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[Note that the following is only a general summary of a rather complex area of the law. Naturally, it should not be relied on as legal advice for any particular situation, but instead is a starting point for further discussion.]

EMPLOYEE WELLNESS PROGRAMS – AN OVERVIEW OF THE LEGAL ISSUES

I. THE HIPAA NONDISCRIMINATION RULES.

When HIPAA Nondiscrimination Issues Arise. HIPAA nondiscrimination issues must be considered if a wellness program is offered (a) in connection with a health plan and (b) the program imposes either (1) a financial penalty or (2) a loss of eligibility under the health plan for failing to participate.

What the HIPAA Nondiscrimination Rules Say. The HIPAA nondiscrimination rules prohibit discrimination, with respect to either cost or eligibility, based on any one the following "health factors:"

-health status,
-medical condition,
-claims experience,
-receipt of health care,
-disability,
-medical history,
-evidence of insurability and
-genetic information.

In the view of the regulators, these HIPAA nondiscrimination rules are broad enough to prohibit wellness programs offered in connection with health plans that might affect cost or eligibility. Fortunately, the regulators have created exemptions that permit these types of wellness programs in some cases (discussed below).

HIPAA Eligibility Discrimination. If the penalty for failing to participate in a HIPAA-governed wellness program is not a financial penalty under the plan but is instead a loss of eligibility for some or all benefits under the plan, no exceptions are available and the wellness program will violate the HIPAA nondiscrimination rules. (Note, however, eligibility can be contingent on completion of a health risk assessment, provided the information is not used to deny, restrict, or delay eligibility or benefits, or to determine individual premiums.)

"Benign Discrimination" - The rules expressly permit discrimination in favor of people with adverse health factors. For example, if someone who is identified as having diabetes is offered lower copayments for office visits (or some other reward that is not normally available to all participants under the plan) in return for participating in a disease management program, that type of discrimination would not violate the nondiscrimination regulations so that program would not need to satisfy the requirements for one of the exemptions discussed below. (Note, however, the regulators' "creative" view of what is and is not benign, as exemplified on their position on opt-out bonuses to high claims individuals.)

The Exemptions in the HIPAA Nondiscrimination Rules for Certain Wellness Programs.

(a) Participatory Wellness Programs – The rules use this term to describe wellness programs that do not offer any financial or eligibility incentive for participating and do not impose any financial or eligibility penalty for not participating. The regs provide that Participatory Wellness Programs do not violate the HIPAA nondiscrimination rules if they meet a single requirement; namely, participation in the program is available to all similarly situated (e.g., employees versus spouses versus children) individuals regardless of health status.

Examples of Participatory Wellness Programs (from the final regulations) that do not violate the HIPAA nondiscrimination rules if they are available to all similarly situated individuals regardless of health status include:

-A program that pays for part or all of the cost of a fitness center membership;
-A "diagnostic testing program" that provides a reward for participating without regard to any test results;
-A program that encourages preventive care by waiving copay requirements;
-A program that pays the cost of a tobacco cessation program or provides a reward for participating without regard to whether the participant stops smoking.
-A program that provides a reward to employees for attending a free monthly health education seminar.
-A program that provides a reward for completing a health risk assessment without regard to any results of the HRA.

(Employers should note that some of the rewards described in these examples would be considered taxable compensation subject to income and payroll tax withholding.)

(b) "Health-Contingent Wellness Programs" – The rules use this term to describe HIPAA-covered wellness programs that make avoiding a penalty contingent on satisfying some standard relating in any way to a health factor. For example, if a plan imposes a penalty for failing to lower cholesterol to a certain level, it is a Health-Contingent Wellness Program. In addition, in the view of the regulators, even imposing a penalty for merely failing to participate in a disease management program is a Health-Contingent Wellness Program, if the disease management program identifies its participants based on specific identified health conditions.

The rules further divide Health-Contingent Wellness Programs into "activity-only wellness programs" and "outcome-based wellness programs". Each of these types of programs is subject to specific requirements under the regulations to enjoy an exemption from the nondiscrimination rules.

-Activity-Only Programs: An activity-only wellness program "requires an individual to perform or complete an activity related to a health factor in order to obtain a reward but does not require the individual to attain or maintain a specific health outcome."

Examples from the regulations include walking, diet or exercise programs. The regulators take the position that these programs discriminate based on a health factor because some people may not be able to participate due to a health factor, such as health condition or disability.

-Outcome-Based Programs: An outcome-based wellness program is one that "requires an individual to attain or maintain a specific health outcome (such as not smoking or attaining certain results on biometric screenings) in order to obtain a reward."

The regulations note that a program that offers a choice between satisfying an "initial standard" relating to a health factor (such as maintaining a healthy cholesterol level) and some alternative method of qualifying for an incentive (such as participating in a nutrition education program designed to help people with higher cholesterol levels lower their cholesterol) is an outcome-based wellness program because a health factor can make it harder to qualify for the incentive (e.g., someone with a high cholesterol level must take the test and then participate in the education program to qualify, while someone with a low cholesterol only has to take the test).

- Requirements for Health-Contingent Wellness Programs - To comply with the HIPAA nondiscrimination regulations, a health-contingent wellness program must satisfy the following requirements. The basic requirements are the same for activity-only programs and outcome-based programs but the rules regarding offering a reasonable alternative standard are more detailed for an outcome-based program than for an activity-only program.

-The program must be reasonably designed to promote health or prevent disease. To satisfy this requirement, the program must have a reasonable chance of improving health or preventing disease, the program cannot be overly burdensome and it cannot be a subterfuge for discriminating based on a health factor.

-The reward for participating in the wellness program coupled with any other rewards under other health-contingent wellness programs under the plan, must not exceed 30% of the cost (this means the total employee plus employer cost) of employee-only coverage under the plan (if the program applies to spouses and dependents as well, this is modified so that the reward for the whole family is limited to 30% of the cost of the type of coverage the employee is actually

enrolled in, such as employee plus spouse or family coverage). For wellness programs that are designed to discourage tobacco use, the maximum incentive is 50% rather than 30%.

-Anyone eligible for the program must be given the opportunity to qualify for the reward at least once each plan year.

-There must be a reasonable alternative method of qualifying for the reward. For an activity-based program, this reasonable alternative must be available for any person for whom it is medically inadvisable or unreasonably difficult because of a medical condition to qualify for the reward. For an outcome-based program, this reasonable alternative must be available to anyone who does not meet the initial standard based on a measurement, test, or screening (such as a cholesterol test or a blood pressure screening or a non-smoking requirement). Note that a waiver of the initial standard for the reward qualifies as a reasonable alternative.

-The availability of a reasonable alternative method of qualifying for the reward must be mentioned in all plan materials that describe the terms of the health-contingent wellness program, including contact information for requesting a reasonable alternative and a statement that recommendations of an individual's personal physician will be accommodated. (This disclosure is not required in materials that merely mention the wellness program is available.) For an outcome-based program, this disclosure also must be provided with any notice that an individual did not satisfy an initial outcome-based test or measurement, such as a biometric screening. The disclosure does not have to explain what the reasonable alternative is, but it must say that an alternative is available and that the employer will work with the individual to provide an alternative. The regulations provide the following sample language that may be used for this purpose:

"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."

The above requirements are fairly straightforward except for the "reasonable alternative" requirement. There are detailed requirements in the regulations for determining what may qualify as a reasonable alternative, particularly for outcome-based programs. Whether an alternative is reasonable depends on all the facts and circumstances but there are some guidelines or examples in the regulations including the following:

-If the reasonable alternative standard is completing an educational program, the plan must make the program available or help the employee find it and may not require the employee to pay for the cost of the program.

-The time commitment required must be reasonable (for example, requiring attendance nightly at a one-hour class would be unreasonable).

-If the reasonable alternative standard is a diet program, the plan is not required to pay for the cost of food but must pay any membership or participation fee.

-If an individual's personal physician states that a plan standard is not medically appropriate for that individual, the plan must provide a reasonable alternative that accommodates the recommendations of the individual's personal physician (but the plan would not necessarily be required to pay for any treatment or service the plan would not otherwise normally cover).

As a condition for qualifying for a reasonable alternative standard for qualifying for an incentive, for activity-based wellness programs, if it is reasonable under the circumstances, a plan can require an individual to provide a statement from a physician or similar reasonable documentation that it is medically inadvisable or unreasonably difficult because of a medical condition for the individual to qualify for the reward without a reasonable alternative.

For an outcome-based program, it is not reasonable to require a physician's statement as a condition for qualifying for the reasonable alternative standard. It is enough that the individual failed to satisfy the initial test or measurement. For example, anyone who uses tobacco must be allowed to qualify for the incentive by participating in a reasonable alternative without having to provide a statement from a physician.

II. Americans with Disabilities Act. Of course, wellness programs, like other employee benefits generally are subject to the ADA and cannot discriminate against employees based on disabilities. That normally is not an issue for typical wellness programs. However, one ADA requirement has caused issues for many types of wellness programs. That provision generally prohibits employers from "requiring" employees to submit to medical exams or to answer disability-related questions. There is an exception for voluntary wellness programs. However, until recently, the EEOC took the position that a wellness program offered under an employer's health plan might not be considered voluntary if it provided a financial incentive, such as a premium discount, for participation, but they provided no guidance on how employers might design their wellness programs to avoid a potential ADA violation.

Fortunately, proposed regulations issued by the EEOC in April 2015, and then final regulations issued by the EEOC on May 17, 2016, eliminated much of the uncertainty about this issue. Under the final regulations, a wellness program that offers an incentive for participation that complies with the HIPAA wellness program requirements generally will also comply with the ADA rule as well, as long as some additional requirements are satisfied, including the following:

--A notice must be provided to participants that describes any medical information that will be obtained and how that information will be used and that describes restrictions that apply to the use and disclosure of that information. The EEOC has provided a sample notice that satisfies these requirements. See: https://www.eeoc.gov/laws/regulations/ada-wellness-notice.cfm

--Information received must be treated as confidential (compliance with HIPAA privacy requirements generally will be adequate for wellness programs that are part of a health plan; no waiver of this requirement is permitted).

--The program must be voluntary with no penalties (other than permitted incentives that comply with the rules described below) or retaliation for failing to participate.

--The maximum incentive for participating in the program and any other wellness programs (that require medical exams or answers to disability-related questions) cannot exceed 30% of the total cost of employee-only coverage (but see GINA, and possibly ADA, clarification below).

The most significant differences between the EEOC rules and the HIPAA requirements involve the limits on the size of the potential penalty.

First, if the EEOC rules apply, the incentive is always limited to 30% of the cost of employee-only coverage (there are special rules for determining this cost), while the HIPAA rules apply the incentive to be up to 30% of the total cost of coverage in which the employee is enrolled, if the program depends on participation by other covered family members. Note that, on May 17, 2016, the EEOC also issued final rules (previously proposed on October 30, 2015) under GINA that prohibits any incentive for the completion of an HRA by the employee or the employee's children, but permits the incentive for the completion of an HRA by the employee's spouse, if the spouse is eligible for the wellness program benefits. Under the May 17, 2016 EEOC final rules, these limits on incentives apply beginning in 2017.

Also, the EEOC limits, unlike the HIPAA limits, can apply to purely participatory programs. For example, an incentive for completing an HRA does not raise any HIPAA non-discrimination issues so it would not be subject to the 30% limit that applies under HIPAA to health-contingent wellness programs. However, that HRA almost certainly includes some disability-related questions, so the requirement to complete the HRA to receive the incentive does raise this ADA issue. That means that any HRA incentive (which, under GINA is only permitted for the spouse's completion of the HRA) would have to be included with any other wellness program incentives that are subject to the EEOC's rules to determine if that 30% total limit is satisfied.

The EEOC rules do not include any special provisions, such as the 50% limit on incentives, for tobacco-related wellness programs. However, a tobacco-related wellness program that does not require any medical exams and does not require participants to answer disability-related questions is not subject to the EEOC rules, so the 50% incentive limit that applies under HIPAA can still apply as long as the program avoids asking any disability-related questions or requiring any tests that would cause the EEOC rules to apply. In particular, note that a program that requires participants to submit to blood test to detect nicotine would be enough to implicate the EEOC rules while a program that relies on affidavits from participants about their use of tobacco would not (assuming there are no other tests or disability-related questions).

It is important to remember that the EEOC's rules do not apply to wellness programs that are strictly voluntary and do

not impose a penalty for failure to participate (or incentive for participating) or to programs that do not require employees to answer any disability-related questions or to submit to medical tests or exams. That means there are some wellness programs that will be subject only to the HIPAA rules, some that are subject to only the EEOC's ADA rules and others that are subject to both or neither of those sets of rules.

December 31, 2015, EEOC v. Flambeau, Inc. (US District Ct. Western District of Wisconsin) held that ADA "bona fide benefit plan" safe harbor allowed Wellness Program to require HRA and a biometric screening as a condition of enrollment. The May 17, 2016 EEOC final rules reject this conclusion.

III. Genetic Information Nondiscrimination Act. GINA protects job applicants, current and former employees, union members and apprentices, and trainees, and prohibits employers (and other covered entities) from using genetic information in making employment decisions. With limited exceptions, GINA prohibits employers from requesting "genetic information" or requiring genetic tests from the employee and from the employee's spouse and children. There is an exception for voluntary wellness programs (as long as they include a statement that any genetic information requested will not be used for "underwriting purposes" as broadly defined under GINA). Until recently, the EEOC took the position that, if there was any reward for participating in the wellness program, participation would not be considered voluntary for purposes of GINA. For example, if a health risk assessment included any request for genetic information, including questions about the employee's family medical history, providing any financial incentive for completing the assessment would violate GINA. On May 17, 2016, the EEOC issued final rules (previously proposed on October 30, 2015) under GINA that prohibits any incentive for the completion of an HRA by the employee or the employee's children, but permits the incentive for the completion of an HRA by the employee's spouse, if the spouse is eligible for the wellness program benefits. The EEOC's description of the final rules states that the final rules are designed to make the rules under HIPAA, ADA and GINA consistent with respect to the incentives that can be provided under a wellness program that is part of the employer's group health plan. However, there are still some significant differences. The final rules under GINA state that the employer must obtain the prior, written, knowing and voluntary consent of the employee (and spouse, if spouse's information is requested) before obtaining the genetic information. The final rules apply to all wellness programs that request genetic information, even if the wellness program is not offered under a group health plan. Finally, the final rules prohibit any request for any genetic information about the employee or the employee's children as a condition of obtaining any incentives.

Genetic information for any individual includes information about: his or her genetic tests or the genetic tests of family members; the manifestation of a disease or disorder in family members (i.e., family medical history); or any request for, or receipt of, genetic services, or participation in clinical research that includes genetic services, by the individual or any family member.

IV. Federal Employment Discrimination Laws. Various other federal employment discrimination laws, including Title VII of the Civil Rights Act, the Age Discrimination in Employment Act and the Pregnancy Discrimination Act require that employee benefits be provided in a manner that does not improperly discriminate based on characteristics such as race, sex, national origin, age or pregnancy. Of course, health plans and wellness programs normally are not designed to intentionally violate these laws but some features of a plan or program may raise discrimination issues.

V. Affordable Care Act. The Affordable Care Act imposes a number of requirements on employer-sponsored medical plans. Changes in the design of medical plans and wellness programs should always be reviewed to determine if they raise any issues under the ACA. For example, for a grandfathered medical plan, increasing cost-sharing requirements based on wellness program participation may cause the plan to lose its grandfathered status. Increased costs may also affect whether the plan qualifies as affordable or as minimum value coverage for purposes of the employer mandate rules that impose penalties on employers with at least 50 full-time equivalent employees who do not offer affordable, minimum value coverage to their full-time employees. (Generally, wellness program tobacco penalties are ignored for affordability test purposes, while non-tobacco penalties are treated as imposed.)

VI. Recommendations. If Wellness Program requires health risk assessment or medical exam for participation, provide no incentive for employee/children and limit incentive/penalty for spouse information to 30% or less of employee only coverage cost. Example, a tobacco related Wellness Program imposes a 50% penalty for failing to participate. Program relies on affidavit from the individual about tobacco use and does not ask any other questions for participation. GINA and ADA are N/A and complies with HIPAA. However, if same program relies on blood test to detect nicotine, GINA and ADA apply. Do not rely on Flambeau, Inc. decision, unless directly applicable. Wait for controlling court decision or comply with EEOC final rules.