

Designing a Compliant Wellness Program

January 2019

Benefits &
Human Resources
Consulting



Insurance | Risk Management | Consulting



Contents

Section 1 – Introduction.....	1
Section 2 – Determining Wellness Program Type	3
Section 3 – Summary of Potentially Applicable Key Laws.....	6
Section 4 – General Educational & Participatory Programs that are not Health Plan-Related.	7
A. Educational Wellness Programs.....	7
B. Participatory Programs that are Not Health Plan-related	7
C. Wellness Programs as Health Plans	8
D. Additional Requirements for Programs that Include a Health Risk Assessment.....	9
E. Rules for All Participatory Programs.....	13
Section 5 – Health Plan-related participatory Programs.....	16
A. HIPAA Nondiscrimination.....	17
B. HIPAA Privacy and Security	17
C. Mental Health Parity and Addiction Equity Act (“MHPAEA”)	18
D. Patient Protection and Affordable Care Act (“PPACA”).....	18
E. Tax Rules for Rewards	20
F. Other Federal Laws	22
Section 6 – Health Plan-Related Activity-Only Programs.....	30
A. HIPAA Nondiscrimination.....	31
B. HIPAA Privacy and Security	36
C. Mental Health Parity and Addiction Equity Act (“MHPAEA”)	37
D. Patient Protection and Affordable Care Act (“PPACA”).....	38
E. Tax Rules for Rewards	39
F. Other Federal Laws	41



Section 7 – Health Plan-Related Outcome-Based Programs	49
A. HIPAA Nondiscrimination.....	50
B. HIPAA Privacy and Security	56
C. Mental Health Parity and Addiction Equity Act (“MHPAEA”)	56
D. Patient Protection and Affordable Care Act (“PPACA”).....	57
E. Tax Rules for Rewards	59
F. Other Federal Laws	60

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.

SECTION 1 – INTRODUCTION

Wellness programs come in many different shapes and sizes and may be called something other than a wellness program. 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 don't apply) is largely determined by the type of program. There are four common types of employer-sponsored wellness programs:

- (1) General educational or participatory & not health plan-related
- (2) Participatory & health plan-related
- (3) Activity-only & health plan-related
- (4) Outcome-based & health plan-related

In describing wellness programs, we refer to rewards that many programs provide for employees who participate in the program or achieve certain outcomes. For example, an employee who completes a health risk assessment questionnaire may receive a 5% reduction in required health plan contributions. Other wellness programs use penalties rather than rewards. For example, a wellness program may include a 10% smoker surcharge. Regulators have made it clear in the regulations that the same rules apply to both rewards and penalties. We use the word “reward” in this discussion guide to include both a positive incentive (reward) and a disincentive (penalty or no reward).

Type 1 – General Educational or Participatory and not Health Plan-Related

General educational or informational programs are designed to provide general health information to employees and sometimes their families. They are voluntary programs that just make information available without requiring the employee to access the information or engage in an activity. These programs are general in nature – they are not individualized and do not provide any medical care.

Participatory programs that are not health plan-related are designed to promote healthy lifestyle choices among employees and sometimes family members, but they go beyond just providing information. They include some type of health-related activity, but are either purely voluntary with no reward or have a reward that is not tied to a health plan.

The good news for these types of plans is that they are subject to fewer federal employment and benefits laws.

Type 2 - Health Plan-Related Participatory Programs

These programs are participatory since they require participation in a health related activity, but don't tie the reward to the results of participation. They are health plan-related since they are limited to employees enrolled in the employer's health plan. Several federal employment and benefits laws apply to these types of programs with more requirements applicable to programs that involve provision of health care (such as a biometric screening).

Type 3 – Health Plan-Related Activity-Only Programs

These programs are activity-only since they require the individual to complete a specific activity in order to receive the reward. They are health plan-related since they only apply to individuals enrolled in the employer's health plan. Additional federal employment and benefits laws apply to these types of programs.

Type 4 – Health Plan-Related Outcome-Based Programs

These programs base the reward on either the existence of a particular health condition or the results of a test such as a biometric screening and the reward is tied to participation in a health plan. These programs are outcome-based since they require the individual to satisfy a health-related standard in order to receive the reward. They are health plan-related since they only apply to employees enrolled in the employer's health plan. Additional federal employment and benefits laws apply to these types of programs. Rules for these programs – especially under HIPAA and PPACA – are more stringent than for other types of wellness programs.

Determining Wellness Program Type and Rules

In the sections that follow we review the rules as they apply to these common types of wellness programs. Section 2 includes a questionnaire that may help you to determine which type of wellness program you have in place (or are considering implementing). Rules for general educational programs along with participatory programs that are not related to the employer's health plan are discussed in section 4. Health plan-related programs are discussed in sections 5 through 7 with participatory programs in section 5, activity-only in section 6, and outcome-based in section 7. Each of these three sections is designed to operate on a stand-alone basis. For example, section 4 describes the rules that apply to an educational program or a participatory program not related to the employer's health plan, but doesn't include the rules that apply to other types of wellness programs. Section 5 covers the rules for activity-only programs. As a result, an employer with a health plan-related wellness program that is participatory need only review the rules in section 5.

SECTION 2 – DETERMINING WELLNESS PROGRAM TYPE

The questionnaire below is intended to help you determine which type of wellness program (or programs) you have in place or are considering implementing.

#	Question	Yes	No
1	<p>Is your wellness program limited to general information with no reward included?</p> <p>General educational programs give employees (and sometimes family members) information about health related issues such as healthy eating habits or the benefits of regular exercise. These programs do not include a reward for participation. Examples include:</p> <ul style="list-style-type: none"> • Workplace posters with tips on how to avoid catching a cold or getting the flu. • Newsletters with articles on the benefits of healthy eating or general nutritional information. • Lunch-n learn sessions on health related topics. • Healthy food choices in vending machines or cafeterias. 	This is a general educational program – see Section 4	Go to question #2
2	<p>Is your wellness program limited to participation in certain health related activities with no reward for participating?</p> <p>Some wellness programs do more than provide general health-related information. They involve some type of participation by employees (and sometimes family members), but do not include a reward for participating. Examples include:</p> <ul style="list-style-type: none"> • An exercise bicycle or treadmill available to employees at lunch, before work, or after work • A walking program at lunch time that employees can join (or not join) • Individualized health coaching • Individualized exercise plan • Individualized healthy eating plan 	This is a participatory program not related to a health plan – see Section 4	Go to question #3
3	<p>Is your wellness program limited to participation in certain health related activities with a reward for participating that is not linked to your health plan and is not itself a health plan?</p> <p>Some wellness programs require participation by employees (and sometimes family members) to</p>	This is a participatory program not related to a health plan – see Section 4	Go to question #4

#	Question	Yes	No
	<p>obtain a reward, but the reward is not related to the employer's health plan. Examples include:</p> <ul style="list-style-type: none"> • A \$20 gift card for attending a smoking cessation class. • A tee shirt for attending an educational class. • A \$50 gift certificate for completing a health risk questionnaire not limited to employees enrolled in the employer's health plan. • Reimbursement of some of the cost of membership in a health club or gym not restricted to employees eligible for the health plan. 		
4	<p>Does your wellness program provide a reward based on participation in certain health related activities regardless of results with a reward for participating that is tied to your health plan or is itself a health plan?</p> <p>Some wellness programs require employees (and sometimes family members) to participate in order to receive a reward, and the reward is linked to the employer's health plan. The reward is provided just for participating regardless of the results. Examples include:</p> <ul style="list-style-type: none"> • A reduction in the employee's health plan contribution for completing a health risk assessment questionnaire, regardless of the results. • A deductible credit for participating in biometrics such as having blood pressure taken or a cholesterol level checked, regardless of the results. • A premium holiday for enrolling in a tobacco cessation program whether or not the individual stops using tobacco. • Waiver of copayments for pregnant women who obtain pre-natal care. 	<p>This is a participatory program related to a health plan – see Section 5</p>	<p>Go to question #5</p>
5	<p>Does your wellness program provide a reward based on completion of a specified activity with the reward linked to a health plan?</p> <p>Some wellness programs require employees (and sometimes family members) to complete an activity in order to earn a reward and the reward provided is linked to the health plan. Examples include:</p>	<p>This is a activity-only program related to a health plan – see Section 6</p>	<p>Go to question #6</p>

#	Question	Yes	No
	<ul style="list-style-type: none"> • A walking program that provides a reduction in the employee's health plan contributions if the employee walks at least 30 minutes every day • A reduction in the employee's health plan contribution based on a specified dietary change such as reducing salt consumption. 		
6	<p>Does your wellness program provide a reward that is based on a health factor such as the results of a biometric test or certain health conditions such as meeting a specific biometric test result and the reward is linked to your health plan?</p> <p>Some wellness programs require employees (and sometimes family members) to satisfy a health-related standard and offer a reward that is tied to a health plan based on a health factor, such as the results of a biometric test or a health condition such as meeting a specific biometric condition. Examples are:</p> <ul style="list-style-type: none"> • A reduction in the employee's health plan contribution if the employee has a body mass index below 30. • A reduction in the employee's health plan contribution if the employee's total cholesterol count below 200. • An increase in the employee's health plan contribution if the employee uses tobacco products. 	This is an outcome-based program related to a health plan – see Section 7	Go to question #7
7	If your wellness program does not fit into any of the above categories, a review of the details of the program design will be needed to determine which federal rules may apply.	Individual review of your wellness program needed.	

NOTE: Wellness programs designed to reduce tobacco use are generally outcome-based programs. If the program provides a reward for attending a smoking cessation class regardless of whether the individual does not smoke or stops smoking, it would be participatory. Otherwise, it is probably outcome-based. Section 7 covers the rules for outcome based wellness programs.



SECTION 3 – SUMMARY OF POTENTIALLY APPLICABLE KEY LAWS

	PPACA	HIPAA Non-discrimination	HIPAA Privacy & Security	ERISA	COBRA	ADEA	ADA	Title VII	FLSA	GINA	Tax Laws	Tax Code Non-discrimination	Cafeteria Plan
General Education & Non-Health Plan and Non-Health Plan-Related Participatory (Section 4)						X	If medical examination or disability-related inquiry included	X	X	If HRA offered	X		
Health Plan-Related Participatory (Section 5)	X	If provides medical care	X	X	X	X	If HRA offered	X	X	X			
Health Plan-Related Activity Only (Section 6)	X	If provides medical care	X	X	X	X	If HRA offered	X	X	X			
Health Plan-Related Outcomes-Based (Section 7)	X	X	X	X	X	X	X	X	X	X	X	X	X

Note: the Mental Health Parity and Addiction Equity Act (“MHPAEA”) may apply to health plan-related wellness programs since nicotine addiction is considered to be a substance use disorder that is subject to the parity rule under MHPAEA.

SECTION 4 – GENERAL EDUCATIONAL & PARTICIPATORY PROGRAMS THAT ARE NOT HEALTH PLAN-RELATED

General educational programs that are designed to provide general health-related information to employees (and sometimes family members) are considered to be participatory programs, unrelated to the health plan. They are voluntary and just make health information available. Participatory programs are designed to promote healthy lifestyles and healthy choices, but not provide individualized health care. Some participatory programs are purely voluntary with no rewards. Others have a reward for participation, but the reward is not related to the employer's health plan and the wellness program itself is not a health plan.

A. Educational Wellness Programs

These programs just provide general health information to employees and often family members. They are purely voluntary with no requirement to participate and no reward. Examples of educational and information programs:

- Workplace posters with tips on how to avoid catching a cold or getting the flu
- Newsletters on the benefits of healthy eating or regular exercise
- Lunch-n-learn sessions on health-related topics
- Healthy food choices in vending machines and/or the cafeteria

Since these programs are limited, they are generally subject to few federal requirements.

B. Participatory Programs that are Not Health Plan-related

These programs do more than just provide general health-related information. They involve participation on the part of employees, and in some cases family members. They either do not provide a reward or provide a reward that is not related to an employer's health plan and the wellness program itself is not a health plan.

Examples of participatory programs that do not have a reward:

- An exercise bicycle or treadmill available for employee use during lunch or other work breaks
- A walking program at lunch time that employees are free to join (or not join)
- Health coaching, exercise plan or healthy eating plan (by non-healthcare professional)

Examples of participatory programs that provide a reward:

- A T-shirt for attending an educational class or seminar
- A \$25 gift card for attending a smoking cessation class

- A \$50 gift card for completing a health risk assessment questionnaire that is offered to employees regardless of whether or not the employee is eligible for the health plan. It could be open to all employees, all full-time employees, or all employees at a specified location
- Reimbursement of some of the cost of a health club or gym membership regardless of whether or not the employee is eligible for your health plan
- A \$100 gift card for the winner of a “biggest loser” contest

C. Wellness Programs as Health Plans

Some wellness programs include services that qualify as “medical” care and may need to comply with additional requirements. A wellness program involves “medical care” if the care is individualized and provided by trained professionals. “Medical care” is defined to mean amounts paid for: (a) the diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body, (b) amounts paid for transportation primarily for and essential to medical care referred to in (a), and (c) amounts paid for insurance covering medical care referred to in (a) and (b). Because wellness programs are designed to prevent disease, they are often programs that provide individualized medical care. For example, flu shots, health coaching by a nurse, counseling by a therapist, or biometric screening would all be examples of medical care. A program that provides a newsletter with health related articles, a “lunch-n-learn” about diabetes, or a weight loss class without a personalized assessment would be informational rather than individualized medical care. Many employers who sponsor a wellness program that includes individualized medical care will link the wellness program to their health plan (usually major medical plan). For example, the reward might be a reduction in a medical deductible or an increase in a required medical plan contribution (penalty).

Other employers have a wellness **program** that is not tied to a health plan such as a major medical plan. The wellness program provides a reward, but the reward is separate from the employer’s regular health plan. For example, the program offers a \$30 gift card to any full-time employee who completes a health risk assessment including employees not enrolled in or even eligible for the employer’s major medical plan. However, if the wellness program provides medical care, the wellness program itself would be a health plan. Examples of medical care that may be provided by a wellness program are: annual flu shots, biometric testing such as a finger stick for glucose or cholesterol levels, and individualized health coaching by a healthcare professional. Wellness programs that provide medical care are health plans by themselves and are subject to the rules applicable to health plans – such as the HIPAA and PPACA nondiscrimination requirements. **If your wellness program provides medical care and is participatory, then the rules outlined in Section 5 would apply. If your wellness program provides medical care and is outcome-based, then the rules outlined in Section 7 would apply.**

NOTE: Wellness programs that provide rewards in the form of a contribution to an account that is related to a health plan such as a health reimbursement arrangement or a healthcare flexible spending account would be considered health plan-related programs rather than general educational programs. See Sections 5 through 7 for requirements.

D. Additional Requirements for Programs that Include a Health Risk Assessment

Additional requirements may apply to a participatory wellness program that is not health plan-related, but includes the use of a health risk assessment (“HRA”). An HRA is a method of determining who might benefit from a wellness (or disease management) program and identifying potential health-related areas of concern for specific individuals. An HRA may be a simple questionnaire, or it may be accompanied by biometric measurements such as blood pressure screening, body mass index calculation, cholesterol screening or testing blood glucose levels. Additional requirements under the ADA and GINA may apply to wellness programs that include an HRA.

Americans with Disabilities Act (“ADA”)

There are two areas of concern under the ADA with regard to wellness programs. First, the ADA prohibits employers from discriminating against individuals with disabilities. For example, a program that provides a reward based on a health condition may discriminate against individuals who have a disability. This may violate the ADA even if the program is designed so that it complies with the HIPAA nondiscrimination requirements. Second, the ADA limits when employers may make medical inquiries or conduct medical examinations. The EEOC issued final regulations in May 2016. ADA regulations apply to employees, former employees, and applicants; they do not apply to spouses or dependents.

The EEOC’s ADA regulations govern employer-sponsored wellness programs that include either disability-related inquiries or medical exams (including biometric screening). An HRA that includes disability-related inquiries would be subject to the EEOC rules even if the HRA is not subject to HIPAA due to the fact that it is not related to a health plan. For example, if an employer makes an HRA available to all employees including employees who are not eligible for the employer’s medical plan (e.g., part-time employees), then the wellness program would be subject to the ADA requirements. A program that includes biometric screening would be a health program subject to both the HIPAA and ADA rules. The ADA regulations require a wellness program to:

- (1) Be reasonably designed** – similar to HIPAA, the program must: (1) have a reasonable chance of promoting health or preventing disease; (2) not be overly burdensome; (3) not be a subterfuge for violating the ADA or other federal laws;

and (4) not be highly suspect in the methods chosen. A program that collects health information or uses tests or screening that does not provide results, follow up information, or advice designed to improve employees' health is not considered to be reasonably designed. For example, if a program does not use collected data to address at least a subset of conditions identified (either for individuals or a group of employees), or if the program exists mainly to shift costs to targeted employees based on health, or if it used simply to give the employer information to estimate future healthcare costs, then it is not reasonably designed.

(2) Be voluntary – employees may not be required to participate, employees may not be denied coverage under any of the group health plans or particular benefit packages within a group health plan based on non-participation, and employees may not be subject to any adverse employment action based on non-participation (e.g., termination of employment).

(3) Provide a notice – the program must provide a notice that: (1) is written so that employees are likely to be able to understand it; (2) clearly explains what medical information will be obtained and the purpose for which the medical information will be obtained; (3) identifies who will receive the medical information and how it will be used; and (4) states the restrictions on disclosures along with the methods that will be used to prevent improper disclosure.

The notice must describe the information to be collected, how the information will be used, with whom it will be shared, how it will be kept confidential, the restrictions on uses and disclosures, and the methods the employer has implemented to prevent improper disclosure of medical information. The EEOC posted a model notice along with several FAQs on its website – [click here](#) to access the model; [click here](#) to access the FAQs.

(4) Keep the information confidential – generally, the information may not be disclosed to an employee's supervisor or manager, individuals who handle medical information generally should not be responsible for making employment decisions, and a notification is required in the event of a breach. A participant may not be required to agree to the sale, exchange, sharing, transfer, or other disclosure of medical information in order to participate in the wellness program or receive an incentive.

(5) Provide reasonable accommodation –for employees if needed to access the wellness program – e.g., a sign language interpreter for a deaf employee or large print material for visually impaired employees.

In response to a court order, the EEOC issued guidance in December 2018 that removed a 30% maximum reward rule 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.

In the preamble to the final regulations, the EEOC expanded upon its interpretation of ADA's insurance safe harbor provision and reaffirmed its position that the insurance safe harbor is not available for wellness programs that include disability-related inquiries or medical examinations. This issue had been addressed by several courts prior to the issuance of these regulations and is likely to be the subject of additional litigation. Based on the EEOC's comments in the preamble (and concurrently issued FAQs), it is likely that the EEOC will continue to challenge employers who rely on the insurance safe harbor when designing their wellness programs. Employers that want to use the safe harbor when designing their wellness programs should discuss the EEOC's position and their program designs with legal counsel with appropriate experience before proceeding.

Genetic Information Nondiscrimination Act (“GINA”)

Employers are prohibited from discriminating against any employee with respect to the compensation, terms, conditions, or privileges of employment on the basis of “genetic information.” In general:

- Employers are not permitted to request, require or purchase genetic information,
- Employers must maintain genetic information as a confidential medical record, and
- Strict limits apply to the disclosure of genetic information.

Under the Genetic Information Nondiscrimination Act (“GINA”), genetic information is broadly defined to include family medical history. Thus, a wellness program that seeks genetic information in the form of family medical history for underwriting purposes violates GINA. Family is broadly defined to include relatives to the fourth degree (e.g., cousins once-removed) and relatives by marriage (e.g., spouse and in-laws).

GINA prohibits the collection of genetic information for underwriting purposes. A health plan may not collect genetic information in connection with enrollment and may not give a reward for providing genetic information regardless of when it is collected. Under the GINA regulations, a health plan that provides a premium reduction for employees who complete an HRA that includes questions about employee family history, violates GINA – even if the HRA is provided after enrollment – because completion of the health risk assessment results in a reduction of premium and is therefore considered to be for purposes of underwriting.

A health plan that includes completion of an HRA may still violate GINA even if there is no premium reduction for completing the assessment (or penalty for not completing it) if the assessment requests genetic information such as family medical history **if the assessment is obtained before coverage begins**. For example, an employer with a

calendar year plan conducts annual enrollment for the upcoming year during November. On December 5, after all elections have been made, the employer sends a health risk questionnaire that requests genetic information with instructions that the assessment must be completed and returned by December 31. The employer has violated the GINA requirements by collecting the information before the January 1 coverage effective date.

Because GINA defines “family member” to include a spouse, information about a spouse’s current medical conditions could be considered genetic information. As a result there was some concern that providing for completion of a HRA by a spouse – even if the HRA did not elicit information about genetic tests or services or about the spouse’s family medical history – would violate GINA if a reward was offered. The EEOC addressed this issue in final regulations issued in May 2016. Under EEOC’s final GINA regulations, if a spouse completes an HRA or undergoes biometric screening, then the wellness program may provide a reward subject to the following requirements:

- (1) The program must be reasonably designed to promote health or prevent disease; must not be overly burdensome; must not be a subterfuge for violating GINA or other laws; and must not be suspect in the method chosen. A wellness program that includes a test, screening or collection of health-related information without providing participants with results (which may be individuals or a group of employees or spouses), follow-up information, or advice designed to improve the participants’ health is not reasonably designed. In addition a program is not considered reasonably designed if it imposes a penalty on (or otherwise disadvantages) an individual because of a spouse’s manifestation of a disease or disorder by preventing or inhibiting the spouse from participating in, or from achieving a certain health outcome. In addition, the employer may not deny access to a group health plan or package of benefits based on a spouse’s refusal to complete a health risk assessment or undergo biometric testing.
- (2) The program must be voluntary - the spouse must provide knowing, voluntary, written authorization.
- (3) 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.
- (4) The spouse must be provided with a notice containing specific information. The 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 healthcare 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.

Unlike the HIPAA and PPACA rules, the EEOC's GINA rules limit incentives to 30% for all wellness programs – including those that are participatory programs – based upon the cost of self-only coverage.

In response to a court order, the EEOC issued guidance in December 2018 that removed a 30% maximum reward rule 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 GINA.

Under the EEOC's regulations, the wellness program may also include completion of health risk assessments or biometric screening for children, but the plan may not provide any incentive for completion of the HRA or biometric screening by children - including adult and adopted children.

E. Rules for All Participatory Programs

Following are summaries of federal laws that generally apply to participatory programs that are not related to an employer's health plan and are not themselves health plans.

Tax Rules for Rewards

Rewards that come in the form of cash (e.g., a cash bonus) or cash-equivalents (e.g., a gift card to a local restaurant) are taxable. If an employer provides a reward in the form of a cash card (e.g., a gift card for a restaurant or store) or cash, the reward results in taxable income to the employee and will be subject to wage withholding and employment taxes. For example, if an employer provides a \$50 gift card to a restaurant for all employees who complete a health risk assessment, each participating employee will have an additional \$50 of income subject to wage withholding and employment taxes.

Rewards such as certain employee discounts, T-shirts, mugs, and other rewards that qualify as *de minimis* fringe benefits under Internal Revenue Code Section 132 are not taxable to employees. Please note that the *de minimis* standard does not apply to cash rewards. For more information, refer to IRS Publication 15-B Employer's Tax Guide to Fringe Benefits. <http://www.irs.gov/publications/p15b/ar02.html>

In May 2017 the IRS provided guidance on certain wellness programs sometimes marketed as "fixed indemnity health plans." These programs are promoted as a way to provide certain benefits to employees at little or no cost to the employer and little or no cost to employees on a take-home pay basis. Under one design, employees are given the opportunity to enroll in coverage under a self-insured health plan. Employees who participate in the self-insured plan pay a small after-tax contribution. The self-insured health plan pays employees a fixed cash payment for participating in certain health-related activities such as calling a toll-free number that provides general health-related

information, attending a seminar that provides general health-related information, participating in a biometric screening, or attending a counseling session. Employees are not charged for participating in any of these activities which are described as a wellness program. The fixed payment that employees receive under the self-insured health plan for each covered activity (e.g., \$1,425 per activity) is much greater than the amount of the employee's after-tax contribution (e.g., \$60 per month) for participating in the self-insured health plan. Under an actuarial analysis, all employees are expected to receive benefit payments under the self-insured health plan that markedly exceed their after-tax contributions.

The IRS clarified that under this program, reimbursements to employees under the self-insured health plan are not excludable from income because the payments under this program do not reimburse covered individuals for expenses incurred for medical care. These reimbursements are merely lump sum payments made regardless of whether any medical care was received. Therefore, excess payments (e.g., a reimbursement of \$1,425 minus the employee's \$60 contribution which equals \$1,365) must be included in the employee's taxable income. Employers that have or are considering implementing one of these programs will want to discuss the IRS rules with an attorney with appropriate experience.

Age Discrimination in Employment Act (“ADEA”)

The ADEA prohibits employment discrimination against employees and job applicants on the basis of age with respect to benefits. Protected individuals must be at least 40 years of age. Thus, a wellness program could violate the ADEA if it terminated or decreased wellness rewards, or otherwise discriminated against employees age 40 or older.

Title VII

Title VII relates to the “terms, conditions, or privileges of employment,” which generally include wellness programs. Thus, if an employer takes into consideration a plan participant's race, religion, sex, color, or national origin, then the wellness program could violate Title VII.

Fair Labor Standards Act (“FLSA”)

Under the FLSA, nonexempt employees must be compensated at not less than time and one-half of regular pay for time worked over 40 hours in any given workweek. Thus, if time spent completing a wellness program is considered to be “compensable time,” then the employer may have to pay overtime. For example, if an employer provides health lectures as part of a wellness program, the time spent could be compensable time. However, the time need not be compensable time if four conditions are met: (1) attendance is outside of the employee's regular work hours; (2) attendance is purely



Insurance | Risk Management | Consulting

voluntary; (3) the lecture is not directly related to the employee's job; and (4) the employee does not do any productive work during the lecture (e.g., answering e-mails).

SECTION 5 – HEALTH PLAN-RELATED PARTICIPATORY PROGRAMS

Participatory health plan-related wellness programs are programs in which the reward is based on participating in the wellness program, and the reward is linked to the employer's health plan. The reward is not based on a health factor such as the existence of a specific medical condition or the results of a specific biometric test or completion of a specific activity. Examples of wellness programs that are related to an employer's health plan, but do not require a participant to complete an activity or meet a specific health-related standard, and thus are participatory, include the following:

- (1) Receiving a premium discount merely for completing a health risk assessment (regardless of the results)
- (2) Receiving a deductible credit merely for participating in biometrics such as having blood pressure taken or a cholesterol level checked (regardless of the results)
- (3) A premium holiday for enrolling in a smoking cessation program regardless of whether the individual stops smoking

Many of these programs include the use of a Health Risk Assessment ("HRA"). An HRA is a method of determining who might most benefit from a wellness (or disease management) program and identifying potential health-related areas of concern for specific individuals. An HRA can take the form of a simple questionnaire, and often, an HRA is accompanied by biometric testing (e.g., blood pressure screening, body mass index calculation, cholesterol screening, blood sugar level testing, etc.).

Tip: *Some programs with a reward based on an activity that were previously viewed as participatory programs under HIPAA, may now be activity-only programs. For example, if a wellness program uses a health risk assessment ("HRA") and based on the results of the HRA there is a required follow up – such as phone calls to a health coach based on conditions identified in the HRA – the wellness program is an activity-only rather than a participatory program. If the follow-up calls are voluntary (i.e., the reward is given even if the calls are not made), then the program would be participatory.*

Employers that provide wellness rewards in the form of "credits" that are assigned to an employee's general purpose health Flexible Spending Account may want to limit the dollar amount to \$500 or less. Limiting the maximum dollar amount can help ensure that their health FSAs do not inadvertently lose their status as HIPAA-excepted benefits. In order to be an excepted benefit, a general purpose health FSA must have a maximum benefit that is limited to the greater of: (1) 2 x the employee's salary reduction election, or (2) the employee's salary reduction amount plus \$500. Under this rule if an employer assigned \$600 in family wellness credits to an employee's health FSA and the employee elected a \$0 salary reduction amount, the FSA would not be an excepted benefit. A general health FSA that is not an excepted benefit will violate PPACA's prohibition against a dollar maximum on essential health benefits and could be subject

to PPACA's \$100 per day per affected person penalty. Employers wishing to assign dollar amounts higher than \$500 will need to design and monitor their health FSAs to ensure that the FSA maximum does not exceed 2 x the salary reduction amount (or \$500, as applicable). As an alternative, employers could credit reward amounts to an FSA that is limited to dental and vision expenses since separate dental and vision plans are almost always excepted benefits.

Wellness programs may be subject to a number of federal and state laws including the Health Insurance Portability and Accountability Act ("HIPAA"), the Patient Protection and Affordable Care Act ("PPACA"), ERISA, COBRA, the Genetic Information Nondiscrimination Act ("GINA"), the Americans with Disabilities Act ("ADA"), the Age Discrimination in Employment Act ("ADEA"), Title VII of the Civil Rights Act (e.g., gender discrimination), the Fair Labor Standards Act ("FLSA"), the Internal Revenue Code, state tax codes, state nondiscrimination laws, and federal cafeteria plan rules and regulations. A brief summary of the major requirements under federal laws follows.

A. HIPAA Nondiscrimination

Participatory wellness programs that include medical care such as biometric testing or flu shots, even if not related to the employer's health plan, are considered health plans and are subject to HIPAA's nondiscrimination requirements. These programs must be available to all similarly situated individuals regardless of health status. There is no maximum on the reward (or penalty) for participatory wellness programs.

Rewards under wellness programs are typically in the form of changes in contributions or benefits such as a reduction in required health contributions or an increase in deductibles. Some employers have conditioned eligibility for a particular health plan option on smoker/nonsmoker status or another health factor. For example, smokers would be eligible for a core option while nonsmokers would be eligible for a core option and would also be able to buy up to an enhanced option. Based on previous informal discussions with Department of Labor representatives, the DOL may view the HIPAA prohibition on discrimination in benefits and eligibility as extending to benefit options within a health plan. As a result it may not be permissible to base option eligibility on health factors such as smoker/nonsmoker status. (Under the ADA, if the wellness program includes disability-related inquiries or a medical examination (e.g., biometric screening), the employer may not restrict the employee's eligibility to a benefit plan or benefit option within a health plan. For example, if an employer offers two options – a \$1,000 deductible option and a \$2,000 deductible option – the employer may not limit enrollment options for employees who do not complete the HRA or undergo biometric screening to the \$2,000 deductible option.)

B. HIPAA Privacy and Security

Many wellness programs will be subject to HIPAA's Privacy and Security rules and regulations. However, these requirements will not apply if the wellness program is linked to a group health plan not subject to HIPAA's Privacy and Security provisions (i.e., a

small self-insured group health plan – one with fewer than 50 eligible individuals, which is administered by the employer that established and maintains the plan). *Note: HIPAA Privacy and Security rules do apply to HIPAA-excepted benefits such as separate dental and vision plans.*

Wellness programs that provide medical care (such as biometric screening) or that are linked to the employer's health plan are subject to the HIPAA Privacy and Security rules. If the wellness program is linked to the employer's medical plan, the employer may want to simply extend the medical plan's privacy & security policies and procedures to the wellness program. If the wellness program is separate – for example the program is offered to employees who are not eligible for the employer's medical plan – the employer may want to adopt and modify the medical plan's privacy and security procedures for use in the wellness program. For example, an employer providing flu shots or biometric screening to part-time employees who are not eligible for the major medical plan would not need to establish a separate plan with separate documents and procedures for the wellness program. Instead, the employer could include the wellness program in the privacy and security policies and procedures for the major medical plan even though the eligibility for the wellness program and major medical program are not the same. One additional step that should not be forgotten is that of obtaining Business Associate Agreements from wellness vendors.

C. Mental Health Parity and Addiction Equity Act (“MHPAEA”)

The Mental Health Parity and Addiction Equity Act (“MHPAEA”) requires health plans to provide parity between benefits for treatment of medical/surgical care and mental health/substance use disorders. For example, health plans are not permitted to include provisions such as higher deductibles or separate deductibles for mental health/substance use disorder treatments. In addition, health plans are not permitted to assign all drugs that are used to treat mental health/substance use disorder conditions to a higher copay tier than is required for prescriptions to treat medical/surgical conditions. Nicotine addiction is considered to be a substance use disorder that is subject to the parity rule under MHPAEA. Some wellness programs use only educational materials or smoking cessation classes as a reasonable alternative under their smoking cessation program. Others cover the cost of prescribed drugs intended to help individuals stop smoking. Programs that cover the cost of prescription drugs provide medical care and are subject to the MHPAEA parity rule. Because regulations to date have not addressed how MHPAEA applies to wellness programs, it is unclear to what extent a wellness program could restrict coverage of prescription drugs without creating a potential problem under MHPAEA. Employers with limitations on smoking cessation drugs or counseling should consult with their legal counsel.

D. Patient Protection and Affordable Care Act (“PPACA”)

If a wellness program varies the deductible, co-payments, coinsurance, or coverage for any of the services listed in the Summary of Benefits and Coverage (“SBC”), then the

calculations for that treatment scenario must assume that the individual is participating in the wellness program and additional language must be included in the SBC. For example, if the wellness program has a diabetes component, the SBC instructions provide the following sample language to be included with the coverage examples: *“Note: These numbers assume the patient is participating in our diabetes wellness program. If you have diabetes and do not participate in the wellness program, your costs may be higher. For more information about the diabetes wellness program, please contact [insert].”* Currently, three treatment scenarios that must be included in the SBC template are pregnancy, diabetes, and a simple fracture.

Under PPACA’s Employer Shared Responsibility requirement, a large employer (generally defined as more than 50 full-time and full-time equivalent employees) that does not offer minimum essential coverage to at least 95% of its full-time employees or a large employer that offers coverage that is either not “affordable” or does not provide “minimum value” may be required to pay a penalty. PPACA regulations issued in 2013 specify how minimum value and affordability may be calculated for employers sponsoring wellness programs that are tied to their health plans.

The IRS’s December 2015 final regulations state that minimum value must be determined without regard to reduced cost-sharing available under a wellness program (with an exception for tobacco-reduction programs described below). For example, if a wellness program has a \$4,000 deductible with a \$200 reduction for completion of a health-related activity, the medical program may not use a \$3,800 deductible when calculating minimum value – it must use the full \$4,000.

A medical plan’s affordability must be determined assuming that each employee fails to satisfy the requirements of the wellness program (with an exception noted below). Regulations include an example where an employer with a \$4,000 required contribution reduces the contribution by \$200 for completion of a health-related activity. This employer may not use a \$3,800 required contribution when calculating affordability – it must use the full \$4,000.

Employers may, however, determine minimum value and affordability by taking into account certain rewards for wellness programs that are designed to reduce tobacco use. When determining minimum value the employer may include the value of differences such as a reduction in a deductible assuming that all individuals will qualify for the reward. For example, if the deductible is \$1,500 but will be reduced by \$300 for any individual who either does not use tobacco or attends a smoking cessation class, the employer may use a \$1,200 deductible in determining minimum value. Similarly, premium rewards (or penalties) may be taken into account in determining affordability by assuming that all individuals will qualify for the reward. If the annual required contribution is \$2,000 and individuals who either don’t smoke or who attend a smoking cessation class receive a \$300 reduction in their contributions, the employer may use \$1,700 as the required contribution for the plan.

New Quality of Care Reporting

Once regulations are issued, non-grandfathered group health plans will be required to submit an annual report to both the Secretary of HHS and enrollees regarding “quality of care” measurements. These quality of care measurements will include information about benefits and reimbursement plan components that implement wellness and health promotion activities. Activities may include things such as personalized wellness and prevention services provided by, coordinated by, or maintained by: (1) a healthcare provider, (2) a wellness and prevention plan manager, or (3) a health, wellness or prevention services organization that conducts health risk assessments or offers individual intervention efforts (e.g., phone or web-based). *Note: Regulations have not been issued as of January 2019.*

The personalized wellness and prevention services could include health risk assessments or ongoing face-to-face, telephonic, or web-based intervention efforts for each of the program’s participants, and may include the following wellness and prevention efforts:

- (1) Smoking cessation;
- (2) Weight management;
- (3) Stress management;
- (4) Physical fitness;
- (5) Nutrition;
- (6) Heart disease prevention;
- (7) Healthy lifestyle support; or
- (8) Diabetes prevention.

The due date for providing a report to the Secretary of HHS has not yet been specified, but presumably, a deadline will be provided when HHS issues implementing regulations. Plans must provide the report to enrollees during each open enrollment period after the effective date specified in the regulations. Providers, prevention plan managers, and wellness organizations may be required to gather the necessary information and provide a report to the plan so that the plan may, in turn, provide a report to enrollees and HHS.

E. Tax Rules for Rewards

If the wellness program otherwise meets applicable nondiscrimination requirements, then a reward in the form of a lower employee premium or an employer-provided contribution to an HRA, HSA, or FSA does not result in taxable income to employees and is not subject to wage withholding or employment taxes. For example, if an employer contributes \$150 to the HRA of each employee who undergoes a cholesterol screening, then the \$150 contribution does not result in additional income for each participating employee.

NOTE: Discrimination (and/or comparability for HSAs) issues may arise under other laws such as the Internal Revenue Code for rewards in the form of increased benefits under a medical plan such as an additional contribution to an HRA. Consult your benefits advisor for additional information regarding employer contributions to HRAs, HSAs, and FSAs. In addition, the Internal Revenue Code sections which prohibit discrimination in favor of highly compensated and key employees will apply.

Likewise, rewards that take the form of reduced premiums, co-payments, or deductibles would not be taxable under Section 105 and 106 of the Internal Revenue Code. (Note: The reward may be taxable under certain situations such as where cash or a cash equivalent reward is paid for an individual who is not the employee's spouse or federal tax dependent.)

Rewards that come in the form of cash (e.g., a cash bonus) or cash-equivalents (e.g., a gift card to a local restaurant) are taxable and will be subject to wage withholding and employment taxes. For example, if an employer provides a \$50 gift card to a restaurant for all employees who complete a health risk assessment, each participating employee will have an additional \$50 of income subject to wage withholding and employment taxes.

Rewards such as certain employee discounts, T-shirts, mugs, and other rewards that qualify as *de minimis* fringe benefits under Internal Revenue Code Section 132 are not taxable to employees. Please note that the *de minimis* standard does not apply to cash rewards. For more information, refer to IRS Publication 15-B Employer's Tax Guide to Fringe Benefits. <http://www.irs.gov/publications/p15b/ar02.html>

Other noncash rewards could be taxable such as discounts on products or merchandise (e.g., weights, MP3 players, etc.). Employers should consult with their tax advisors with any questions about the taxation of rewards.

In May 2017, the IRS provided guidance on certain wellness programs sometimes marketed as "fixed indemnity health plans." These programs are promoted as a way to provide certain benefits to employees at little or no cost to the employer and little or no cost to employees on a take-home pay basis. Under one design, employees are given the opportunity to enroll in coverage under a self-insured health plan. Employees who participate in the self-insured plan pay a small after-tax contribution. The self-insured health plan pays employees a fixed cash payment for participating in certain health-related activities such as calling a toll-free number that provides general health-related information, attending a seminar that provides general health-related information, participating in a biometric screening, or attending a counseling session. Employees are not charged for participating in any of these activities which are described as a wellness program. The fixed payment that employees receive under the self-insured health plan for each covered activity (e.g., \$1,425 per activity) is much greater than the amount of the employee's after-tax contribution (e.g., \$60 per month) for participating in the self-

insured health plan. Under an actuarial analysis, all employees are expected to receive benefit payments under the self-insured health plan that markedly exceed their after-tax contributions.

The IRS clarified that under this program, reimbursements to employees under the self-insured health plan are not excludable from income because the payments under this program do not reimburse covered individuals for expenses incurred for medical care. These reimbursements are merely lump sum payments made regardless of whether any medical care was received. Therefore, excess payments (e.g., a reimbursement of \$1,425 minus the employee's \$60 contribution which equals \$1,365) must be included in the employee's taxable income. Employers that have or are considering implementing one of these programs will want to discuss the IRS rules with an attorney with appropriate experience.

F. Other Federal Laws

Some of the federal laws such as the prohibition against discrimination based on age will apply to all types of programs. Others will apply to some, but not all, wellness programs. For example, the Genetic Information Nondiscrimination Act ("GINA") rules will apply to most wellness programs that use health risk assessments, but would not apply to a program that only provides a reward for attending a smoking cessation class.

Cafeteria Plans

Under the Section 125 cafeteria plan regulations, if the decrease in premium is "insignificant," an employer may structure its cafeteria plan to automatically change a newly qualifying employee's salary reduction to reflect the reduced premium. If the decrease in premium is "significant," an employee may elect to have his or her salary reduction prospectively changed to reflect the decreased premium. The Section 125 regulations would also permit mid-year changes when an employee loses a wellness reward and thus must pay a higher monthly premium (e.g., an employee starts smoking). For more information on the impact of cost changes on permissible salary reduction changes, refer to Treasury Regulation Section 1.125-4(f)(2). Unfortunately, the existing cafeteria plan regulations were issued before the wellness program regulations were finalized. As a result, it is unclear how any retroactive rewards would be treated under the cafeteria plan. Hopefully, the IRS will provide updated guidance in the future.

Americans with Disabilities Act ("ADA")

There are two areas of concern under the ADA with regard to wellness programs. First, the ADA prohibits employers from discriminating against individuals with disabilities. For example, a program that provides a reward based on a health condition may discriminate against individuals who have a disability. This may violate the ADA even if the program is designed so that it complies with the HIPAA nondiscrimination

requirements. Second, the ADA limits when employers may make medical inquiries or conduct medical examinations. The EEOC issued final regulations in May 2016. ADA regulations apply to employees, former employees, and applicants; they do not apply to spouses or dependents.

The EEOC's ADA regulations govern employer-sponsored wellness programs that include either disability-related inquiries or medical exams (including biometric screening). An HRA that includes disability-related inquiries would be subject to the EEOC rules even if the HRA is not subject to HIPAA due to the fact that it is not related to a health plan. For example, if an employer makes an HRA available to all employees including employees who are not eligible for the employer's medical plan (e.g., part-time employees), then the wellness program would be subject to the ADA requirements. A program that includes biometric screening would be a health program subject to both the HIPAA and ADA rules. The ADA regulations require a wellness program to:

- (1) Be reasonably designed** – similar to HIPAA, the program must: (1) have a reasonable chance of promoting health or preventing disease; (2) not be overly burdensome; (3) not be a subterfuge for violating the ADA or other federal laws; and (4) not be highly suspect in the methods chosen. A program that collects health information or uses tests or screening that does not provide results, follow up information, or advice designed to improve employees' health is not considered to be reasonably designed. For example, if a program does not use collected data to address at least a subset of conditions identified (either for individuals or a group of employees), or if the program exists mainly to shift costs to targeted employees based on health, or if it used simply to give the employer information to estimate future healthcare costs, then it is not reasonably designed.
- (2) Be voluntary** – employees may not be required to participate, employees may not be denied coverage under any of the group health plans or particular benefit packages within a group health plan based on non-participation, and employees may not be subject to any adverse employment action based on non-participation (e.g., termination of employment).
- (3) Provide a notice** – the program must provide a notice that: (1) is written so that employees are likely to be able to understand it; (2) clearly explains what medical information will be obtained and the purpose for which the medical information will be obtained; (3) identifies who will receive the medical information and how it will be used; and (4) states the restrictions on disclosures along with the methods that will be used to prevent improper disclosure.

The notice must describe the information to be collected, how the information will be used, with whom it will be shared, how it will be kept confidential, the restrictions on uses and disclosures, and the methods the employer has implemented to prevent improper disclosure of medical information. The EEOC posted a model notice along with several FAQs on its website – [click here](#) to access the model; [click here](#) to access the FAQs.

(4) Keep the information confidential – generally, the information may not be disclosed to an employee’s supervisor or manager, individuals who handle medical information generally should not be responsible for making employment decisions, and a notification is required in the event of a breach. A participant may not be required to agree to the sale, exchange, sharing, transfer, or other disclosure of medical information in order to participate in the wellness program or receive an incentive.

(5) Provide reasonable accommodation –for employees if needed to access the wellness program – e.g., a sign language interpreter for a deaf employee or large print material for visually impaired employees.

In response to a court order, the EEOC issued guidance in December 2018 that removed a 30% maximum reward rule 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.

In the preamble to the final regulations the EEOC expanded upon its interpretation of ADA’s insurance safe harbor provision and reaffirmed its position that the insurance safe harbor is not available for wellness programs that include disability-related inquiries or medical examinations. This issue had been addressed by several courts prior to the issuance of these regulations and is likely to be the subject of additional litigation. Based on the EEOC’s comments in the preamble (and concurrently issued FAQs), it is likely that the EEOC will continue to challenge employers who rely on the insurance safe harbor when designing their wellness programs. Employers that want to use the safe harbor when designing their wellness programs should discuss the EEOC’s position and their program designs with legal counsel with appropriate experience before proceeding.

Genetic Information Nondiscrimination Act (“GINA”)

Employers are prohibited from discriminating against any employee with respect to the compensation, terms, conditions, or privileges of employment on the basis of “genetic information.” In general:

- Employers are not permitted to request, require or purchase genetic information,

- Employers must maintain genetic information as a confidential medical record, and
- Strict limits apply to the disclosure of genetic information.

Under the Genetic Information Nondiscrimination Act (“GINA”), genetic information is broadly defined to include family medical history. Thus, a wellness program that seeks genetic information in the form of family medical history for underwriting purposes violates GINA. Family is broadly defined to include relatives to the fourth degree (e.g., cousins once-removed) and relatives by marriage (e.g., spouse and in-laws).

GINA prohibits the collection of genetic information for underwriting purposes. A health plan may not collect genetic information in connection with enrollment and may not give a reward for providing genetic information regardless of when it is collected. Under the GINA regulations, a health plan that provides a premium reduction for employees who complete an HRA that includes questions about employee family history, violates GINA – even if the HRA is provided after enrollment – because completion of the health risk assessment results in a reduction of premium and is therefore considered to be for purposes of underwriting.

A health plan that includes completion of an HRA may still violate GINA even if there is no premium reduction for completing the assessment (or penalty for not completing it) if the assessment requests genetic information such as family medical history **if the assessment is obtained before coverage begins**. For example, an employer with a calendar year plan conducts annual enrollment for the upcoming year during November. On December 5, after all elections have been made, the employer sends a health risk questionnaire that requests genetic information with instructions that the assessment must be completed and returned by December 31. The employer has violated the GINA requirements by collecting the information before the January 1 coverage effective date.

Because GINA defines “family member” to include a spouse, information about a spouse’s current medical conditions could be considered genetic information. As a result there was some concern that providing for completion of a HRA by a spouse – even if the HRA did not elicit information about genetic tests or services or about the spouse’s family medical history – would violate GINA if a reward was offered. The EEOC addressed this issue in final regulations issued in May 2016. Under EEOC’s final GINA regulations, if a spouse completes an HRA or undergoes biometric screening, then the wellness program may provide a reward subject to the following requirements:

- (1) The program must be reasonably designed to promote health or prevent disease; must not be overly burdensome; must not be a subterfuge for violating GINA or other laws; and must not be suspect in the method chosen. A wellness program that includes a test, screening or collection of health-related information without providing participants with results (which may be individuals or a group of employees or spouses), follow-up information, or

- advice designed to improve the participants' health is not reasonably designed. In addition a program is not considered reasonably designed if it imposes a penalty on (or otherwise disadvantages) an individual because of a spouse's manifestation of a disease or disorder by preventing or inhibiting the spouse from participating in, or from achieving a certain health outcome. In addition, the employer may not deny access to a group health plan or package of benefits based on a spouse's refusal to complete a health risk assessment or undergo biometric testing.
- (2) The program must be voluntary - the spouse must provide knowing, voluntary, written authorization.
 - (3) 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.
 - (4) The spouse must be provided with a notice containing specific information. The 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 healthcare 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.

Unlike the HIPAA and PPACA rules, the EEOC's GINA rules limit incentives to 30% for all wellness programs – including those that are participatory programs – based upon the cost of self-only coverage.

In response to a court order, the EEOC issued guidance in December 2018 that removed a 30% maximum reward rule 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 GINA.

Under the EEOC's regulations, the wellness program may also include completion of health risk assessments or biometric screening for children, but the plan may not provide any incentive for completion of the HRA or biometric screening by children - including adult and adopted children.

ERISA

If a private employer (for-profit or nonprofit) is involved and an exception under ERISA does not otherwise apply, and the program provides individualized "medical care," then

the program is likely an ERISA plan. The program involves “medical care” if the care is individualized and provided by trained professionals. For example, flu shots, health coaching by a nurse, counseling by a therapist, or biometric screening would all be example of medical care if provided through an employer. However, if a program only offers general education, it is not “medical care.” For example, a newsletter with health condition articles, a “lunch-n-learn” about diabetes, and a weight loss class without a personalized assessment are all example of general education.

If a wellness program is an “employee welfare benefit plan” under ERISA, it will have to satisfy ERISA’s applicable compliance requirements, including the following:

- (1) There must be a plan document;
- (2) Plan terms must be followed and strict fiduciary standards adhered to;
- (3) SPDs (SMMs, and SMRs) must be provided to plan participants;
- (4) Form 5500 must be filed annually (subject to certain exceptions); and
- (5) Claims procedures must be established and followed.

Wellness programs that constitute group health plans must also meet certain special requirements: (a) additional requirements under the DOL claims procedure regulations; (b) additional SPD disclosures; and (c) special timing rules for SMMs.

In some cases an employer offers a wellness program that is participatory with either no reward or a reward that is not tied to the employer’s major medical plan, but the wellness program itself is a health plan subject to ERISA because it provides medical care (e.g., annual flu shots or biometric screening). If the eligibility for the wellness program and major medical plan are different – for example, full-time employees are eligible for major medical but both full-time and part-time employees are eligible for the wellness program – the employer may, but is not required, to create a separate ERISA plan just for the wellness program. Even though the eligibility is different, the employer can include the wellness program as part of the ERISA plan that includes major medical. The ERISA plan would need to be amended to reflect both the wellness benefits and the difference in eligibility. In addition, financial information on the wellness program must also be included on the employer’s Form 5500 filing.

PPACA added more special requirements, including enhanced internal claims and appeals requirements and external review procedures applicable to non-grandfathered plans. In the preamble to the amended PPACA appeals regulations issued on June 24, 2011, the Departments of Health and Human Services, Labor, and Treasury included examples of situations in which a claim would involve “medical judgment” and therefore be subject to the federal external review process for an adverse benefit determination. Included among those examples is a determination based on whether a participant would be entitled to a reasonable alternative standard under an employer-sponsored wellness program.

Thus, non-grandfathered plans denying a request for a reasonable alternative standard (or a waiver of an otherwise applicable standard) to obtain a reward related to a standard-based wellness program should be ready to follow the PPACA appeals procedures, including the requirement to make available an external review by an Independent Review Organization.

COBRA

A health plan that is subject to COBRA and is linked with a wellness program, must include some of the wellness program provisions as part of COBRA coverage offered by the health plan. In general, if the wellness program provides a reward in the form of a different benefit such as a reduced deductible, it must be offered to COBRA qualified beneficiaries. For example, if the wellness program provides a \$100 reduction in the annual deductible for any individual who completes a health risk assessment questionnaire, regardless of the results, qualified beneficiaries must be given the same opportunity. Rewards in the form of reduced premiums do not need to be offered to COBRA qualified beneficiaries.

Health plans must comply with any applicable COBRA requirements. The most significant obligations are listed below:

- (1) Provision of a General Notice:** Each participant and his or her spouse must receive a General Notice when coverage under the program first begins;
- (2) Provision of an Election Notice:** Each Qualified Beneficiary must receive an Election Notice with a notice of the Qualified Beneficiary's rights and obligations for a specific qualifying event (e.g., termination of a covered employee's employment or reduction of a covered employee's hours of employment, etc.) The Election Notice for the wellness program may be combined with the Election Notice for the employer's major medical plan(s);
- (3) Provision of a Notice of Unavailability (if applicable):** Certain individuals who expect to receive COBRA continuation coverage but are not entitled to such coverage must be provided with a Notice of Unavailability;
- (4) Coverage:** if a Qualified Beneficiary elects COBRA continuation coverage under the wellness program, he or she generally may receive such coverage for a basic coverage period which is the same period of time as any other COBRA continuation period (e.g., 18 months for certain qualifying events, 36 months for other qualifying events). The Qualified Beneficiary would be entitled to any incentives available to active employees and would also be permitted to elect any other group health coverage offered to other employees during open enrollment; and

(5) Provision of an Early Termination Notice (if applicable): If COBRA continuation terminates before the end of the maximum coverage period, the Qualified Beneficiary must be provided with a Notice of Termination.

Employers should review their existing plan materials and COBRA policies and procedures to ensure that applicable wellness programs are included in any written COBRA policies and procedures.

Age Discrimination in Employment Act (“ADEA”)

The ADEA prohibits employment discrimination against employees and job applicants on the basis of age with respect to benefits. Protected individuals must be at least 40 years of age. Thus, a wellness program could violate the ADEA if it terminated or decreased wellness rewards, or otherwise discriminated against employees age 40 or older.

Title VII

Title VII relates to the “terms, conditions, or privileges of employment,” which generally include wellness programs. Thus, if an employer takes into consideration a plan participant’s race, religion, sex, color, or national origin, then the wellness program could violate Title VII.

Fair Labor Standards Act (“FLSA”)

Under the FLSA, nonexempt employees must be compensated at not less than time and one-half of regular pay for time worked over 40 hours in any given workweek. Thus, if time spent completing a wellness program is considered to be “compensable time,” then the employer may have to pay overtime. For example, if an employer provides health lectures as part of a wellness program, the time spent could be compensable time. However, the time need not be compensable time if four conditions are met: (1) attendance is outside of the employee’s regular work hours; (2) attendance is purely voluntary; (3) the lecture is not directly related to the employee’s job; and (4) the employee does not do any productive work during the lecture (e.g., answering e-mails).

SECTION 6 – HEALTH PLAN-RELATED ACTIVITY-ONLY PROGRAMS

Activity-only wellness programs are those that base the reward on a health-related activity. For example, a wellness program that requires an individual to walk 30 minutes every day to receive the reward would be an activity-only program. If, on the other hand, the program only requires an individual to keep a record of the amount of time she spends exercising each week with the reward based solely on recording the information (even if the individual records that she spent no time exercising), it would probably be viewed as a participatory program. Which category applies must be determined based on all of the facts and circumstances. The rules for activity-only programs are contained in this section. The rules for participatory programs that are health plan-related are contained in Section 5.

Some programs include the use of a health risk assessment (“HRA”). An HRA is a method of determining who might most benefit from a wellness (or disease management) program and identify potential health-related areas of concern for specific individuals. An HRA can take the form of a simple questionnaire, and often, an HRA is accompanied by biometric testing (e.g., blood pressure screening, body mass index calculation, cholesterol screening, blood sugar level testing, etc.).

Tip: Some programs with a reward based on an activity that were previously viewed as participatory programs under HIPAA, may now be activity-only programs. For example, if a wellness program uses a health risk assessment (“HRA”) and based on the results of the HRA there is a required follow up – such as phone calls to a health coach based on conditions identified in the HRA – the wellness program is activity-only rather than participatory. If the follow-up calls are voluntary (i.e., the reward is given even if the calls are not made), then the program would be participatory.

Employers that provide wellness rewards in the form of “credits” that are assigned to an employee’s general purpose health Flexible Spending Account may want to limit the dollar amount to \$500 or less. Limiting the maximum dollar amount can help ensure that their health FSAs do not inadvertently lose their status as HIPAA-excepted benefits. In order to be an excepted benefit, a general purpose health FSA must have a maximum benefit that is limited to the greater of: (1) 2 x the employee’s salary reduction election, or (2) the employee’s salary reduction amount plus \$500. Under this rule if an employer assigned \$600 in family wellness credits to an employee’s health FSA and the employee elected a \$0 salary reduction amount, the FSA would not be an excepted benefit. A general health FSA that is not an excepted benefit will violate PPACA’s prohibition against a dollar maximum on essential health benefits and could be subject to PPACA’s \$100 per day per affected person penalty. Employers wishing to assign dollar amounts higher than \$500 will need to design and monitor their health FSAs to ensure that the FSA maximum does not exceed 2 x the salary reduction amount. As an alternative, employers could credit reward amounts to an FSA that is limited to dental and vision expenses since separate dental and vision plans are almost always excepted

benefits.

Wellness programs may be subject to a number of federal and state laws including the Health Insurance Portability and Accountability Act (“HIPAA”), the Patient Protection and Affordable Care Act (“PPACA”), ERISA, COBRA, the Genetic Information Nondiscrimination Act (“GINA”), the Americans with Disabilities Act (“ADA”), the Age Discrimination in Employment Act (“ADEA”), Title VII of the Civil Rights Act (e.g., gender discrimination), the Fair Labor Standards Act (“FLSA”), the Internal Revenue Code, state tax codes, state nondiscrimination laws, and federal cafeteria plan rules and regulations. A brief summary of the major requirements under federal laws follows.

A. HIPAA Nondiscrimination

Wellness programs that offer a reward related to a health plan that condition receipt of the reward upon completing a certain health-related activity such as an exercise or diet program are subject to the HIPAA nondiscrimination rules. The HIPAA nondiscrimination rules provide that group health plans may not discriminate in health coverage among individuals on the basis of a “health factor,” in terms of eligibility, benefits or costs. There are eight “health factors” that may not be used to discriminate against individuals in providing health coverage: (1) health status; (2) medical condition (physical or mental illness); (3) claims experience; (4) receipt of health care; (5) medical history; (6) genetic information; (7) disability; and (8) evidence of insurability. Wellness programs that are related to the employer’s health plan and provide a reward dependent upon an individual meeting a “specific health-related standard” such as completion of a specific activity differentiate in terms of benefits or costs based upon health status. Wellness programs that comply with HIPAA’s nondiscrimination requirements are an exception to this requirement, they are permitted to vary benefits and/or costs by a limited amount. Wellness programs are permitted to discriminate in favor of employees who have a health condition – called benign discrimination. For example, a wellness plan could include free glucose testing or test strips for diabetics.

Wellness programs that are, or that are a part of, HIPAA-exempt health plans are not subject to HIPAA’s nondiscrimination rules. For example, a wellness reward provided not subject to HIPAA’s portability rules.

Rewards under wellness programs are typically in the form of changes in contributions or benefits such as a reduction in required health contributions or an increase in a deductible. Some employers have wanted to condition eligibility for a particular health plan option on smoker/nonsmoker status or another health factor. For example, smokers would be eligible for a core option while nonsmokers would be eligible for a core option and would also be able to buy up to an enhanced option. Based on previous informal discussions with Department of Labor representatives, the DOL may view the HIPAA prohibition on discrimination in benefits and eligibility as extending to benefit

options within a health plan. As a result it may not be permissible to base option eligibility on health factors such as smoker/nonsmoker status. (Under the ADA, if the wellness program includes disability-related inquiries or a medical examination (e.g., biometric screening), the employer may not restrict the employee's eligibility to a benefit plan or benefit option within a health plan. For example, if an employer offers two options – a \$1,000 deductible option and a \$2,000 deductible option – the employer may not limit enrollment options for employees who do not complete the HRA or undergo biometric screening to the \$2,000 deductible option.)

There are five general rules that apply to all health plan-related activity-only wellness programs:

(1) Maximum Reward

The total plan-based reward for all of the employer's wellness programs that require satisfaction of an activity-only standard must not exceed 30% of the cost of employee-only coverage under the employer's health plan. If dependents (including spouses or dependent children) may participate in the wellness program, the reward must not exceed 30% of the cost of coverage for the applicable level of coverage. If there is more than one activity-only program or if there is an outcome-based program in addition to the activity-only program, the maximum reward (or penalty) for all such wellness programs combined may not exceed 30%.

An employer may use a reward up to 50% for a wellness program that is designed to reduce tobacco use. If the employer's only wellness program is a tobacco reduction program, the entire 50% is available for the program. If other wellness programs or benefits are included, the maximum available for all wellness programs combined is 50% with the non-tobacco related programs are limited to 30%. For example, an employer could not use 50% for a tobacco reduction program plus 30% for a non-tobacco program with a total of 80%. (If the program includes disability-related inquiries or biometric testing and is subject to the ADA it is unclear what, if any, reward may be offered.) See page 42 for more detailed information.)

Generally, the reward must be paid in the year in which it was earned. If the reward is earned mid-year – for example because an employee satisfies a reasonable alternative standard mid-year, the employer may make a retroactive payment to cover the months before the standard or reasonable alternative standard was met. Alternatively, the program may prorate the annual reward over the remaining months in the plan year. For example if the reward under a calendar year plan is \$20 per month and the standard is met on July 1, the plan may prorate the monthly amount and pay \$40 per month for July through December. If the standard is not satisfied until near the end of the plan year, the employer may pay the reward within a reasonable period

after the end of the plan year. In no event may the plan apply the reward to the following plan year.

Rewards under wellness programs are typically in the form of changes in contributions or benefits such as a reduction in required health contributions or an increase in a deductible. Some employers have wanted to condition eligibility for a particular health plan option on smoker/nonsmoker status or another health factor. For example, smokers would be eligible for a core option while nonsmokers would be eligible for a core option and would also be able to buy up to an enhanced option. Based on previous informal discussions with Department of Labor representatives, the DOL may view the HIPAA prohibition on discrimination in benefits and eligibility as extending to benefit options within a health plan. As a result it may not be permissible to base option eligibility on health factors such as smoker/nonsmoker status. (Under the ADA, if the wellness program includes disability-related inquiries or a medical examination (e.g., biometric screening), the employer may not restrict the employee's eligibility to a benefit plan or benefit option within a health plan. For example, if an employer offers two options – a \$1,000 deductible option and a \$2,000 deductible option – the employer may not limit enrollment options for employees who do not complete the HRA or undergo biometric screening to the \$2,000 deductible option.)

It is permissible to design a wellness program that favors those with health conditions (benign discrimination). For example, an employer may structure a wellness program that includes a reduced contribution for employees who complete a walking program and automatically provide the reward for individuals who are unable to walk for a medical reason (e.g., an employee recovering from surgery).

If the wellness program includes an HRA or biometric screening and spouses are eligible, then additional GINA requirements. At this time it is unclear, what if any rewards may be offered to employees and spouses under a program subject to GINA.) See page 44 for more detailed information.

(2) Reasonable Design

The program must be reasonably designed to promote health or prevent disease. Programs are reasonably designed to promote health and prevent disease if they: (1) provide a reasonable chance to improve health or prevent disease; (2) are not overly burdensome; (3) are not a subterfuge for discrimination based on health; and (4) are not “highly suspect” in the method chosen to promote health or prevent disease.

Wellness programs that include disability-related questions and/or medical examinations (such as biometric screening) for employees are also subject to

the requirements of the Americans with Disabilities Act (“ADA”) which also requires that the program be reasonably designed. The final ADA regulations include the four HIPAA requirements but also state that a program that collects health information or uses tests or screenings that does not provide results, follow up information, or advice designed to improve employees’ health is not considered to be reasonably designed. For example, if a program does not use collected data to address at least a subset of conditions identified (either for individuals or a group of employees), or if the program exists mainly to shift costs to targeted employees based on health, or if it used simply to give the employer information to estimate future healthcare costs, then it is not reasonably designed. (See page 42 for more information about ADA’s requirements.)

For programs that include spousal completion of an HRA, GINA’s requirements will also apply. Final GINA regulations include the four HIPAA requirements along with the additional limitations added by the ADA. In addition, under GINA a program is not considered reasonably designed if it imposes a penalty on (or otherwise disadvantages) an individual because of a spouse’s manifestation of a disease or disorder by preventing or inhibiting the spouse from participating in, or from achieving a certain health outcome. (See page 44 for more information about GINA’s requirements.)

(3) Annual Opportunity

The program must allow eligible individuals at least one opportunity per year to qualify for the reward. Some programs determine eligibility for the reward shortly before the beginning of a new medical plan year (e.g., a plan that reduces the monthly premium for the next year for those individuals who certify at annual enrollment that they have completed a specific activity.)

An individual who does not satisfy the initial standard must be given a reasonable alternative standard. It may take some time for individuals who do not meet the initial standard for the year to request, establish, and satisfy a reasonable alternative standard. As a result, wellness programs that determine eligibility for the reward prior to or at the beginning of a plan year may still have individuals qualifying during the plan year.

(4) Reasonable Alternative Standard

The program reward must be available to all similarly situated individuals and must include a reasonable alternative standard for individuals who do not satisfy the standard. In order to be reasonable, the alternative standard must satisfy the following rules (as applicable):

- a. If the alternative standard is completion of an educational program, the plan must make the educational program available or help the individual find the program and pay the cost of the program. It cannot require the individual to find or pay for the program.
- b. If the alternative standard is a diet program, the plan must pay for any membership or participation fee. The plan is not required to pay the cost of food.
- c. The time commitment required must be reasonable. The regulations state that requiring attendance nightly at a one-hour class would not be reasonable.
- d. If the individual's personal physician states that a plan standard (and if applicable the recommendations of the plan's medical professional) is not medically appropriate for that individual, the plan must provide a different reasonable alternative standard that accommodates the personal physician's recommendations.

The alternative standard may itself be a participatory, activity-only, or outcomes-based standard. If the alternative standard is activity-only, it must follow the rules for activity-only standards. If the alternative is outcome-based, it must follow those rules. If it is participatory, those rules must be followed.

In addition, if an individual is unable to meet an activity-only standard because it would be unreasonably difficult or inadvisable for medical reasons, the wellness program must provide the individual with a reasonable alternative standard as a way to earn the reward. The plan sponsor may require a physician's note confirming that satisfying the standard would be either medically inadvisable or unreasonably difficult for a medical reason. If the individual's physician states that a plan's standard is not medically appropriate, the plan must provide a reasonable alternative standard that accommodates the recommendation of the individual's physician.

The employer does not need to have a reasonable alternative developed in advance. The reasonable alternative can be designed once a request for one has been received. The reasonable alternative may be generic or it may be individualized. Waiving the standard (and paying the reward) is always a reasonable alternative.

Programs subject to ADA's requirements (i.e., programs that include disability-related inquiries and/or medical examinations such as biometric screening for employees), must also provide a reasonable accommodation for employees with a disability. For example, the program may need to provide large print versions of materials for employees with visual impairments. (See

page 42 for more information about ADA's requirements.)

(5) Required Disclosure

The program must disclose (in all materials describing the terms of the program, including annual enrollment materials) the availability of a reasonable alternative standard – or the possibility of a waiver of the underlying standard, if applicable.

A program need only disclose that a reasonable alternative standard (or waiver of the standard) is available in all materials describing the wellness program. For example, if information about a wellness program is included in open enrollment materials, the statement about the availability of a reasonable alternative standard must be included in those materials. Materials that include reference to a premium discount would be required to disclose the existence of an alternative standard. In addition, the program must disclose that a reasonable alternative standard is available in any notice informing the individual that he/she did not satisfy the activity-only standard. The Department of Labor provided sample language in June 2013:

“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 June 2013 regulations also included the following additional sample language in the examples:

“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.)”

Under the EEOC's GINA regulations, spousal notice and consent would be required for a program that includes an HRA or biometric screening. (See page 44 for more details about GINA's requirements.)

B. HIPAA Privacy and Security

Many wellness programs will be subject to HIPAA's Privacy and Security rules and

regulations. However, these requirements will not apply if the wellness program is, or is part of, a group health plan not subject to HIPAA's Privacy and Security provisions (i.e., a small self-insured group health plan – one with fewer than 50 eligible individuals – which is administered by the employer that established and maintains the plan). *Note: HIPAA Privacy and Security rules do apply to HIPAA-excepted benefits such as separate dental and vision plans.*

Wellness programs that provide medical care (such as biometric screening) or that are linked to the employer's health plan are subject to the HIPAA Privacy and Security rules. If the wellness program is linked to the employer's medical plan, then the employer may want to simply extend the medical plan's privacy & security policies and procedures to the wellness program. If the wellness program is separate – for example the program is offered to employees who are not eligible for the employer's medical plan – the employer may want to adopt and modify the medical plan's privacy and security procedures for use in the wellness program. For example, an employer providing flu shots or biometric screening to part-time employees who are not eligible for the major medical plan would not need to establish a separate plan with separate documents and procedures for the wellness program. Instead, the employer could include the wellness program in the privacy and security policies and procedures for the major medical plan even though the eligibility for the wellness program and major medical program are not the same. One additional step that should not be forgotten is that of obtaining business associate agreements from wellness vendors.

C. Mental Health Parity and Addiction Equity Act (“MHPAEA”)

The Mental Health Parity and Addiction Equity Act (“MHPAEA”) requires health plans to provide parity between benefits for treatment of medical/surgical care and mental health/substance use disorders. For example, health plans are not permitted to include provisions such as higher deductibles or separate deductibles for mental health/substance use disorder treatments. In addition, health plans are not permitted to assign all drugs that are used to treat mental health/substance use disorder conditions to a higher copay tier than is required for prescriptions to treat medical/surgical conditions. Nicotine addiction is considered to be a substance use disorder that is subject to the parity rule under MHPAEA. Some wellness programs use only educational materials or smoking cessation classes as a reasonable alternative under their smoking cessation program. Others cover the cost of prescribed drugs intended to help individuals stop smoking. Programs that cover the cost of prescription drugs provide medical care and are subject to the MHPAEA parity rule. Because regulations to date have not addressed how MHPAEA applies to wellness programs, it is unclear to what extent a wellness program could restrict coverage of prescription drugs without creating a potential problem under MHPAEA. Employers with limitations on smoking cessation drugs or counseling should consult with their legal counsel.

D. Patient Protection and Affordable Care Act (“PPACA”)

If a wellness program varies the deductible, co-payments, coinsurance, or coverage for any of the services listed in the Summary of Benefits and Coverage (“SBC”), then the calculations for that treatment scenario must assume that the individual is participating in the wellness program and additional language must be included in the SBC. For example, if the wellness program has a diabetes component, the SBC instructions provide the following sample language to be included with the coverage examples: *“Note: These numbers assume the patient is participating in our diabetes wellness program. If you have diabetes and do not participate in the wellness program, your costs may be higher. For more information about the diabetes wellness program, please contact [insert].”* Currently, three treatment scenarios that must be included in the SBC template are pregnancy, diabetes, and a simple fracture.

Under PPACA’s Employer Shared Responsibility requirement, a large employer (generally defined as more than 50 full-time and full-time equivalent employees) that does not offer minimum essential coverage to at least 95% of its full-time employees or a large employer that offers coverage that is either not “affordable” or does not provide “minimum value” may be required to pay a penalty. PPACA regulations issued in 2013 specify how minimum value and affordability may be calculated for employers sponsoring wellness programs that are tied to their health plans.

The IRS’s December 2015 final regulations state that minimum value must be determined without regard to reduced cost-sharing available under a wellness program (with an exception for tobacco-reduction programs described below). For example, if a wellness program has a \$4,000 deductible with a \$200 reduction for completion of a health-related activity, the medical program may not use a \$3,800 deductible when calculating minimum value – it must use the full \$4,000.

A medical plan’s affordability must be determined assuming that each employee fails to satisfy the requirements of the wellness program (with an exception noted below). Regulations include an example where an employer with a \$4,000 required contribution reduces the contribution by \$200 for completion of a health-related activity. This employer may not use a \$3,800 required contribution when calculating affordability – it must use the full \$4,000.

Employers may, however, determine minimum value and affordability by taking into account certain rewards for wellness programs that are designed to reduce tobacco use. When determining minimum value the employer may include the value of differences such as a reduction in a deductible assuming that all individuals will qualify for the reward. For example, if the deductible is \$1,500 but will be reduced by \$300 for any individual who either does not use tobacco or attends a smoking cessation class, the employer may use a \$1,200 deductible in determining minimum value. Similarly, premium rewards (or penalties) may be taken into account in determining affordability by assuming that all individuals will qualify for the reward. If the annual required

contribution is \$2,000 and individuals who either don't smoke or who attend a smoking cessation class receive a \$300 reduction in their contributions, the employer may use \$1,700 as the required contribution for the plan.

New Quality of Care Reporting Requirement

Once regulations are issued, non-grandfathered group health plans will be required to submit an annual report to both the Secretary of HHS and enrollees regarding "quality of care" measurements. These quality of care measurements will include information about benefits and reimbursement plan components that implement wellness and health promotion activities. Activities may include things such as personalized wellness and prevention services provided by, coordinated by, or maintained by: (1) a healthcare provider, (2) a wellness and prevention plan manager, or (3) a health, wellness or prevention services organization that conducts health risk assessments or offers individual intervention efforts (e.g., phone or web-based). *Note: Regulations have not been issued as of January 2019.*

The personalized wellness and prevention services could include health risk assessments or ongoing face-to-face, telephonic or web-based intervention efforts for each of the program's participants, and may include the following wellness and prevention efforts:

- (1) Smoking cessation;
- (2) Weight management;
- (3) Stress management;
- (4) Physical fitness;
- (5) Nutrition;
- (6) Heart disease prevention;
- (7) Healthy lifestyle support; or
- (8) Diabetes prevention.

The due date for providing a report to the Secretary of HHS has not yet been specified, but presumably, a deadline will be provided when HHS issues implementing regulations. Plans must provide the report to enrollees during each open enrollment period after the effective date specified in the regulations. Providers, prevention plan managers, and wellness organizations may be required to gather the necessary information and provide a report to the plan so that the plan may, in turn, provide a report to enrollees and HHS.

E. Tax Rules for Rewards

If the wellness program otherwise meets applicable nondiscrimination requirements, a reward in the form of a lower employee premium or an employer-provided contribution to an HRA, HSA, or FSA does not result in taxable income to employees and is not subject to wage withholding or employment taxes. For example, if an employer

contributes \$150 to the HRA of each employee who undergoes a cholesterol screening, the \$150 contribution does not result in additional income for each participating employee. (Note: The reward may be taxable under certain situations where a cash or cash equivalent reward is paid for an individual who is not the employee's spouse or federal tax dependent.)

Note: Discrimination (and/or comparability for HSAs) issues may arise under other laws such as the Internal Revenue Code for rewards in the form of increased benefits under a medical plan such as an additional contribution to an HRA. Consult your benefits advisor for additional information regarding employer contributions to HRAs, HSAs, and FSAs. In addition, the Internal Revenue Code sections which prohibit discrimination in favor of highly compensated and key employees will also apply.

Likewise, rewards that take the form of reduced premiums, co-payments or deductibles would not be taxable under Section 105 and 106 of the Internal Revenue Code. (Note: The reward may be taxable under certain situations where a cash or cash equivalent reward is paid for an individual who is not the employee's spouse or tax dependent.)

Rewards that come in the form of cash (e.g., a cash bonus) or cash-equivalent (e.g., a gift card to a local restaurant) are taxable and will be subject to wage withholding and employment taxes. For example, if an employer provides a \$50 gift card to a restaurant for all employees who complete a health risk assessment, each participating employee will have an additional \$50 of income subject to wage withholding and employment taxes.

Rewards such as certain employee discounts, T-shirts, mugs, and other rewards that qualify as *de minimis* fringe benefits under Internal Revenue Code Section 132 are not taxable to employees. Please note that the *de minimis* standard does not apply to cash rewards. For more information, refer to IRS Publication 15-B "Employer's Tax Guide to Fringe Benefits." <http://www.irs.gov/publications/p15b/ar02.html>

Other noncash rewards could be taxable such as discounts on products or merchandise (e.g., weights, MP3 players, etc.). Employers should consult with their tax advisors with any questions about the taxation of rewards.

In May 2017, the IRS provided guidance on certain wellness programs sometimes marketed as "fixed indemnity health plans." These programs are promoted as a way to provide certain benefits to employees at little or no cost to the employer and little or no cost to employees on a take-home pay basis. Under one design, employees are given the opportunity to enroll in coverage under a self-insured health plan. Employees who participate in the self-insured plan pay a small after-tax contribution. The self-insured health plan pays employees a fixed cash payment for participating in certain health-related activities such as calling a toll-free number that provides general health-related information, attending a seminar that provides general health-related information,

participating in a biometric screening, or attending a counseling session. Employees are not charged for participating in any of these activities which are described as a wellness program. The fixed payment that employees receive under the self-insured health plan for each covered activity (e.g., \$1,425 per activity) is much greater than the amount of the employee's after-tax contribution (e.g., \$60 per month) for participating in the self-insured health plan. Under an actuarial analysis, all employees are expected to receive benefit payments under the self-insured health plan that markedly exceed their after-tax contributions.

The IRS clarified that under this program, reimbursements to employees under the self-insured health plan are not excludable from income because the payments under this program do not reimburse covered individuals for expenses incurred for medical care. These reimbursements are merely lump sum payments made regardless of whether any medical care was received. Therefore, excess payments (e.g., a reimbursement of \$1,425 minus the employee's \$60 contribution which equals \$1,365) must be included in the employee's taxable income. Employers that have or are considering implementing one of these programs will want to discuss the IRS rules with an attorney with appropriate experience.

F. Other Federal Laws

Some federal laws such as the prohibition against discrimination based on age will apply to all types of programs. Others will apply to some, but not all, wellness programs. For example, the Genetic Information Nondiscrimination Act ("GINA") rules will apply to most wellness programs that use health risk assessments, but would not apply to a program that only provides a reward for attending a smoking cessation class. Following is a brief summary of the major federal laws that may apply to activity-only wellness programs.

Cafeteria Plans

Under the Section 125 cafeteria plan regulations, if a decrease in the employee's required contribution is "insignificant," an employer may structure its cafeteria plan to automatically change a newly qualifying employee's salary reduction to reflect the reduced required contribution. If the decrease in required contribution is "significant," an employee may elect to have his or her salary reduction prospectively changed to reflect the decreased contribution. The Section 125 regulations would also permit mid-year changes when an employee loses a wellness reward and thus must pay a higher monthly contribution (e.g., an employee starts smoking). For more information on the impact of cost changes on permissible salary reduction changes, refer to Treasury Regulation Section 1.125-4(f)(2). Unfortunately, the existing cafeteria plan regulations were issued before the wellness program regulations were finalized. As a result, it is unclear how any retroactive rewards would be treated under the cafeteria plan. Hopefully, the IRS will provide updated guidance in the future.

Americans with Disabilities Act (“ADA”)

There are two areas of concern under the ADA with regard to wellness programs. First, the ADA prohibits employers from discriminating against individuals with disabilities. For example, a program that provides a reward based on a health condition or completion of an activity may discriminate against individuals who have a disability. This may violate the ADA even if the program is designed so that it complies with the HIPAA nondiscrimination requirements. Second, the ADA limits when employers may make medical inquiries or conduct medical examinations. The EEOC issued final regulations in May 2016. ADA regulations apply to employees, former employees, and applicants; they do not apply to spouses or dependents.

The EEOC’s ADA regulations govern employer-sponsored wellness programs that include either disability-related inquiries or medical exams (including biometric screening). For example, a wellness program could include disability-related questions in a health risk assessment or biometric testing and based on the employee’s responses to the questions or results of the biometric screening the employee may be required to contact a health coach. An HRA that includes disability-related inquiries would be subject to the EEOC rules even if the HRA is not subject to HIPAA due to the fact that it is not related to a health plan. For example, if an employer makes an HRA available to all employees including employees who are not eligible for the employer’s medical plan (e.g., part-time employees), then the wellness program would be subject to the ADA requirements. A program that includes biometric screening would be a health program subject to both the HIPAA and ADA rules. The ADA regulations require a wellness program to:

- (1) Be reasonably designed** – similar to HIPAA, the program must: (1) have a reasonable chance of promoting health or preventing disease; (2) not be overly burdensome; (3) not be a subterfuge for violating the ADA or other federal laws; and (4) not be highly suspect in the methods chosen. A program that collects health information or uses tests or screening that does not provide results, follow up information, or advice designed to improve employees’ health is not considered to be reasonably designed. For example, if a program does not use collected data to address at least a subset of conditions identified (either for individuals or a group of employees), or if the program exists mainly to shift costs to targeted employees based on health, or if it used simply to give the employer information to estimate future healthcare costs, then it is not reasonably designed.
- (2) Be voluntary** – employees may not be required to participate, employees may not be denied coverage under any of the group health plans or particular benefit packages within a group health plan based on non-participation, and employees may not be subject to any adverse employment action based on non-participation (e.g., termination of employment).

- (3) Provide a notice** – the program must provide a notice that (1) is written so that employees are likely to be able to understand it; (2) clearly explains what medical information will be obtained and the purpose for which the medical information will be obtained; (3) identifies who will receive the medical information and how it will be used; and (4) states the restrictions on disclosures along with the methods that will be used to prevent improper disclosure.

The notice must describe the information to be collected, how the information will be used, with whom it will be shared, how it will be kept confidential, the restrictions on uses and disclosures, and the methods the employer has implemented to prevent improper disclosure of medical information. The EEOC posted a model notice along with several FAQs on its website – [click here](#) to access the model; [click here](#) to access the FAQs.

- (4) Keep the information confidential** – generally, the information may not be disclosed to an employee’s supervisor or manager, individuals who handle medical information generally should not be responsible for making employment decisions, and a notification is required in the event of a breach. A participant may not be required to agree to the sale, exchange, sharing, transfer, or other disclosure of medical information in order to participate in the wellness program or receive an incentive.

- (5) Provide reasonable accommodation** –for employees if needed to access the wellness program – e.g., a sign language interpreter for a deaf employee or large print material for visually impaired employees.

In response to a court order, the EEOC issued guidance in December 2018 that removed a 30% maximum reward rule 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.

In the preamble to the final regulations, the EEOC expanded upon its interpretation of ADA’s insurance safe harbor provision and reaffirmed its position that the insurance safe harbor is not available for wellness programs that include disability-related inquiries or medical examinations. This issue had been addressed by several courts prior to the issuance of these regulations and is likely to be the subject of additional litigation. Based on the EEOC’s comments in the preamble (and concurrently issued FAQs), it is likely that the EEOC will continue to challenge employers who rely on the insurance safe harbor when designing their wellness programs. Employers that want to use the safe harbor when designing their wellness programs should discuss the EEOC’s position and their program designs with legal counsel with appropriate experience before proceeding.

Genetic Information Nondiscrimination Act (“GINA”)

Employers are prohibited from discriminating against any employee with respect to the compensation, terms, conditions, or privileges of employment on the basis of “genetic information.” In general:

- Employers are not permitted to request, require or purchase genetic information,
- Employers must maintain genetic information as a confidential medical record, and
- Strict limits apply to the disclosure of genetic information.

Under the Genetic Information Nondiscrimination Act (“GINA”), genetic information is broadly defined to include family medical history. Thus, a wellness program that seeks genetic information in the form of family medical history for underwriting purposes violates GINA. Family is broadly defined to include relatives to the fourth degree (e.g., cousins once-removed) and relatives by marriage (e.g., spouse and in-laws).

GINA prohibits the collection of genetic information for underwriting purposes. A health plan may not collect genetic information in connection with enrollment and may not give a reward for providing genetic information regardless of when it is collected. Under the GINA regulations, a health plan that provides a premium reduction for employees who complete an HRA that includes questions about employee family history, violates GINA – even if the HRA is provided after enrollment – because completion of the health risk assessment results in a reduction of premium and is therefore considered to be for purposes of underwriting.

A health plan that includes completion of an HRA may still violate GINA even if there is no premium reduction for completing the assessment (or penalty for not completing it) if the assessment requests genetic information such as family medical history **if the assessment is obtained before coverage begins**. For example, an employer with a calendar year plan conducts annual enrollment for the upcoming year during November. On December 5, after all elections have been made, the employer sends a health risk questionnaire that requests genetic information with instructions that the assessment must be completed and returned by December 31. The employer has violated the GINA requirements by collecting the information before the January 1 coverage effective date.

Because GINA defines “family member” to include a spouse, information about a spouse’s current medical conditions could be considered genetic information. As a result there was some concern that providing for completion of a HRA by a spouse – even if the HRA did not elicit information about genetic tests or services or about the spouse’s family medical history – would violate GINA if a reward was offered. The EEOC addressed this issue in final regulations issued in May 2016. Under EEOC’s final GINA regulations, if as part of an activity-only program a spouse completes an HRA or undergoes biometric screening (for example, the spouse may be required to contact a

health coach based on responses to an HRA or the results of biometric screening), then the wellness program may provide a reward subject to the following requirements:

- (1) The program must be reasonably designed to promote health or prevent disease; must not be overly burdensome; must not be a subterfuge for violating GINA or other laws; and must not be suspect in the method chosen. A wellness program that includes a test, screening or collection of health-related information without providing participants with results (which may be individuals or a group of employees or spouses), follow-up information, or advice designed to improve the participant's health is not reasonably designed. In addition a program is not considered reasonably designed if it imposes a penalty on (or otherwise disadvantages) an individual because of a spouse's manifestation of a disease or disorder by preventing or inhibiting the spouse from participating in, or from achieving a certain health outcome. In addition, the employer may not deny access to a group health plan or package of benefits based on a spouse's refusal to complete a health reimbursement assessment or undergo biometric testing.
- (2) The program must be voluntary - the spouse must provide knowing, voluntary, written authorization.
- (3) 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.
- (4) The spouse must be provided with a notice containing specific information. The 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 healthcare 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.

Unlike the HIPAA and PPACA rules, the EEOC's GINA rules limit incentives to 30% for all wellness programs – including those that are participation only programs – based upon the cost of self-only coverage.

In response to a court order, the EEOC issued guidance in December 2018 that removed a 30% maximum reward rule 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 GINA.

Under the EEOC's regulations, the wellness program may also include completion of health risk assessments or biometric screening for children, but the plan may not provide any incentive for completion of the HRA or biometric screening by children -

including adult and adopted children.

ERISA

If a private employer (for-profit or nonprofit) is involved and an exception under ERISA does not otherwise apply, and the program provides individualized “medical care,” then the program is likely an ERISA plan. The program involves “medical care” if the care is individualized and provided by trained professionals. For example, flu shots, health coaching by a nurse, counseling by a therapist, or biometric screening would all be example of medical care if provided through an employer. However, if a program only offers general education, it is not “medical care.” For example, a newsletter with health condition articles, a “lunch-n-learn” about diabetes, and a weight loss class without a personalized assessment are all example of general education.

If a wellness program is an “employee welfare benefit plan” under ERISA, it will have to satisfy ERISA's applicable compliance requirements, including the following:

- (1) There must be a plan document;
- (2) Plan terms must be followed and strict fiduciary standards adhered to;
- (3) SPDs (SMMs and SMRs) must be provided to plan participants;
- (4) Form 5500 must be filed annually (subject to certain exceptions); and
- (5) Claims procedures must be established and followed.

Wellness programs that constitute group health plans must also meet certain special requirements: (a) additional requirements under the DOL claims procedure regulations; (b) additional SPD disclosures; and (c) special timing rules for SMMs.

PPACA added more special requirements, including enhanced internal claims and appeals requirements and external review procedures applicable to non-grandfathered plans. In the preamble to the amended PPACA appeals regulations issued on June 24, 2011, the Departments of Health and Human Services, Labor, and Treasury included examples of situations in which a claim would involve “medical judgment” and therefore be subject to the federal external review process for an adverse benefit determination. Included among those examples is a determination based on whether a participant would be entitled to a reasonable alternative standard under an employer-sponsored wellness program.

Thus, non-grandfathered plans denying a request for a reasonable alternative standard (or a waiver of an otherwise applicable standard) to obtain a reward related to a standard-based wellness program should be ready to follow the PPACA appeals procedures, including the requirement to make available an external review by an Independent Review Organization.

COBRA

A health plan that is subject to COBRA and is linked with a wellness program, must include some of the wellness program provisions as part of COBRA coverage offered by the health plan. In general, if the wellness program provides a reward in the form of a different benefit such as a reduced deductible, it must be offered to COBRA qualified beneficiaries. For example, if the wellness program provides a \$100 reduction in the annual deductible for any individual who completes a health risk assessment question, regardless of the results, qualified beneficiaries must be given the same opportunity. Rewards in the form of reduced premiums do not need to be offered to COBRA qualified beneficiaries.

Health plans must comply with any applicable COBRA requirements. The most significant obligations are listed below:

- (1) **Provision of a General Notice:** Each participant and his or her spouse must receive a General Notice when coverage under the program first begins;
- (2) **Provision of an Election Notice:** Each Qualified Beneficiary must receive an Election notice with a notice of the Qualified Beneficiary's rights and obligations for a specific qualifying event (e.g., termination of a covered employee's employment or reduction of a covered employee's hours of employment, etc.) The Election Notice for the wellness program may be combined with the Election Notice for the employer's major medical plan(s);
- (3) **Provision of a Notice of Unavailability (if applicable):** Certain individuals who expect to receive COBRA continuation coverage but are not entitled to such coverage must be provided with a Notice of Unavailability;
- (4) **Coverage:** if a Qualified Beneficiary elects COBRA continuation coverage under the wellness program, he or she generally may receive such coverage for a basic coverage period which is the same period of time as any other COBRA continuation period (e.g., 18 months for certain qualifying events, 36 months for other qualifying events). The Qualified Beneficiary would be entitled to any incentives available to active employees and would also be permitted to elect any other group health coverage offered to other employees during open enrollment; and
- (5) **Provision of an Early Termination Notice (if applicable):** If COBRA continuation terminates before the end of the maximum coverage period, the Qualified Beneficiary must be provided with a Notice of Termination.

Employers should review their existing plan materials and COBRA policies and procedures to ensure that applicable wellness programs are included in any written COBRA policies and procedures.

Age Discrimination in Employment Act (“ADEA”)

The ADEA prohibits employment discrimination against employees and job applicants on the basis of age with respect to benefits. Protected individuals must be at least 40 years of age. Thus, a wellness program could violate the ADEA if it terminated or decreased wellness rewards, or otherwise discriminated against employees age 40 or older.

Title VII

Title VII relates to the “terms, conditions, or privileges of employment,” which generally include wellness programs. Thus, if an employer takes into consideration a plan participant’s race, religion, sex, color, or national origin, then the program could violate Title VII.

Fair Labor Standards Act (“FLSA”)

Under the FLSA, nonexempt employees must be compensated at not less than time and one-half of regular pay for time worked over 40 hours in any given workweek. Thus, if time spent completing a wellness program is considered to be “compensable time,” then the employer may have to pay overtime. For example, if an employer provides health lectures as part of a wellness program, the time spent could be compensable time. However, the time need not be compensable time if four conditions are met: (1) attendance is outside of the employee’s regular work hours; (2) attendance is purely voluntary; (3) the lecture is not directly related to the employee’s job; and (4) the employee does not do any productive work during the lecture (e.g., answering e-mails).

SECTION 7 – HEALTH PLAN-RELATED OUTCOME-BASED PROGRAMS

Outcome-based wellness programs are those that base the reward on a health factor such as the results of a biometric test or a health condition such as diabetes. Examples of outcome-based plans include programs that condition a reward on having a cholesterol count under 200 or a Body Mass Index (“BMI”) less than 30. Rewards such as smoker/nonsmoker rewards or penalties are outcome-based if the reward is only earned if the individual does not use tobacco or quits using tobacco.

Many outcome-based wellness programs include the use of a health risk assessment (“HRA”). An HRA is a method of determining who might most benefit from a wellness (or disease management) program and identifying potential health-related areas of concern for specific individuals. An HRA can take the form of a simple questionnaire, and often, an HRA is accompanied by biometric testing (e.g., blood pressure screening, body mass index calculation, cholesterol screening, blood sugar level testing, etc.).

Employers that provide wellness rewards in the form of “credits” that are assigned to an employee’s general purpose health Flexible Spending Account should limit the dollar amount to \$500 or less. Limiting the maximum dollar amount can help to ensure that their health FSAs do not inadvertently lose their status as HIPAA-excepted benefits. In order to be an excepted benefit, a general purpose health FSA must have a maximum benefit that is limited to the greater of: (1) 2 x the employee’s salary reduction election, or (2) the employee’s salary reduction amount plus \$500. Under this rule if an employer assigned \$600 in family wellness credits to an employee’s health FSA and the employee elected a \$0 salary reduction amount, the FSA would not be an excepted benefit. A general health FSA that is not an excepted benefit will violate PPACA’s prohibition against a dollar maximum on essential health benefits and could be subject to PPACA’s \$100 per day per affected person penalty. Employers wishing to assign dollar amounts higher than \$500 will need to design and monitor their health FSAs to ensure that the FSA maximum does not exceed 2 x the salary reduction amount. As an alternative, employers could credit reward amounts to an FSA that is limited to dental and vision expenses since separate dental and vision plans are almost always excepted benefits.

Wellness programs may be subject to a number of federal and state laws including the Health Insurance Portability and Accountability Act (“HIPAA”), the Patient Protection and Affordable Care Act (“PPACA”), ERISA, COBRA, the Genetic Information Nondiscrimination Act (“GINA”), the Americans with Disabilities Act (“ADA”), the Age Discrimination in Employment Act (“ADEA”), Title VII of the Civil Rights Act (e.g., gender discrimination), the Fair Labor Standards Act (“FLSA”), the Internal Revenue Code, state tax codes, state nondiscrimination laws, and federal cafeteria plan rules and

regulations. Because nicotine addiction is considered a substance use disorder, if a wellness program includes tobacco reduction or cessation, the requirements of the Mental Health Parity and Addiction Equity Act (“MHPAEA”) may also apply.

A brief summary of the major requirements under federal laws follows.

A. HIPAA Nondiscrimination

Wellness programs that offer a reward related to a health plan and those that condition receipt of the reward upon a health factor such as a cholesterol count under 200 are subject to the HIPAA nondiscrimination rules. The HIPAA nondiscrimination rules provide that group health plans may not discriminate in health coverage among individuals on the basis of a “health factor,” in terms of eligibility, benefits or costs. There are eight “health factors” that may not be used to discriminate against individuals in providing health coverage: (1) health status; (2) medical condition (physical or mental illness); (3) claims experience; (4) receipt of health care; (5) medical history; (6) genetic information; (7) disability; and (8) evidence of insurability. Wellness programs that are related to the employer’s health plan and provide a reward dependent upon an individual meeting a “specific health-related standard” differentiate in terms of benefits or costs based upon health status. Wellness programs that comply with HIPAA’s nondiscrimination requirements are an exception to this requirement; they are permitted to vary benefits and/or costs by a limited amount. Wellness programs are permitted to discriminate in favor of employees who have a health condition – called benign discrimination. For example, a wellness plan could include free glucose testing or test strips for diabetics.

Wellness programs that are, or that are a part of, HIPAA-exempt health plans are not subject to HIPAA’s nondiscrimination rules. For example, a wellness reward provided under a stand-alone vision plan (such as a lower co-payment for participants who have annual vision checkups) is not subject to HIPAA’s nondiscrimination rules.

Rewards under wellness programs are typically in the form of changes in contributions or benefits such as a reduction in required health contributions or an increase in a deductible. Some employers have wanted to condition eligibility for a particular health plan option on smoker/nonsmoker status or another health factor. For example, smokers would be eligible for a core option while nonsmokers would be eligible for a core option and would also be able to buy up to an enhanced option. Based on previous informal discussions with Department of Labor representatives, the DOL may view the HIPAA prohibition on discrimination in benefits and eligibility as extending to benefit options within a health plan. As a result it may not be permissible to base option eligibility on health factors such as smoker/nonsmoker status. (Under the ADA, if the wellness program includes disability-related inquiries or a medical examination (e.g., biometric screening), the employer may not restrict the employee’s eligibility to a benefit

plan or benefit option within a health plan. For example, if an employer offers two options – a \$1,000 deductible option and a \$2,000 deductible option – the employer may not limit enrollment options for employees who do not complete the HRA or undergo biometric screening to the \$2,000 deductible option.)

There are five general rules that apply to all health plan-related outcome-based wellness programs:

(1) Maximum Reward

The total plan-based reward for all of the employer’s wellness programs that require satisfaction of an outcome-based standard must not exceed 30% of the cost of employee-only coverage under the employer’s health plan. If dependents (including spouses or dependent children) may participate in the wellness program, the reward must not exceed 30% of the cost of coverage for the applicable level of coverage. If there is more than one outcome-based program or if there is an activity-only program in addition to the outcome-based program, the maximum reward (or penalty) for all such wellness programs combined may not exceed 30%.

An employer may use a reward up to 50% for a wellness program that is designed to reduce tobacco use. If the employer’s only wellness program is a tobacco reduction program, the entire 50% is available for the program. If other wellness programs or benefits are included, the maximum available for all wellness programs combined is 50% with the non-tobacco related programs are limited to 30%. For example, an employer could not use 50% for a tobacco reduction program plus 30% for a non-tobacco program with a total of 80%. (If the program includes disability-related inquiries or biometric testing and is subject to the ADA, it is unclear what, if any, reward may be offered.) See page 61 for more detailed information.

Generally, the reward must be paid in the year in which it was earned. If the reward is earned mid-year – for example because an employee satisfies a reasonable alternative standard mid-year, the employer may make a retroactive payment to cover the months before the standard or reasonable alternative standard was met. Alternatively, the program may prorate the annual reward over the remaining months in the plan year. For example if the reward under a calendar year plan is \$20 per month and the standard is met on July 1, the plan may prorate the monthly amount and pay \$40 per month for July through December. If the standard is not satisfied until near the end of the plan year, the employer may pay the reward within a reasonable period after the end of the plan year. In no event may the plan apply the reward to the following plan year.

Rewards under wellness programs are typically in the form of changes in

contributions or benefits such as a reduction in required health contributions or an increase in a deductible. Some employers have wanted to condition eligibility for a particular health plan option on smoker/nonsmoker status or another health factor. For example, smokers would be eligible for a core option while nonsmokers would be eligible for a core option and would also be able to buy up to an enhanced option. Based on previous informal discussions with Department of Labor representatives, the DOL may view the HIPAA prohibition on discrimination in benefits and eligibility as extending to benefit options within a health plan. As a result it may not be permissible to base option eligibility on health factors such as smoker/nonsmoker status. (Under the ADA, if the wellness program includes disability-related inquiries or a medical examination (e.g., biometric screening), the employer may not restrict the employee's eligibility to a benefit plan or benefit option within a health plan. For example, if an employer offers two options – a \$1,000 deductible option and a \$2,000 deductible option – the employer may not limit enrollment options for employees who do not complete the HRA or undergo biometric screening to the \$2,000 deductible option.)

It is permissible to design a wellness program that favors those with health conditions (benign discrimination). For example, an employer may structure a wellness program that tests cholesterol levels and provides free dietary counseling to individuals with total cholesterol about a specified value such as 200, but does not provide any other type of reward (i.e., there is no reward for having total cholesterol below the target number).

If the wellness program includes an HRA or biometric screening and spouses are eligible, then additional GINA requirements will apply. At this time it is unclear what, if any, incentive may be offered. See page 63 for more detailed information.

(2) Reasonable Design

The program must be reasonably designed to promote health or prevent disease. Programs are reasonably designed to promote health and prevent disease if they: (1) provide a reasonable chance to improve health or prevent disease; (2) are not overly burdensome; (3) are not a subterfuge for discrimination based on health; and (4) are not “highly suspect” in the method chosen to promote health or prevent disease.

Wellness programs that include disability-related questions and/or medical examinations (such as biometric screening) for employees are also subject to the requirements of the Americans with Disabilities Act (“ADA”) which also requires that the program be reasonably designed. The final ADA regulations include the four HIPAA requirements but also state that a program that collects health information or uses tests or screenings that does not provide

results, follow up information, or advice designed to improve employees' health is not considered to be reasonably designed. For example, if a program does not use collected data to address at least a subset of conditions identified (either for individuals or a group of employees), or if the program exists mainly to shift costs to targeted employees based on health, or if it used simply to give the employer information to estimate future healthcare costs, then it is not reasonably designed. (See page 61 for more information about ADA's requirements.)

For programs that include spousal completion of an HRA, GINA's requirements will also apply. Final GINA regulations include the four HIPAA requirements along with the additional limitations added by the ADA. In addition, under GINA a program is not considered reasonably designed if it imposes a penalty on (or otherwise disadvantages) an individual because of a spouse's manifestation of a disease or disorder by preventing or inhibiting the spouse from participating in, or from achieving a certain health outcome. (See page 63 for more information about GINA's requirements.)

(3) Annual Opportunity

The program must allow eligible individuals at least one opportunity per year to qualify for the reward. Some programs determine eligibility for the reward shortly before the beginning of a new medical plan year (e.g., a plan that reduces the monthly premium for the next year for those individuals who certify at annual enrollment that they have been tobacco-free for six months).

An individual who does not satisfy the initial standard must be given a reasonable alternative standard. It may take some time to request, establish and satisfy a reasonable alternative standard to individuals who do not meet the initial standard for the year. As a result wellness programs that determine eligibility for the reward prior to or at the beginning of a plan year may still have individuals qualifying during the plan year.

(4) Reasonable Alternative Standard

The program reward must be available to all similarly situated individuals and must include a reasonable alternative standard for individuals who do not satisfy the standard. In order to be reasonable, the alternative standard must satisfy the following rules (as applicable):

- a. If the alternative standard is completion of an educational program, then the plan must make the educational program available or help the individual find the program and pay the cost of the program. It can't require the individual to find or pay for the program.
- b. If the alternative standard is a diet program, then the plan must pay for any membership or participation fee. The plan is not required to pay the cost of food.

- c. The time commitment required must be reasonable. The regulations state that requiring attendance nightly at a one-hour class would not be reasonable.

The reasonable alternative standard cannot be the same standard as the initial standard without additional time to satisfy the standard. For example, if the standard is a BMI under 30, the reasonable alternative standard cannot be to achieve a BMI under 31 on the same day. The alternative could be a small amount or percentage reduction over a realistic period of time.

If an individual is unable to meet an outcome-based standard, then the wellness program must provide the individual with a reasonable alternative standard as a way to earn the reward. The plan sponsor may not require a physician's note confirming that satisfying the standard would be either medically inadvisable or unreasonably difficult for a medical reason. In addition, the individual must be given the opportunity to comply with the recommendation of his/her own physician as a second reasonable alternative standard. The individual may make a request to involve his/her personal physician at any time during the year and the physician may modify his/her recommendations at any time based on medical appropriateness.

The alternative standard may itself be a participatory, activity-only or outcome-based standard. If the alternative standard is activity-only, it must follow the rules for activity-only standards. If the alternative is outcome-based, it must follow those rules. If it is participatory, those rules must be followed.

The employer does not need to have a reasonable alternative developed in advance. The reasonable alternative can be designed once a request for one has been received. The reasonable alternative may be generic or it may be individualized. Waiving the standard (and paying the reward) is always a reasonable alternative.

Programs subject to ADA's requirements (i.e., programs that include disability-related inquiries and/or medical examinations such as biometric screening for employees), must also provide a reasonable accommodation for employees with a disability. For example, the program may need to provide large print versions of materials for employees with visual impairments. (See page 61 for more information about ADA's requirements.)

In recognition of the difficulty of overcoming tobacco addiction, the rules allow for repeated attempts to stop smoking and require reasonable alternative standards each year. The reasonable alternative standard may be the same for each year or may be different. For example, the reasonable alternative standard to tobacco cessation in Year 1 could be an educational seminar, with attendance entitling an individual to the full reward, regardless of whether the individual stopped smoking. The Year 2 reasonable alternative standard could be a new nicotine replacement therapy, the completion of which, would entitle the individual to the full reward. Or the reasonable alternative standard could be attending an educational smoking cessation seminar each year.

(5) Required Disclosure

The program must disclose (in all materials describing the terms of the program, including annual enrollment materials) the availability of a reasonable alternative standard – or the possibility of a waiver of the underlying standard, if applicable. Materials describing the reasonable alternative standard must include a statement that the individual’s personal physician’s recommendations will be accommodated by the program.

A program need only disclose that a reasonable alternative standard (or waiver of the standard) is available in all materials describing the wellness program. For example, if information about a wellness program is included in open enrollment materials, the statement about the availability of a reasonable alternative standard must be included in those materials. Materials that include reference to a premium discount would be required to disclose the existence of an alternative standard. In addition, the program must disclose that a reasonable alternative standard is available in any notice informing the individual that he/she did not satisfy the outcome-based standard. The Department of Labor provided sample language in June 2013:

“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 June 2013 regulations also included the following additional sample language in the examples:

“Your health plan wants to help you take charge of your health.

Rewards are available to all employees who participate in our Cholesterol Awareness Wellness Program. If your total cholesterol count is under 200, you will receive the reward. If not, you will still have an opportunity to qualify for the reward. We will work with you and your doctor to find a Health Smart program that is right for you“

Under the EEOC’s GINA regulations, spousal notice and consent would be required for a program that includes an HRA or biometric screening. (See page 63 for more details about GINA’s requirements.)

B. HIPAA Privacy and Security

Many wellness programs will be subject to HIPAA’s Privacy and Security rules and regulations. However, these requirements will not apply if the wellness program is, or is part of, a group health plan not subject to HIPAA’s Privacy and Security provisions (i.e., a small self-insured group health plan – one with fewer than 50 eligible individuals – which is administered by the employer that established and maintains the plan). Note: HIPAA Privacy and Security rules do apply to HIPAA-excepted benefits such as separate dental and vision plans.

Wellness programs that provide medical care (such as biometric screening) or that are linked to the employer’s health plan are subject to the HIPAA Privacy and Security rules. If the wellness program is linked to the employer’s medical plan, the employer may want to simply extend the medical plan’s privacy and security policies and procedures to the wellness program. If the wellness program is separate – for example the program is offered to employees who are not eligible for the employer’s medical plan – the employer may want to adopt and modify the medical plan’s privacy and security procedures for use in the wellness program. For example, an employer providing flu shots or biometric screening to part-time employees who are not eligible for the major medical plan would not need to establish a separate plan with separate documents and procedures for the wellness program. Instead, the employer could include the wellness program in the privacy and security policies and procedures for the major medical plan even though the eligibility for the wellness program and major medical program are not the same. One additional step that should not be forgotten is that of obtaining Business Associate Agreements from wellness vendors.

C. Mental Health Parity and Addiction Equity Act (“MHPAEA”)

The Mental Health Parity and Addiction Equity Act (“MHPAEA”) requires health plans to provide parity between benefits for treatment of medical/surgical care and mental health/substance use disorders. For example, health plans are not permitted to include provisions such as higher deductibles or separate deductibles for mental health/substance use disorder treatments. In addition, health plans are not permitted to assign all drugs that are used to treat mental health/substance use disorder conditions

to a higher copay tier than is required for prescriptions to treat medical/surgical conditions. Nicotine addiction is considered to be a substance use disorder that is subject to the parity rule under MHPAEA. Although not entirely clear, based on regulations under both HIPAA and PPACA, differences in required contributions appear to be permissible for smokers and non-smokers as long as part of a compliant wellness program. Some wellness programs use only educational materials or smoking cessation classes as a reasonable alternative under their smoking cessation program. Others cover the cost of prescribed drugs intended to help individuals stop smoking. Programs that cover the cost of prescription drugs provide medical care and are subject to the MHPAEA parity rule. Because regulations to date have not addressed how MHPAEA applies to wellness programs, it is unclear to what extent a wellness program could restrict coverage of prescriptions drugs without creating a potential problem under MHPAEA. Employers with limitations on smoking cessation drugs or counseling should consult with their legal counsel.

D. Patient Protection and Affordable Care Act (“PPACA”)

If a wellness program varies the deductible, co-payments, coinsurance or coverage for any of the services listed in the Summary of Benefits and Coverage (“SBC”), the calculations for that treatment scenario must assume that the individual is participating in the wellness program and additional language must be included in the SBC. For example, if the wellness program has a diabetes component, the SBC instructions provide the following sample language to be included with the coverage examples: *“Note: These numbers assume the patient is participating in our diabetes wellness program. If you have diabetes and do not participate in the wellness program, your costs may be higher. For more information about the diabetes wellness program, please contact [insert].”* Currently, two treatment scenarios that must be included in the SBC template are pregnancy, diabetes, and a simple fracture.

Under PPACA’s Employer Shared Responsibility requirement, a large employer (generally defined as more than 50 full-time and full-time equivalent employees) that does not offer minimum essential coverage to at least 95% of its full-time employees or a large employer that offers coverage that is either not “affordable” or does not provide “minimum value” may be required to pay a penalty. PPACA regulations issued in 2013 specify how minimum value and affordability may be calculated for employers sponsoring wellness programs that are tied to their health plans.

The IRS’s December 2015 final regulations state that minimum value must be determined without regard to reduced cost-sharing available under a wellness program (with an exception for tobacco-reduction programs described below). For example, if a wellness program has a \$4,000 deductible with a \$200 reduction for completion of a health-related activity, the medical program may not use a \$3,800 deductible when calculating minimum value – it must use the full \$4,000.

A medical plan’s affordability must be determined assuming that each employee fails to

satisfy the requirements of the wellness program (with an exception noted below). Regulations include an example where an employer with a \$4,000 required contribution reduces the contribution by \$200 for completion of a health-related activity. This employer may not use a \$3,800 required contribution when calculating affordability – it must use the full \$4,000.

Employers may, however, determine minimum value and affordability by taking into account certain rewards for wellness programs that are designed to reduce tobacco use. When determining minimum value the employer may include the value of differences such as a reduction in a deductible assuming that all individuals will qualify for the reward. For example, if the deductible is \$1,500 but will be reduced by \$300 for any individual who either does not use tobacco or attends a smoking cessation class, the employer may use a \$1,200 deductible in determining minimum value. Similarly, premium rewards (or penalties) may be taken into account in determining affordability by assuming that all individuals will qualify for the reward. If the annual required contribution is \$2,000 and individuals who either don't smoke or who attend a smoking cessation class receive a \$300 reduction in their contributions, the employer may use \$1,700 as the required contribution for the plan.

New Quality of Care Reporting Requirement

Once regulations are issued, non-grandfathered group health plans will be required to submit an annual report to both the Secretary of HHS and enrollees regarding “quality of care” measurements. These quality of care measurements will include information about benefits and reimbursement plan components that implement wellness and health promotion activities. Activities may include things such as personalized wellness and prevention services provided by, coordinated by, or maintained by: (1) a healthcare provider, (2) a wellness and prevention plan manager, or (3) a health, wellness or prevention services organization that conducts health risk assessments or offers individual intervention efforts (e.g., phone or web-based). *Note: Regulations have not been issued as of January 2019.*

The personalized wellness and prevention services could include health risk assessments or ongoing face-to-face, telephonic or web-based intervention efforts for each of the program's participants, and may include the following wellness and prevention efforts:

- (1) Smoking cessation;
- (2) Weight management;
- (3) Stress management;
- (4) Physical fitness;
- (5) Nutrition;
- (6) Heart disease prevention;
- (7) Healthy lifestyle support; or
- (8) Diabetes prevention.

The due date for providing a report to the Secretary of HHS has not yet been specified, but presumably, a deadline will be provided when HHS issues implementing regulations. Plans must provide the report to enrollees during each open enrollment period after the effective date specified in the regulations. Providers, prevention plan managers, and wellness organizations may be required to gather the necessary information and provide a report to the plan so that the plan may, in turn, provide a report to enrollees and HHS.

E. Tax Rules for Rewards

If the wellness program otherwise meets applicable nondiscrimination requirements, a reward in the form of a lower employee premium or an employer-provided contribution to an HRA, HSA, or FSA does not result in taxable income to employees and is not subject to wage withholding or employment taxes. For example, if an employer contributes \$150 to the HRA of each employee who undergoes a cholesterol screening, the \$150 contribution does not result in additional income for each participating employee. (Note: The reward may be taxable under certain situations where a cash or cash equivalent reward is paid for an individual who is not the employee's spouse, employee's child up to age 26, or the employee's federal tax dependent.)

NOTE: Discrimination (and/or comparability for HSAs) issues may arise under other laws such as the Internal Revenue Code for rewards in the form of increased benefits under a medical plan such as an additional contribution to an HRA. Consult your benefits advisor for additional information regarding employer contributions to HRAs, HSAs, and FSAs. In addition, the Internal Revenue Code sections which prohibit discrimination in favor of highly compensated and key employees will also apply.

Likewise, rewards that take the form of reduced premiums, co-payments, or deductibles would not be taxable under Section 105 and 106 of the Internal Revenue Code. (Note: The reward may be taxable under certain situations where a cash or cash equivalent reward is paid for an individual who is not the employee's spouse, employee's child up to age 26, or the employee's federal tax dependent.)

Rewards that come in the form of cash (e.g., a cash bonus) or cash-equivalent (e.g., a gift card to a local restaurant) are taxable and will be subject to wage withholding and employment taxes. For example, if an employer provides a \$50 gift card to a restaurant for all employees who complete a health risk assessment, each participating employee will have an additional \$50 of income subject to wage withholding and employment taxes. A reward in the form of reimbursement for some or all of the cost of a gym membership is taxable and subject to wage withholding and employment taxes (re-confirmed in an April 2016 IRS memorandum).

Rewards such as certain employee discounts, T-shirts, mugs, and other rewards that qualify as *de minimis* fringe benefits under Internal Revenue Code Section 132 are not

taxable to employees. Please note that the *de minimis* standard does not apply to cash rewards. For more information, refer to IRS Publication 15-B “Employer’s Tax Guide to Fringe Benefits.” <http://www.irs.gov/publications/p15b/ar02.html>

Other noncash rewards could be taxable such as discounts on products or merchandise (e.g., weights, iPads, etc.). Employers should consult with their tax advisors with any questions about the taxation of rewards.

In May 2017, the IRS provided guidance on certain wellness programs sometimes marketed as “fixed indemnity health plans.” These programs are promoted as a way to provide certain benefits to employees at little or no cost to the employer and little or no cost to employees on a take-home pay basis. Under one design, employees are given the opportunity to enroll in coverage under a self-insured health plan. Employees who participate in the self-insured plan pay a small after-tax contribution. The self-insured health plan pays employees a fixed cash payment for participating in certain health-related activities such as calling a toll-free number that provides general health-related information, attending a seminar that provides general health-related information, participating in a biometric screening, or attending a counseling session. Employees are not charged for participating in any of these activities which are described as a wellness program. The fixed payment that employees receive under the self-insured health plan for each covered activity (e.g., \$1,425 per activity) is much greater than the amount of the employee’s after-tax contribution (e.g., \$60 per month) for participating in the self-insured health plan. Under an actuarial analysis, all employees are expected to receive benefit payments under the self-insured health plan that markedly exceed their after-tax contributions.

The IRS clarified that under this program, reimbursements to employees under the self-insured health plan are not excludable from income because the payments under this program do not reimburse covered individuals for expenses incurred for medical care. These reimbursements are merely lump sum payments made regardless of whether any medical care was received. Therefore, excess payments (e.g., a reimbursement of \$1,425 minus the employee’s \$60 contribution which equals \$1,365) must be included in the employee’s taxable income. Employers that have or are considering implementing one of these programs will want to discuss the IRS rules with an attorney with appropriate experience.

F. Other Federal Laws

Some federal laws such as the prohibition against discrimination based on age will apply to all types of programs. Others will apply to some, but not all, wellness programs. For example, the Genetic Information Nondiscrimination Act (“GINA”) rules will apply to most wellness programs that use health risk assessments, but would not apply to a program that provides a reward for attending a smoking cessation class. Following is a brief summary of the major federal laws that may apply to outcome-based wellness programs.

Cafeteria Plans

Under the Section 125 cafeteria plan regulations, if a decrease in the employee's required contribution is "insignificant," an employer may structure its cafeteria plan to automatically change a newly qualifying employee's salary reduction to reflect the reduced required contribution. If the decrease in required contribution is "significant," an employee may elect to have his or her salary reduction prospectively changed to reflect the decreased contribution. The Section 125 regulations would also permit mid-year changes when an employee loses a wellness reward and thus must pay a higher monthly contribution (e.g., an employee starts smoking). For more information on the impact of cost changes on permissible salary reduction changes, refer to Treasury Regulation Section 1.125-4(f)(2). Unfortunately, the existing cafeteria plan regulations were issued before the wellness program regulations were finalized. As a result, it is unclear how any retroactive rewards would be treated under the cafeteria plan. Hopefully, the IRS will provide updated guidance in the future.

Americans with Disabilities Act ("ADA")

There are two areas of concern under the ADA with regard to wellness programs. First, the ADA prohibits employers from discriminating against individuals with disabilities. For example, a program that provides a reward based on a health condition may discriminate against individuals who have a disability. This may violate the ADA even if the program is designed so that it complies with the HIPAA nondiscrimination requirements. Second, the ADA limits when employers may make medical inquiries or conduct medical examinations. The EEOC issued final regulations in May 2016. ADA regulations apply to employees, former employees, and applicants; they do not apply to spouses or dependents.

The EEOC's ADA regulations govern employer-sponsored wellness programs that include either disability-related inquiries or medical exams (including biometric screening). An HRA that includes disability-related inquiries would be subject to the EEOC rules even if the HRA is not subject to HIPAA due to the fact that it is not related to a health plan. For example, if an employer makes an HRA available to all employees including employees who are not eligible for the employer's medical plan (e.g., part-time employees), then the wellness program would be subject to the ADA requirements. A program that includes biometric screening would be a health program subject to both the HIPAA and ADA rules. The ADA regulations require a wellness program to:

- (1) **Be reasonably designed** – similar to HIPAA, the program must: (1) have a reasonable chance of promoting health or preventing disease; (2) not be overly burdensome; (3) not be a subterfuge for violating the ADA or other federal laws; and (4) not be highly suspect in the methods chosen. A program that collects health information or uses tests or screening that does not provide results, follow up information, or advice designed to improve employees' health is not considered to be reasonably designed. For example, if a program does not use

collected data to address at least a subset of conditions identified (either for individuals or a group of employees), of if the program exists mainly to shift costs to targeted employees based on health, or if it used simply to give the employer information to estimate future healthcare costs, then it is not reasonably designed.

- (2) **Be voluntary** – employees may not be required to participate, employees may not be denied coverage under any of the group health plans or particular benefit packages within a group health plan based on non-participation, and employees may not be subject to any adverse employment action based on non-participation (e.g., termination of employment).
- (3) **Provide a notice** – the program must provide a notice that (1) is written so that employees are likely to be able to understand it; (2) clearly explains what medical information will be obtained and the purpose for which the medical information will be obtained; (3) identifies who will receive the medical information and how it will be used; and (4) states the restrictions on disclosures along with the methods that will be used to prevent improper disclosure.

The notice must describe the information to be collected, how the information will be used, with whom it will be shared, how it will be kept confidential, the restrictions on uses and disclosures, and the methods the employer has implemented to prevent improper disclosure of medical information. The EEOC posted a model notice along with several FAQs on its website – [click here](#) to access the model; [click here](#) to access the FAQs.

- (4) **Keep the information confidential** – generally, the information may not be disclosed to an employee’s supervisor or manager, individuals who handle medical information generally should not be responsible for making employment decisions, and a notification is required in the event of a breach. A participant may not be required to agree to the sale, exchange, sharing, transfer, or other disclosure of medical information in order to participate in the wellness program or receive an incentive.
- (5) **Provide reasonable accommodation** –for employees if needed to access the wellness program – e.g., a sign language interpreter for a deaf employee or large print material for visually impaired employees.

In response to a court order, the EEOC issued guidance in December 2018 that removed a 30% maximum reward rule 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.

In the preamble to the final regulations, the EEOC expanded upon its interpretation of

ADA's insurance safe harbor provision and reaffirmed its position that the insurance safe harbor is not available for wellness programs that include disability-related inquiries or medical examinations. This issue had been addressed by several courts prior to the issuance of these regulations and is likely to be the subject of additional litigation. Based on the EEOC's comments in the preamble (and concurrently issued FAQs), it is likely that the EEOC will continue to challenge employers who rely on the insurance safe harbor when designing their wellness programs. Employers that want to use the safe harbor when designing their wellness programs should discuss the EEOC's position and their program designs with legal counsel with appropriate experience before proceeding.

Genetic Information Nondiscrimination Act ("GINA")

Employers are prohibited from discriminating against any employee with respect to the compensation, terms, conditions, or privileges of employment on the basis of "genetic information." In general:

- Employers are not permitted to request, require or purchase genetic information,
- Employers must maintain genetic information as a confidential medical record, and
- Strict limits apply to the disclosure of genetic information.

Under the Genetic Information Nondiscrimination Act ("GINA"), genetic information is broadly defined to include family medical history. Thus, a wellness program that seeks genetic information in the form of family medical history for underwriting purposes violates GINA. Family is broadly defined to include relatives to the fourth degree (e.g., cousins once-removed) and relatives by marriage (e.g., spouse and in-laws).

GINA prohibits the collection of genetic information for underwriting purposes. A health plan may not collect genetic information in connection with enrollment and may not give a reward for providing genetic information regardless of when it is collected. Under the GINA regulations, a health plan that provides a premium reduction for employees who complete an HRA that includes questions about employee family history, violates GINA – even if the HRA is provided after enrollment – because completion of the health risk assessment results in a reduction of premium and is therefore considered to be for purposes of underwriting.

A health plan that includes completion of an HRA may still violate GINA even if there is no premium reduction for completing the assessment (or penalty for not completing it) if the assessment requests genetic information such as family medical history **if the assessment is obtained before coverage begins**. For example, an employer with a calendar year plan conducts annual enrollment for the upcoming year during November. On December 5, after all elections have been made, the employer sends a health risk questionnaire that requests genetic information with instructions that the assessment

must be completed and returned by December 31. The employer has violated the GINA requirements by collecting the information before the January 1 coverage effective date.

Because GINA defines “family member” to include a spouse, information about a spouse’s current medical conditions could be considered genetic information. As a result there was some concern that providing for completion of a HRA by a spouse – even if the HRA did not elicit information about genetic tests or services or about the spouse’s family medical history – would violate GINA if a reward was offered. The EEOC addressed this issue in final regulations issued in May 2016. Under EEOC’s final GINA regulations, if a spouse completes an HRA or undergoes biometric screening, then the wellness program may provide a reward subject to the following requirements:

- (1) The program must be reasonably designed to promote health or prevent disease; must not be overly burdensome; must not be a subterfuge for violating GINA or other laws; and must not be suspect in the method chosen. A wellness program that includes a test, screening or collection of health-related information without providing participants with results (which may be individuals or a group of employees or spouses), follow-up information, or advice designed to improve the participant’s health is not reasonably designed. In addition a program is not considered reasonably designed if it imposes a penalty on (or otherwise disadvantages) an individual because of a spouse’s manifestation of a disease or disorder by preventing or inhibiting the spouse from participating in, or from achieving a certain health outcome. In addition, the employer may not deny access to a group health plan or package of benefits based on a spouse’s refusal to complete a health risk assessment or undergo biometric testing.
- (2) The program must be voluntary - the spouse must provide knowing, voluntary, written authorization.
- (3) 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.
- (4) The spouse must be provided with a notice containing specific information. The 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 healthcare 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.

Unlike the HIPAA and PPACA rules, the EEOC’s GINA rules limit incentives to 30% for all wellness programs – including those that are participation only programs – based upon the cost of self-only coverage.

In response to a court order, the EEOC issued guidance in December 2018 that removed a 30% maximum reward rule 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 GINA.

Under the EEOC's regulations, the wellness program may also include completion of health risk assessments or biometric screening for children, but the plan may not provide any incentive for completion of the HRA or biometric screening by children – including adult and adopted children.

ERISA

If a private employer (for-profit or nonprofit) is involved and an exception under ERISA does not otherwise apply, and the program provides individualized “medical care,” then the program is likely an ERISA plan. The program involves “medical care” if the care is individualized and provided by trained professionals. For example, flu shots, health coaching by a nurse, counseling by a therapist, or biometric screening would all be examples of medical care if provided through an employer. However, if a program only offers general education, it is not “medical care.” For example, a newsletter with health condition articles, a “lunch-n-learn” about diabetes, and a weight loss class without a personalized assessment are all example of general education.

If a wellness program is an “employee welfare benefit plan” under ERISA, then it will have to satisfy ERISA's applicable compliance requirements, including the following:

- (1) There must be a plan document;
- (2) Plan terms must be followed, and plan sponsor must adhere to strict fiduciary standards;
- (3) SPDs (SMMs and SMRs) must be provided to plan participants;
- (4) Form 5500 must be filed annually (subject to certain exceptions); and
- (5) Claims procedures must be established and followed.

Wellness programs that constitute group health plans must also meet certain special requirements: (a) additional requirements under the DOL claims procedure regulations; (b) additional SPD disclosures; and (c) special timing rules for SMMs.

PPACA added more specific requirements, including enhanced internal claims and appeals requirements and external review procedures applicable to non-grandfathered plans. In the preamble to the amended PPACA appeals regulations issued on June 24, 2011, the Departments of Health and Human Services, Labor, and Treasury included examples of situations in which a claim would involve “medical judgment” and therefore be subject to the federal external review process for an adverse benefit determination.

Included among those examples is a determination based on whether a participant would be entitled to a reasonable alternative standard under an employer-sponsored wellness program.

Thus, non-grandfathered health plans denying a request for a reasonable alternative standard (or a waiver of an otherwise applicable standard) to obtain a reward related to a standard-based wellness program should be ready to follow the PPACA appeals procedures, including the requirement to make available an external review by an Independent Review Organization.

COBRA

A health plan that is subject to COBRA and is linked with a wellness program, must include some of the wellness program provisions as part of COBRA coverage offered by the health plan. In general, if the wellness program provides a reward in the form of a different benefit such as a reduced deductible, it must be offered to COBRA qualified beneficiaries. For example, if the wellness program provides a \$100 reduction in the annual deductible for any individual who completes a health risk assessment questionnaire, regardless of the results, qualified beneficiaries must be given the same opportunity. Rewards in the form of reduced premiums do not need to be offered to COBRA qualified beneficiaries.

Health plans must comply with any applicable COBRA requirements. The most significant obligations are listed below:

- (1) Provision of a General Notice:** Each participant and his or her spouse must receive a General Notice when coverage under the program first begins;
- (2) Provision of an Election Notice:** Each Qualified Beneficiary must receive an Election Notice with a notice of the Qualified Beneficiary's rights and obligations for a specific qualifying event (e.g., termination of a covered employee's employment or reduction of a covered employee's hours of employment, etc.) The Election Notice for the wellness program may be combined with the Election Notice for the employer's major medical plan(s);
- (3) Provision of a Notice of Unavailability (if applicable):** Certain individuals who expect to receive COBRA continuation coverage, but are not entitled to such coverage, must be provided with a Notice of Unavailability;
- (4) Coverage:** if a Qualified Beneficiary elects COBRA continuation coverage under the wellness program, he or she generally may receive such coverage for a basic coverage period which is the same period of time as any other COBRA continuation period (e.g., 18 months for certain qualifying events, 36 months for other qualifying events). The Qualified Beneficiary would be entitled to any incentives available to active employees and would also be

permitted to elect any other group health coverage offered to other employees during open enrollment; and

(5) Provision of an Early Termination Notice (if applicable): If COBRA continuation terminates before the end of the maximum coverage period, the Qualified Beneficiary must be provided with a Notice of Termination.

Employers should review their existing plan materials and COBRA policies and procedures to ensure that applicable wellness programs are included in any written COBRA policies and procedures.

Age Discrimination in Employment Act (“ADEA”)

The ADEA prohibits employment discrimination against employees and job applicants on the basis of age with respect to benefits. Protected individuals must be at least 40 years of age. Thus, a wellness program could violate the ADEA if it terminated or decreased wellness rewards, or otherwise discriminated against employees age 40 or older.

Title VII

Title VII relates to the “terms, conditions, or privileges of employment,” which generally include wellness programs. Thus, if an employer takes into consideration a plan participant’s race, religion, sex, color, or national origin, then the program could violate Title VII.

Fair Labor Standards Act (“FLSA”)

Under the FLSA, nonexempt employees must be compensated at not less than time and one-half of regular pay for time worked over 40 hours in any given workweek. Thus, if time spent completing a wellness program is considered to be “compensable time,” then the employer may have to pay overtime. For example, if an employer provides health lectures as part of a wellness program, the time spent could be compensable time. However, the time need not be compensable time if four conditions are met: (1) attendance is outside of the employee’s regular work hours; (2) attendance is purely voluntary; (3) the lecture is not directly related to the employee’s job; and (4) the employee does not do any productive work during the lecture (e.g., answering e-mails).