based**
	to find program unassisted). Plan may not require employee to pay for cost of program. • If time commitment required, must be reasonable (example: requiring nightly attendance at one-hour class would be unreasonable). • If alternative is diet program, plan must pay any membership or participation fee (not required to pay for food). • If individual's personal physician says plan standard is not medically appropriate for individual, plan must provide alternative that accommodates recommendations of personal physician. Plan may impose cost sharing for medical items or services furnished pursuant to physician's recommendations.	
Doctor's Note Allowed?	Yes – if reasonable under circumstances, plan may seek verification from individual's personal physician that health factor makes it unreasonably difficult or medically inadvisable to satisfy Activity-Based wellness program. Reasonable under circumstances if medical judgment required to evaluate validity of request for alternative.	No – since alternative for Outcome-Based standards must be provided to all who fail test (regardless of health reason). But if alternative is Activity-Based, go back to Activity-Based column, where doctor's note may be allowed.

<u>If Alternative Itself if Activity-Based or Outcome-Based . . .</u>

NEW! The tricky part comes when the alternative chosen is Health-Contingent as well. Plans must decide whether the alternative is Activity-Based, in which case they must run through the same analysis above and may need to offer a medical reasonable alternative, or Outcome-Based, in which case they may need to provide a second alternative to anyone who fails the standard.

In addition, the agencies provide new "Special Rules" where the alternative is another Outcome-Based standard, including that an individual then can request to just follow his or her doctor's orders to satisfy the alternative and earn the reward. The agencies said that these "Special Rules" are intended to "prevent a never-ending cycle of reasonable alternative standards being required by plans," while also ensuring that the ultimate alternative is, "in fact, reasonable" based on the judgment of the individual's personal physician.

	HEALTH-CONTINGENT WELLNESS PROGRAMS	
	Activity-Based	**Outcome-Based**
NEW! **If Alternative Standard is Activity-Based or Outcome-Based Itself**	• If alternative is a second Activity-Based standard, must start at top of Activity-Based column and may need to offer another alternative due to medical reasons. Example: If Activity-Based standard is to run 3 miles, and individual has medical reason cannot run, may set alternative as Activity-Based standard of walking twice a week. If individual also cannot walk due to medical reasons, would need third alternative. • If alternative is Outcome-Based, run through analysis in Outcome-Based column to determine whether additional alternative needed.	• If alternative is Activity-Based, run through analysis in Activity-Based column to determine whether additional alternative needed. • If alternative is second Outcome-Based standard, must start at top of Outcome-Based column and may need to offer another alternative, plus two special rules below. **Special Rules if Alternative is Also Outcome-Based:** • If alternative is to meet different level of same standard, must give additional time to comply. Example: If standard is BMI, and alternative is BMI that is easier to reach, must give realistic time to reach, such as within year. Individual then earns same reward as if met initial standard (so plan may need to pay reward retroactively). • Must allow individual to request that alternative will be to comply with recommendations of personal physician (if personal physician "joins in"). Individual can make request at any time, and personal physician can adjust recommendations at any time, consistent with medical appropriateness.

#5 NOTICE OF REASONABLE ALTERNATIVE

As in the proposed rules, the plan must disclose in all plan materials describing the program the availability of the reasonable alternative standard to qualify for the reward or the possibility of a waiver of the otherwise applicable standard. **NEW!** The final rules require that this disclosure also include contact information and a statement that an individual's personal physician will be accommodated.

The Preamble provides that if plan materials merely mention that a program is available without describing the terms, the disclosure is not required, such as in the Summaries of Benefits and Coverage (SBCs). However, the Preamble states that a plan disclosure that references a premium differential based on a wellness program, such as tobacco use or the results of a biometric exam, would be considered a disclosure describing the terms of a wellness program and must include the notice language.

NEW! The final rules also update the sample language for the notice:

> "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, with your doctor) to find a wellness program with the same reward that is right for you in light of your health status."

	HEALTH-CONTINGENT WELLNESS PROGRAMS	
	Activity-Based	**Outcome-Based**
#5 **Notice of Reasonable Alternative**	• Must disclose in all plan materials describing wellness program the availability of reasonable alternative to earn reward or waiver of standard • **NEW!** Must include contact information and statement that recommendations of individual's personal physician will be accommodated • **NEW!** Updated sample language	Same **NEW!** Also must include in any disclosure to individual that he or she did not satisfy Outcome-Based standard (such as in screening results)

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All plans that have wellness programs or any type of incentive or reward program, such as for exercise, tobacco cessation, biometric screenings, health fairs, case management, coaching, weight loss, and nutrition should review these rules and make sure their programs are in compliance before January 1, 2014. Under the ACA, noncompliant programs could be subject to penalties under the Internal Revenue Code and Public Health Service Act of up to $100 per day. Noncompliant programs also could be subject to enforcement actions under ERISA, where the Department of Labor has been specifically asking about these programs in their routine health plan audits.

While the basic structure of these programs remains the same, there are significant changes, particularly related to when alternatives must be offered. Many plans will want to offer wellness programs to encourage healthier behaviors, control plan costs, and to possibly boost credits under the minimum value or affordability rules under the ACA (which have their own strict requirements as to when wellness program incentives can be counted). The time to start planning is now.