AHLA PG Briefing

# Direct-to-Employer Wellness Programs: Promising but Complex

*Labor and Employment; Health Information and Technology; and Payers, Plans, and Managed Care Practice Groups • May 2018*

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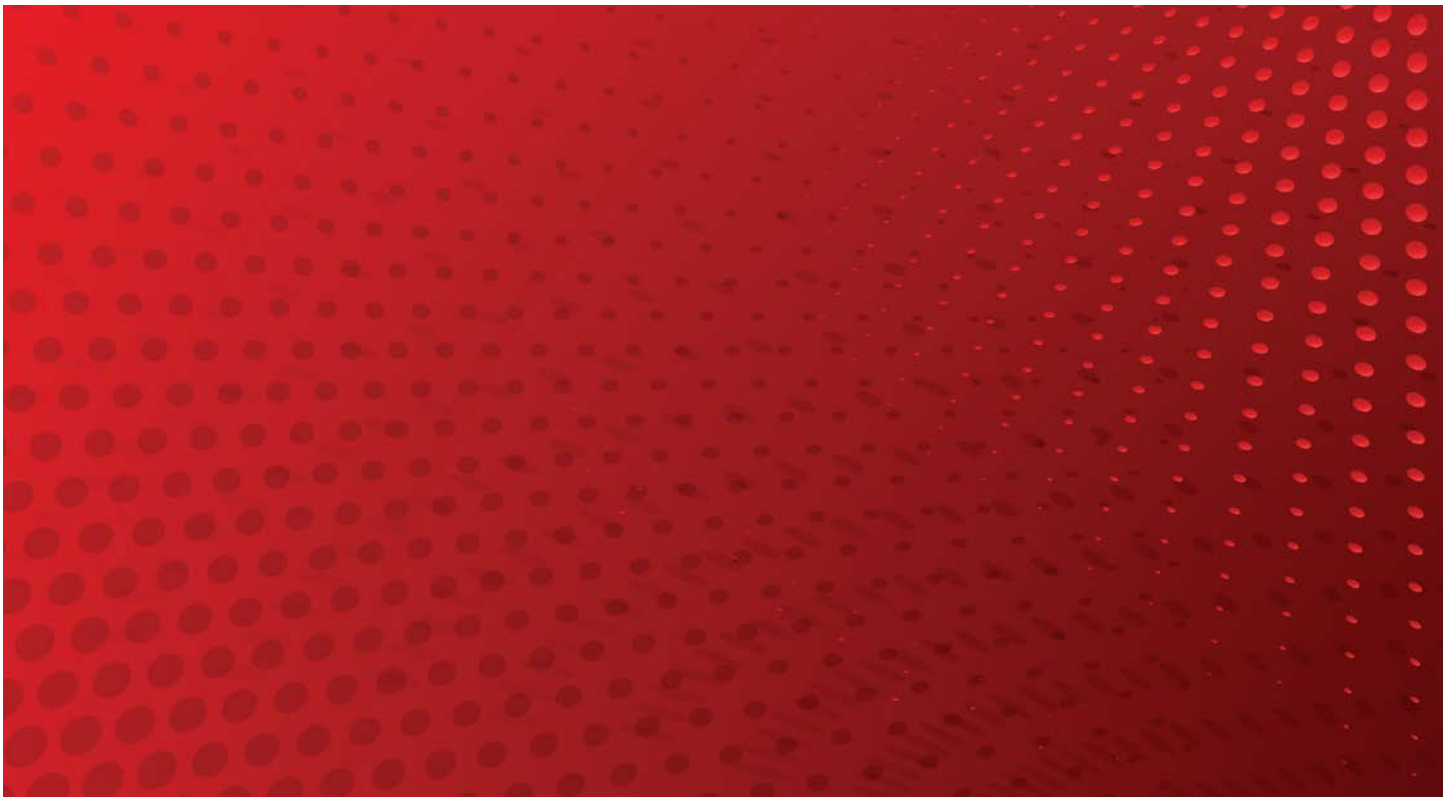


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## I. INTRODUCTION

For decades, employers have offered health care benefits focused on coverage for medical services and items (e.g., hospital stays, physician office visits, and prescription drugs), made available through group health plans offered by contracted full-risk insurers (e.g., Blue Cross Blue Shield plans, UnitedHealthcare) or through self-funded health benefit options offered by employers. Alongside such programs, employers have offered wellness programs, which have become increasingly prevalent in recent years.

Employer workplace wellness programs, designed to promote the health and wellbeing of employees, are expanding rapidly. Although health insurers have traditionally offered wellness programs in connection with their group health plan offerings, employers are also engaging non-insurer vendors for standalone wellness program offerings. At the same time, legal challenges have clouded the future of key wellness program features that have become common.

Increasingly, vendors are offering wellness program services without fully appreciating the scope of federal legal requirements applicable to both the employers and the vendors. As such, vendors not only invite risk to themselves, but also to their clients with respect to federal anti-discrimination and data privacy laws, as well as other compliance obligations. Vendors must also be prepared to adjust to the shifting regulatory landscape as court decisions and ongoing agency rulemaking continue to alter the standards for these programs.

In order to effectively advise clients on how to design, implement, and market wellness program services to employers, and on key reimbursement and structuring issues, health care attorneys must understand the wide array of legal requirements applicable to wellness programs, which remains an active area for legislation, rulemaking, and litigation.

## II. WHY EMPLOYERS ARE ADOPTING WELLNESS PROGRAMS

A number of factors have contributed to the proliferation of wellness programs, including:

1) The expansion of federal laws and regulations and clarification of legal requirements that have incrementally permitted and promoted different types of wellness program offerings.
2) The desire by insurers and self-insured employers to reduce the cost of providing group health plans by promoting access to preventative care services, promoting participation in disease management programs, and improving the overall health and wellness of employees.
3) The desire by employees to reduce their out-of-pocket costs for premiums

and cost-sharing obligations (e.g., deductibles, coinsurance, copayments).

4) The need to improve access to care, as employees may avoid or delay seeking care under their group health plans, which increasingly have high deductibles and narrow provider networks.
5) The operational and commercial benefits to employers from fewer injuries, reduced absenteeism, and improved productivity, particularly as a growing percentage of the workforce are older and/or managing multiple chronic conditions (e.g., diabetes, high blood pressure, obesity).
6) The growing public acceptance of health monitoring activities (e.g., wearables, Bluetooth-connected blood pressure and blood glucose measurement devices).
7) The overall trend towards healthier lifestyle choices (e.g., declining tobacco use, bike-share programs, improved diet, exercise).
8) As more employers offer wellness programs, they are becoming a *de facto* fringe benefit offering and a means to help attract and retain personnel.

Notably, these benefits illustrate how wellness programs can also promote the so-called *Triple Aim* of (1) improving patient experiences; (2) improving health outcomes; and (3) reducing the cost of care.[1]

## III. ENTITIES OFFERING WELLNESS PROGRAMS

Wellness programs have also been spurred by the availability of vendors offering such programs, although there is a chicken-and-egg element to this. Most traditional health insurers now offer wellness programs either as a part of or optional supplement to their group health plans. And increasingly, non-insurer vendors are entering the marketplace to offer standalone wellness programs to employers, particularly those with self-insured group health plans. According to the Kaiser Family Foundation, corporate wellness services is an $8 billion industry, with more than 5,600 vendors.[2]

Moreover, due to the clinical nature of many wellness program offerings, vendors owned by or affiliated with health care provider entities and groups are entering the fray. In part, this trend has been aided by the growing number of integrated delivery systems and the propagation of large, diversified provider organizations that have the requisite clinical and administrative infrastructure to effectively and efficiently manage such programs.

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[1] *See*, *e.g.*, Donald M. Berwick, Thomas W. Nolan, and John Whittington, *The Triple Aim: Care, Health And Cost*, 27 HEALTH AFFAIRS, May/June 2008, 759-769, *available at* https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.27.3.759.

[2] Karen Pollitz and Matthew Rae, *Workplace Wellness Programs Characteristics and Requirements*, Kaiser Family Found., (May 19, 2016), *available at* http://www.kff.org/private-insurance/issue-brief/workplace-wellness-programs-characteristics-and-requirements/.

## IV. RESPECTIVE RIGHTS AND OBLIGATIONS OF EMPLOYERS AND VENDORS

Although certain large employers may possess the scale and expertise to implement their own wellness programs directly, employers generally contract with third-party vendors for the design and operation of their wellness programs, akin to other fringe benefits. Under these arrangements, vendors will likely receive some form of program management fee, which can take on different forms and vary for different wellness program elements. For example:

- A per member per month fee, based on the number of total or participating individuals
- A tiered monthly fee (e.g., $7,000 for 1-50 employees, $8,500 for 51-100 employees)
- Fee-for-service payments (e.g., for flu shots, biometric examinations)

In addition to furnishing the "front-facing" elements of wellness program services, such as offering educational programs, publishing newsletters, conducting biomedical screenings, and administering flu vaccinations, vendors must also maintain administrative, technical and other background resources, which can include data analytics, web and application development, IT support, medical recordkeeping, and compliance. To accomplish these tasks, vendors must engage a variety of personnel and subcontractors, including:

- Licensed health care practitioners (e.g., physicians, psychologists, counselors, physician assistants, nurse practitioners, registered nurses, registered dieticians)
- Paraprofessionals, including medical assistants and technicians
- Program administrators and support personnel (e.g., compliance personnel, IT and data analytics, software programmers)
- Subcontracted web and mobile application service vendors (for telehealth platforms and dashboard programmers)
- Equipment and/or diagnostic testing vendors (e.g., for clinical laboratory tests and diagnostic imaging)
- Other vendors and suppliers typically engaged by health care providers (e.g., for medical supplies, medications)

An additional layer of complexity is added when employers look to supplement their wellness programs with health clinics, which have become an increasingly popular way to increase employee access to medical care during this era of narrow networks and high deductible health plan options. Whether operated directly by employers, where permitted under applicable law, or through a growing industry of vendors and management companies, such clinics offer a venue for wellness program services as well as a broader array of clinical health care services, ranging from basic first aid to more comprehensive medical care

that includes primary care, specialty, and ancillary services (e.g., clinical laboratory testing, pharmacy services, telemedicine services).

As with traditional wellness program, health clinic arrangements have assumed a variety of forms, each with its unique set of rights, obligations, and legal issues. For example, employers and their vendors must address in any health clinic services agreement the following issues (not exhaustive):

- The identity of the party that is furnishing health care services and the party that performs administrative functions. This has implications not only in states that have adopted the corporate practice of medicine, but also in connection with licensure, malpractice insurance coverage, contractual considerations, and the identity of the party that owns the medical records.
- The scope of services to be furnished at the clinic.
- Whether the clinic will be credentialed as a provider in the group health plan options offered by the employer, or whether it will be a free or discounted clinic.
- Whether the clinic will be available to the family and dependents of employees.
- The type of staffing and parties responsible for clinical and non-clinical roles.
- The party that will contract for and pay for equipment lease, space leases, supplies, and other operating expenses.
- The method of reimbursement to the provider vendor, including whether the vendor will assume financial risk, if any, for such services and whether that will subject the vendor to any regulatory oversight.
- Ownership and use of related intellectual property and confidential information.
- Whether the arrangement with a vendor will be exclusive and whether the parties will be subject to any restrictive covenants (e.g., non-solicitation, non-competes)
- Whether the provider will accept any form of indemnification provision and whether the parties must rely on common law to address potential risk. Providers may, for example, be reluctant to sign indemnification clauses because most malpractice policies do not cover contractually assumed liability unless it is pursuant to a contract with a health plan.

## V. TYPES OF WELLNESS PROGRAMS

Although wellness programs take on various forms, they fall into a handful of categories based on the limited frameworks available under applicable law. In general, the key differentiators are:

### *Whether the Wellness Program is Related to a Group Health Plan*

A "group health plan" is an employee welfare benefit plan, as defined under the Employment Retirement Income Security Act (ERISA), that provides *medical care* to employees directly or through insurance and reimbursement.[3] As a result, a wellness program may be related to a group health plan if the program:

- is offered by or through the group health plan;
- is offered only to group health plan enrollees;
- includes incentives that relate to a group health plan; or
- includes amounts paid for the provision of *medical care*.

As a result, wellness programs that include incentives involving a health plan premium discount or cost-sharing reductions may constitute group health plans. Further, because "medical care" is defined broadly and includes, in relevant part, the provision of medical services that relate to the "diagnosis, cure, mitigation, treatment, or prevention of disease,"[4] even if a wellness program is not otherwise related to a group health plan, if the program offers medical services such as biometric screenings or flu shots, the program may still be deemed to relate to a group health plan.

Notwithstanding the foregoing, certain onsite employer health clinics are categorically excluded from the definition of a group health plan. More specifically, the regulatory definition of an ERISA employee welfare benefit plan excludes onsite clinics "for the treatment of minor injuries or illness or rendering first aid in case of accidents occurring during working hours."[5] Because group health plans are a subset of welfare benefit plans, any clinic that does not qualify as an employee welfare benefit plan is also, by extension, not a group health plan. If, however, a clinic offers a wider array of medical care services (e.g., primary care and specialist physician services, diagnostic and laboratory testing, pharmacy services), that go beyond the treatment of minor injuries/illnesses or first aid, the clinic would no longer meet this narrow exception and would constitute a group health plan.

### *The Inclusion of Incentives*

Although not required, many wellness programs includes incentives (e.g., rewards, penalties) to encourage employees to participate and achieve certain targets. Although certain incentives may relate to a group health plan (e.g., reduced group health plan premiums and/or cost-sharing obligations, contributions to an employee's health savings account or "HSA"), others may not

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[3] 29 U.S.C. § 1191b(a)(1).

[4] 29 U.S.C. § 1191b(a)(2)(A)-(C).

[5] 29 C.F.R. § 2510.3-1(c)(2); *see also* 26 U.S.C. §9832(c)(G).

(e.g., gift cards, t-shirts).

## *The Specific Types of Program Activities & Requirements*

*1) Educational Activities & Workplace Environment Changes*
The most basic of wellness programs, educational activities and workplace environment changes focus on educating and changing the workplace environment to promote health and wellness. These programs often appeal to employers who are new to wellness and include:

- Educational programs, newsletters and fliers/posters on topics such as nutrition, exercise, and hygiene directed to a general audience.
- Healthy food options for cafeterias, vending machines, catered events/meetings, snacks, etc.
- Prohibitions or restrictions on where smoking is permitted.

In general, these programs do not include incentives and are not related to group health plans. As such, these programs are subject to relatively few compliance obligations.

*2) Participatory Programs*
More complex wellness programs include those that involve the voluntary participation of employees. Because participatory programs may or may not be related to group health plans or include incentives, examples of such programs vary:

- *Examples of Participatory Program Activities Unrelated to Group Health Plan without Incentives*
    - Lunch time educational presentations (onsite or web-based)
    - Neighborhood walking programs
    - Use of an onsite fitness center
    - General nutrition or exercise plan counseling

- *Examples of Participatory Program Activities Unrelated to Group Health Plan with Incentives*
    - A program that reimburses employees for all or part of the cost for memberships in a fitness center [6]
    - A program that provides a reward to employees for attending a monthly, no-cost health education seminar[7]
    - A $25 gift card to attend a general educational program
    - T-shirts for walking program participants

[6] 29 C.F.R. § 2590.702(f)(1)(ii)(A).
[7] 29 C.F.R. § 2590.702(f)(1)(ii)(E).

- *Examples of Participatory Program Activities Related to Group Health Plan without Incentives*
    - Flu shots
    - Completing a health risk assessment

- *Examples of Participatory Program Activities Related to Group Health Plan with Incentives*
    - A program that encourages preventive care through the waiver of the copayment or deductible requirement under a group health plan for the costs of, for example, prenatal care or well-baby visits.[8]
    - A program that reimburses employees for the costs of participating, or that otherwise provides a reward for participating, in a smoking cessation program without regard to whether the employee quits smoking.[9]
    - A program that provides a reward to employees who complete a health risk assessment regarding current health status, without any further action (educational or otherwise) required by the employee with regard to the health issues identified as part of the assessment.[10]
    - A reduced group health plan premium for undergoing a biometric examination.

*3) Health-Contingent Programs*

A health-contingent program is one that "requires an individual to satisfy a standard related to a health factor to obtain a reward (or requires an individual to undertake more than a similarly situated individual based on a health factor in order to obtain the same reward)."[11] Under the Health Insurance Portability and Accountability Act (HIPAA), "health factors" can mean any of the following factors:

- Health status
- Medical condition (including both physical and mental illnesses)
- Claims experience
- Receipt of health care
- Medical history
- Genetic information
- Evidence of insurability (e.g., conditions arising out of acts of domestic violence; participation in high-risk activities such as motorcycling and skiing)
- Disability[12]

Under the rules implementing HIPAA, two categories of health-contingent

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8 29 C.F.R. § 2590.702(f)(1)(ii)(C).
9 29 C.F.R. § 2590.702(f)(1)(ii)(D).
10 29 C.F.R. § 2590.702(f)(1)(ii)(F).
11 29 C.F.R. § 2590.702(f)(1)(iii).
12 29 C.F.R. § 2590.702(a).

wellness programs are available:

*a) Activities-Only Programs*

An activity-only wellness program is a type of health-contingent wellness program that requires an individual to perform or complete an activity related to a health factor in order to obtain a reward but does not require the individual to attain or maintain a specific health outcome.

Examples include walking, diet, or exercise programs, which some individuals may be unable to participate in or complete (or have difficulty participating in or completing) due to a health factor, such as severe asthma, pregnancy, or a recent surgery.[13]

*b) Outcomes-Based Programs*

An outcome-based wellness program is a type of health-contingent wellness program that requires an individual to attain or maintain a specific health outcome (such as not smoking or attaining certain results on biometric screenings) in order to obtain a reward. An outcome-based wellness program typically has two tiers. That is, for individuals who do not attain or maintain the specific health outcome, compliance with an educational program or an activity may be offered as an alternative to achieve the same reward. This alternative pathway, however, does not mean that the overall program, which has an outcome-based component, is not an outcome-based wellness program. That is, if a measurement, test, or screening is used as part of an initial standard and individuals who meet the standard are granted the reward, the program is considered an outcome-based wellness program.

For example, if a wellness program tests individuals for specified medical conditions or risk factors (including biometric screening such as testing for high cholesterol, high blood pressure, abnormal body mass index, or high glucose level) and provides a reward to individuals identified as within a normal or healthy range for these medical conditions or risk factors, while requiring individuals who are identified as outside the normal or healthy range (or at risk) to take additional steps (such as meeting with a health coach, taking a health or fitness course, adhering to a health improvement action plan, complying with a walking or exercise program, or complying with a health care provider's plan of care) to obtain the same reward, the program is an outcome-based wellness program.[14]

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13 29 C.F.R. § 2590.702(f)(1)(iv).

14 *Id.*

## VI. KEY LEGAL CONSIDERATIONS FOR WELLNESS PROGRAMS[15]

Wellness programs are subject to a wide range of federal laws, that:

- impose requirements on wellness program offerings (e.g., limits on incentives)
- prohibit certain types of discrimination
- limit the acquisition, use, disclosure of employee information

Wellness programs may, for example, be subject to the following anti-discrimination requirements, the applicability of which may depend on the program differentiators identified in Section 5 above (e.g., whether the program is part of a group health plan, and whether medical care is provided). For example, if wellness programs are offered as part of or in connection with a group health plan, the benefits will be regulated (in whole, or in part) by HIPAA, ERISA, and the Patient Protection and Affordable Care Act (ACA). Further, even if the wellness program is a stand-alone offering, the program may also be subject to such laws if they involve the provision of medical care.[16] Finally, these differentiators may determine whether the Americans with Disabilities Act (ADA) or HIPAA discrimination laws apply to such programs, or both. This area of the law is evolving in the courts as a result of the attempts by the government to regulate and/or provide guidance on what is acceptable with respect to these wellness programs.

| Law | Prohibited Basis of Discrimination |
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| **Health Insurance Portability and Accountability Act of 1996 (HIPAA)**[17] | • For participatory wellness programs:<br>o Such programs must be available to all similarly situated individuals.[18]<br>o Employers may not discriminate based on any health factor and either offer no incentives or |

15 Wellness programs also may implicate certain federal and state tax issues, which fall outside the scope of this article.

16 The authors delineate several factors in Section 5 above that can help determine whether a wellness program is offered as part of or in connection with a group health plan, although a more comprehensive overview goes beyond the scope of this article.

17 Pub. L. 104–191, 110 Stat. 1936 (Aug. 21, 1996).

18 For example, employees may be categorized into similarly situated groups if based on bona-fide employment classifications that are consistent with the employer's usual business practice, based on the relevant facts and circumstances (e.g., full-time versus part-time status, different geographic location, membership in a collective bargaining unit, date of hire, length of service, current employee versus former employee status, and different occupations). *See e.g.,* 29 C.F.R. § 2590.702(d)(1). With respect to non-employee beneficiaries, they may be distinguished into groups of similarly situated individuals if the distinction is based on any of the following: a bona fide employment-based classification of the participant through whom the beneficiary is receiving coverage; the relationship to the participant (e.g., as a spouse or as a dependent child); marital status; with respect to children of a participant, age or student status; or any other factor if the factor is not a health factor. *See e.g.,* 29 C.F.R. § 2590.702(d)(2).

| Law | Prohibited Basis of Discrimination |
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| | offer an incentive that does not require the individual to satisfy a health factor-based program standard.[19]<br>o No cap on incentives.<br><br>• For health-contingent wellness programs, HIPAA compliance obligations for activity-only and outcome-based wellness programs require:<br>o opportunities for individuals to qualify for an incentive at least once annually; [20]<br>o caps on incentives at 30% of the total cost of health plan coverage under which the employee is (or the employee and any dependents are) receiving coverage, based on contributions of the employer and employee (50% for tobacco-related incentives);[21]<br>o a reasonable design to promote health and prevent disease;[22]<br>o incentives must be available to all similarly situated individuals, provided that the program must offer a reasonable alternative (or waiver) for incentives based on health status;[23] and<br>o notice of reasonable alternatives or waivers be given to program participants.[24] |
| **Americans with Disabilities Act (ADA)** | • The ADA prohibits certain employers and their agents[25] from discriminating against any "qualified individual"[26] with respect to "job application procedures, the hiring, advancement, or discharge of employees, employee compensation, job training, and other terms, conditions, and privileges of employment" based on that individual's disability.[27] |

19 29 C.F.R. § 2590.702(f)(2) and 29 C.F.R. § 2590.702(f)(4)(v).
20 29 C.F.R. § 2590.702(f)(3)(i); 29 C.F.R. § 2590.702(f)(4)(i).
21 29 C.F.R. § 2590.702(f)(3)(ii) & (f)(5); 29 C.F.R. § 2590.702(f)(4)(ii).
22 29 C.F.R. 2590.702(f)(3)(iii); 29 C.F.R. § 2590.702(f)(4)(iii).
23 29 C.F.R. 2590.702(f)(3)(iv)(A)(1)-(2); 29 C.F.R. § 2590.702(f)(4)(iv).
24 29 C.F.R. 2590.702(f)(3)(v).
25 42 U.S.C. § 12111(5). The definition of "employer" mirrors the Title VII definition.
26 42 U.S.C. § 12111(8). A "qualified individual" is an individual who, with or without reasonable accommodation, can perform the essential functions of the employment position that such individual holds or desires.
27 29 U.S.C. §§ 623(a) and 630(l).

| Law | Prohibited Basis of Discrimination |
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| | • The ADA imposes specific requirements on wellness programs that include disability-related inquiries or medical examinations (e.g., biometric examinations), and would apply to wellness programs not covered by the HIPAA standards, mentioned above, to the extent they are unrelated to a health plan.<br>• The ADA requires that wellness programs be voluntary and satisfy a reasonable design requirement, similar to that under HIPAA.[28]<br>• The ADA imposes a cap on incentives, equal to 30% of the total cost of health plan coverage, which will supersede the 50% ceiling under HIPAA for incentives related to smoking cessation if the wellness program includes disability-related inquiries or medical examinations. If these elements are absent, the HIPAA standards could apply and permit larger smoking cessation-related incentives that equal up to 50% cap of the total cost of health plan coverage.[29] NOTE: Per a recent court ruling in *AARP v. EEOC*, discussed below, although this standard remains in place for 2018, pending the release of new federal regulations, the current incentive provisions will no longer apply beginning on January 1, 2019.<br>• Wellness programs must furnish notices to employees that specify the employer's or other Covered Entity's[30] ability to collect and use medical information,[31] which must be kept confidential.[32] |

28 29 C.F.R. § 1630.14(d)(1). Where the program "has a reasonable chance of improving the health of, or preventing disease in, participating employees, and it is not overly burdensome, is not a subterfuge for violating the ADA or other laws prohibiting employment discrimination, and is not highly suspect in the method chosen to promote health or prevent disease."

29 *See* Appendix to Part 1630 (Interpretive Guidance on Title I of the ADA), *available at* https://www.federalregister.gov/documents/2000/06/08/00-14476/interpretive-guidance-on-title-i-of-the-americans-with-disabilities-act.

30 As defined in 29 C.F.R. § 1630.2(b), *available at* https://www.gpo.gov/fdsys/pkg/CFR-2017-title29-vol4/xml/CFR-2017-title29-vol4-part1630.xml.

31 Model notifications, *available at* https://www.eeoc.gov/eeoc/newsroom/release/6-16-16.cfm (last visited May 14, 2018).

32 29 C.F.R. § 1630.14(d)(4). Exceptions include: "(A) Supervisors and managers may be informed regarding necessary restrictions on the work or duties of the employee and necessary accommodations; (B) First aid and safety personnel may be informed, when appropriate, if the disability might require emergency treatment; and (C) Government officials investigating compliance with this part shall be provided relevant information on request."

| Law | Prohibited Basis of Discrimination |
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| | • Employers must offer reasonable accommodations to permit disabled employees to access wellness program benefits.[33] |
| **Title VII of the Civil Rights Act of 1964 (Title VII)** [34] | • Title VII prohibits certain employers and their agents[35] from discriminating against any employee with respect to his or her "compensation, terms, conditions, or privileges of employment" based on that individual's race, color, religion, sex, or national origin.[36] Because Title VII has been interpreted to apply to health insurance and other fringe benefits offered by employers, it can reach all types of wellness programs.[37]<br>• To comply with Title VII, a wellness program must avoid both *disparate treatment* and *disparate impact* discrimination.[38] |
| **Age Discrimination in Employment Act of 1967 (ADEA)** [39] | • The ADEA prohibits certain employers and their agents[40] from discriminating against any employee |

33 Appendix to Part 1630 (Interpretive Guidance on Title I of the ADA) ("Under the ADA, regardless of whether a wellness program includes disability-related inquiries or medical examinations, reasonable accommodations must be provided, absent undue hardship, to enable employees with disabilities to earn whatever financial incentive an employer or other covered entity offers.")

34 42 U.S.C. §§ 2000e et seq.

35 42 U.S.C. § 2000e(a) & (b). An employer includes individuals, governments, governmental agencies, political subdivisions, labor unions, partnerships, associations, corporations, legal representatives, mutual companies, joint-stock companies, trusts, unincorporated organizations, trustees, trustees in cases under Title 11 or receiver, with 15 or more employees over a specified period, as well as any agent of the aforementioned, or a bona fide private membership club. Specifically excluded are the United States, a corporation wholly owned by the Government of the United States, an Indian tribe, or any department or agency of the District of Columbia subject by statute to procedures of the competitive service.

36 42 U.S.C. § 2000e-2(a)(1).

37 Newport News Shipbuilding and Dry Dock Co. v. EEOC, 462 U.S. 669, 682 (1983) ("Health insurance and other fringe benefits are 'compensation, terms, conditions, or privileges of employment.'").

38 "Disparate treatment" involves an employer practice that intentionally discriminates based on a protected criterion. For example, a wellness program that is restricted to native born Americans or a wellness program gym discount that is limited to men. "Disparate impact" involves a facially neutral employer practice that disproportionately harms individuals of a protected class. For example, when women disproportionately fail a fitness test target necessary to: (i) participate in a wellness program; (ii) qualify for a program benefit incentive (e.g., gift cards); and/or (iii) avoid a program penalty (e.g., higher premiums).

39 29 U.S.C. §§ 621-634.

40 29 U.S.C. § 630(a) & (b). An "employer" for the ADEA is different from the Title VII definition and includes any individual, partnership, association, labor organization, corporation, business trusts, legal representatives or any organized group of persons with

| Law | Prohibited Basis of Discrimination |
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| | with respect to his or her "compensation, terms, conditions, or privileges of employment" based on that individual's age.[41]<br>• Because the ADEA has been interpreted to apply to health insurance and other fringe benefits offered by employers, it can reach all types of wellness programs.[42]<br>• Like Title VII, the ADEA prohibits both disparate treatment and disparate impact discrimination. However, unlike Title VII, a facially neutral criterion may be permitted if it is based on a reasonable factor other than age.[43] |
| **Genetic Information Nondiscrimination Act of 2008 (GINA)** [44] | • GINA prohibits certain employers[45] from discriminating against employees[46] with respect to "the compensation, terms, conditions or privileges of employment" based on that individual's genetic information.[47]<br>• Genetic information is defined to include family medical histories (e.g., the medical history of blood relatives, children and spouses), as well as the results of genetic tests. As such, GINA prohibits employers from discriminating based on any such |

20 or more employees over a specified period, as well as any agent of the foregoing and a State or political subdivision of a State and any agency or instrumentality of a State or a political subdivision of a State, and any interstate agency. An employer does not include the United States, or a corporation wholly owned by the Government of the United States.

41 29 U.S.C. §§ 623(a) & 630(l).

42 Newport News Shipbuilding and Dry Dock Co. v. EEOC., 462 U.S. 669, 682 (1983) ("Health insurance and other fringe benefits are 'compensation, terms, conditions, or privileges of employment.'"); *see* EEOC Compliance Manual (Oct. 3, 2000), Chapter 3, *available at* https://www.eeoc.gov/policy/docs/benefits.html ("If an employer provides fringe benefits to its employees, it generally must do so without regard to an employee's age. Employers may, however, provide lower benefits to older than to younger workers in limited circumstances.").

43 Smith v. City of Jackson, 544 U.S. 228, 233 (2005) ("Unlike Title VII, however, §4(f)(1) of the ADEA, 81 Stat. 603, contains language that significantly narrows its coverage by permitting any 'otherwise prohibited' action 'where the differentiation is based on reasonable factors other than age.'").

44 Pub. Law 110-233 (May 21, 2008), which amended ERISA at 29 U.S.C. § 1182.

45 GINA, at Section 201(2)(B).

46 GINA, at Section 201(2)(A).

47 GINA, at Section 202(a)(1).

| Law | Prohibited Basis of Discrimination |
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| | information captured in connection with a health risk assessment (HRA)[48] or biometric examination.[49]<br>• GINA may apply to all types of wellness programs, but scrutiny can be avoided if the program does not, for example, include an HRA or biometric examination, or include inquiries involving family medical histories. |
| **Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA)[50]** | • MHPAEA prohibits certain employers from having group health plans that impose more restrictive financial requirements or treatment limitations imposed on mental health and substance use benefits compared to medical and surgical benefits.<br>• MHPAEA does not apply to employers with 50 or fewer employees and applies only to wellness programs that are related to group health plans.<br>• Notably, because a substance use disorder could include tobacco use, wellness programs involving tobacco cessations programs should be mindful of MHPAEA requirements. |

Notably, wellness programs have been the subject of litigation, particularly by the EEOC against employers on the issue of whether such programs fall within the safe harbors of the ADA, GINA, and other antidiscrimination laws and whether such programs are truly voluntary. Employers have generally prevailed in certain instances, notably in the Eleventh Circuit's decision in *Seff v. Broward County,* 691 F. 3d 1221 (11th Cir. 2012). In *Seff*, an employer imposed a premium surcharge on employees who did not participate in the wellness program, which required employees to undergo a biometric screening and HRA. An employee sued claiming that the program violated the ADA, but the District Court held that the program met the ADA safe harbor because it was part of a bona fide benefit plan, and the program was based on underwriting, classifying, or administering risk and was not a subterfuge for discrimination. The appeals court upheld the lower court decision, explaining that even if the wellness program was not described in the employer's benefit plan documents, the wellness program was sponsored by the employer's insurer, available only to plan enrollees, and presented as part of its benefit plan in marketing materials. The Seventh Circuit also concluded that the program was based on underwriting, classifying, or administering risk, as the employer used the aggregated HRA and biometric screening data to evaluate its benefit plan options and manage its risk.

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48 An HRA is typically a questionnaire that captures information on the individual's health and on potential health issues (e.g., medical history, health status, lifestyle questions).

49 29 C.F.R. § 1635.3(c).

50 The MHPAEA amended the Mental Health Parity Act of 1996.

This case is notable for its examination of when a wellness plan is part of a group health plan, and clarifies that the plan's written documents need not include a specific provision establishing a wellness program in order for the program be meet the ADA's safe harbor standard; provided that there is other evidence to support the wellness program's inclusion as a term of such plan. Here, that evidence included the fact that the employer's wellness program was sponsored by the contracted health insurer, was available only to group health plan enrollees, and because two employee handouts presented the wellness program as part of the group health plan.[51]

More recently, however, the Seventh Circuit Court of Appeals decision, in *EEOC v. Flambeau, Inc.*, 846 F.3d 941 (7th Cir. 2017), has muddied the waters by introducing uncertainty on whether the Eleventh Circuit's reasoning in *Seff* is valid. *Flambeau* faced a comparable fact pattern to the one in *Seff*, and the District Court in *Flambeau* had found that the program qualified for the ADA safe harbor. Although the Seventh Circuit in *Flambeau* also ruled in favor of the employer, it did not rule on the merits of the ADA arguments, instead finding in favor of the employer because the dispute was moot because the individual was no longer employed by the employer and because the individual was not entitled to damages. Instead, on the substantive question of whether wellness programs could qualify for the ADA safe harbor protection, the court explained that "[t]he EEOC's theory of discrimination assumes that the ADA's insurance safe harbor does not cover at least some wellness plans. Whether that is true, and for what kinds of wellness plans it might be true, were open questions at relevant times in 2012 and 2013. They remain open even today."

In *EEOC v. Orion Energy Systems, Inc.*, 208 F.Supp.3d 989 (E.D. Wisc. 2016), which settled in April 2017 for $100,000,[52] the district court, on a summary judgment motion, found in favor of the employer, ruling that its wellness program was voluntary based on the law then-applicable, prior to the EEOC's 2016 regulations, but rejected the employer's position that it qualified for safe harbor protection under the ADA, with the EEOC arguing that *Seff* and *Flambeau* were wrongly decided and that the reasoning in those cases were "repudiated" by the EEOC's 2016 regulations. On this question, the district court declined to follow *Seff* and *Flambeau*, finding these decisions to be at odds with the statutory safe harbor exception, which the court explained was intended to protect the operation of insurance companies. According to the court, the "implementation of a wellness program usually occurs after the insurance company establishes the premium and is 'one step removed from basic underwriting.'"[53] Because this case

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51 Seff v. Broward County, 691 F. 3d 1221, 1224 (11th Cir. 2012).

52 EEOC Press Release, available at https://www.eeoc.gov/eeoc/newsroom/release/4-5-17a.cfm.

53 EEOC v. Orion Energy Systems, Inc., 208 F.Supp.3d 989 (E.D. Wisc. 2016).

was not governed by the 2016 EEOC regulations, but instead was based on the law existing prior to these rules, the repudiation of these rules in *AARP v. EEOC*, discussed below, should not have a material bearing on the holding here.

Finally, most recently, in *AARP v. EEOC*, 2017 WL 6542014 (D.D.C 2017), the District Court for the District of Columbia vacated certain health screening incentive provisions from the EEOC final rules that took effect January 1, 2017, and that bears directly on when health screening requirements are considered "voluntary" under the ADA and GINA. The court expressed serious concerns about the EEOC's reasoning in promulgating the final rules and noted that sufficient explanation had not been provided to support the decision of the EEOC to view 30% incentive levels as "voluntary." The court initially remanded the rules to the EEOC for reconsideration, but after the EEOC indicated that new rules governing such incentives may not be put in place until 2021, the court determined to vacate the health screening incentive portion of the wellness program rules effective January 1, 2019. Although the court kept these rules in place for the time being to avoid "disruption and confusion," their future and what level and type of incentive that is consistent with what is considered "voluntary" remains uncertain, pending possible further EEOC guidance and potential future litigation. In the meantime, employers should consult appropriate counsel to determine their respective wellness program (and incentive) structure and compliance strategy as 2019 approaches.

Wellness programs may also be subject to the following limitations on the collection, use, and disclosure of employee information.

| Law | Data Privacy & Security Requirements |
|---|---|
| **HIPAA** | • HIPAA data privacy and security requirements, including implementing regulations, apply only to covered entities and business associates. As a result, HIPAA neither reaches employers acting solely in their capacity as employers nor applies to wellness programs that do not otherwise involve covered entities.[54]<br>• HIPAA will apply to wellness programs involving covered entities, such as programs operated through group health plans.<br>• If HIPAA applies, wellness program service providers may need to enter into business associate agreements with the group health plans and ensure that protected health |

[54] *See* HHS FAQ guidance at https://www.hhs.gov/hipaa/for-professionals/privacy/workplace-wellness/index.html.

| | |
|---|---|
| | information acquired from plan-associated wellness program activities are not improperly used or disclosed.[55]<br>• Even though some wellness programs may avoid application of HIPAA requirements, certain state privacy laws may apply, as well as federal law protections for certain information (e.g., genetic information) may still apply. |
| **GINA** | • GINA restricts the collection, use, and disclosure of information related to genetic information.<br>• Under GINA, in connection with a wellness program, an employer may not request, require, or purchase the genetic information of an employee (or a family member) unless, in relevant part:<br>o health or genetic services are offered by the employer, including such services offered as part of a wellness program;<br>o the employee provides prior, knowing, voluntary, and written authorization;<br>o only the employee (or family member if the family member is receiving genetic services) and the licensed health care professional or board certified genetic counselor involved in providing such services receive individually identifiable information concerning the results of such services; and<br>o any individually identifiable genetic information provided under subparagraph (C) in connection with the services provided under subparagraph (A) is only available for purposes of such services and shall not be disclosed to the employer except in aggregate terms that do not disclose the identity of specific employees.[56]<br>• As such, an employer may access genetic information if the |

[55] Even wellness programs offered outside of a group health plan may still be subject to HIPAA when operated by healthcare providers and other entities that perform HIPAA-covered functions in certain contexts (e.g., operating a healthcare facility or group practice). For such entities, HIPAA will apply to all their operations, including their wellness program services, unless they meet the HIPAA requirements for a hybrid entity, which includes administrative, structural and technical compliance requirements. For example, the hybrid entity must designate the specific business components that are and are not covered by HIPAA and implement safeguards to prevent the improper use or disclose of protected health information from a covered to a non-covered function. In practical terms, hybrid entities are often be difficult to implement and manage effectively. As such, wellness program providers may opt to treat the entirety of their operations as if they are subject to HIPAA to ensure that missteps do not occur and that they remain HIPAA-compliant.

[56] GINA, at Section 202(b)(2)(A)-(D).

| | |
|---|---|
| | data was acquired on a voluntary basis and is presented in a manner consistent with the requirements of HIPAA, discussed above (e.g., aggregated or de-identified data). |

## VII. FREQUENTLY ASKED QUESTIONS

In general, the applicability of any particular legal standards will depend on the type of wellness program at issue. Below are selected frequently asked questions that arise for vendors looking to implement wellness programs on behalf of employers:

*1) Under HIPAA and GINA, how can the results of biometric testing be safely shared with the employer?*

Biometric screenings are often attractive because wellness programs can use this data to identify employees and target conditions that could benefit most from wellness program activities or medical attention, promoting the general goals of wellness programs (e.g., improved employee health, lowering costs, managing risk). Further, employers could use aggregated data from such screenings to fine tune their wellness programs and strategies.

Under HIPAA,[57] protected health information (e.g., biometric test results) captured by the program vendor may not be shared with the employer unless authorized under HIPAA. As such, employers, without the written authorization of the employees, an employer (in its plan sponsor role) may access protected health information only to the extent necessary to administer its plan if the sponsor's plan document 1) provides and certifies that it would separate personnel who perform plan administration functions and those who do not; 2) would not use or disclose such information for employment-related actions; and 3) implements safeguards to protect and segregate the information.[58]

Employers may also access and use aggregated or de-identified[59] data that would not otherwise allow the employer to know or discern the PHI of a particular individual (e.g., the percentage of employees who received flu vaccinations or have high blood pressure).

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57 Although HIPAA may not apply to the employer, an employer sponsored group health plan that operates the wellness program would constitute a covered entity under HIPAA.

58 *See, e.g.,* https://www.hhs.gov/hipaa/for-professionals/privacy/workplace-wellness/index.html.

59 More information on HIPAA de-identification standards is available at https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html.

To avoid scrutiny under GINA's data privacy requirements, wellness programs should limit their HRAs and other assessments to exclude inquiries involving genetics and family history, including open-ended inquiries that could cause employees to input genetic information. As an alternative, employers may request such information using an HRA after enrollment, provided there is no incentive for its completion and that it is furnished voluntarily. In order to meet this "voluntary" prong, wellness programs should not mandate or penalize employees for non-submission.

In addition, GINA requires the segregation and protection of confidential genetic information. Specifically, such information must be maintained on separate forms and in separate medical files and be treated as confidential medical records, consistent with the requirements of the ADA.[60]

For entities subject to HIPAA, GINA will not prohibit such entities from using or disclosing genetic information for a purpose that is permissible for HIPAA protected health information.

*2) What are the laws that must be considered when a wellness program consists of a decrease in premiums for an employee losing weight or reducing blood pressure, and how should these programs be structured to comply with HIPAA, ADA, and Civil Rights law?*

This type of wellness program would be categorized as health-content and outcomes-based. As a result, such programs could be subject to all of the laws discussed in this article, depending on certain factors. In general, however, for this type of program to comply with HIPAA, the ADA, and anti-discrimination laws, vendors should ensure that:

- The program and incentives are offered to all similarly situated individuals[61] and do not discriminate on the basis of age, race, color religion, sex or national origin.
- The discount does not exceed 30% of the total cost of health plan coverage.
- The program goals are reasonably designed to promote health and prevent disease.
- Reasonable alternatives (or waivers) are available for individuals unable to achieve the goals due to their health status.

In general, although obesity and high blood pressure do not constitute disabilities under the ADA, recent court decisions suggest that certain individuals with such conditions could qualify.[62] As such, vendors should consult with legal counsel

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60 GINA, at Section 206(a), citing 42 U.S.C. § 12112(d)(3)(B).

61 Criteria for similarly situated individuals are explained in footnote 18, *supra*.

62 *See*, *e.g.*, Anderson v. Macy's, Inc., 943 F. Supp. 2d 531 (W.D. Pa. 2013) (Concluding that obesity could not be "definitionally exclude[d]" as a disability when caused by an

when implementing wellness program offerings involving such conditions and ensure that the program is voluntary and comply with the ADA limitations on disability-related inquiries and medical exams.

*3) When is a wellness plan subject to ERISA requirements such as Summary Plan Descriptions, Form 5500s?*

For wellness program offerings that constitute a group health plans (e.g., full service onsite clinics),[63] they are subject to ERISA, and employers who administer such offerings must comply with applicable ERISA disclosure and reporting requirements that apply to other health benefits offered to employees, unless subject to an exception. For example, maintaining a written plan document; distributing Summary Plan Descriptions, Summaries of Material Modifications and Summaries of Material Reduction in Covered Services or Benefits to all clinic participants; filing an annual Form 5500 (unless there are fewer than 100 clinic participants); complying with ERISA claims and appeals procedures; and offering employees and, if applicable, their dependents extended COBRA coverage.

Such ERISA requirements may apply, irrespective of how such wellness program offerings are bundled with other health benefit offerings. As such, employers may, for example, prefer to incorporate an onsite clinic benefit as part of an existing health benefit plan, which can simplify administration and consolidate other compliance obligations, thereby avoiding the potential for missteps and penalties. Other employers may, however, elect to offer the clinic as a separate benefit plan, which offers opportunities for standalone, non-health plan wellness program vendors to administer them, but cross-references key provisions from the existing health benefit plan.

*4) What type of wellness plans should be avoided to ensure that the ADEA or the Mental Health Parity Act is not violated?*

To avoid violating the ADEA, wellness programs should, for example, ensure that wellness program eligibility requirements and rewards are uniform for employees who are 40 and older and who are younger than 40.

For mental health and substance use disorders (e.g., nicotine addiction) that are subject to the parity requirements under the MHPAEA, wellness programs that offer medical care services (e.g., coverage for smoking cessation drugs, counseling) should ensure that such offerings are not subject to qualification or

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underlying physiological condition."); Gogos v. AMS Mech. Sys., Inc., 737 F.3d 1170 (7th Cir. 2013) (Concluding that hypertension could qualify as a disability when the impairment substantially limits a major life activity, irrespective of the frequency and duration of such episodes).

63 See discussion *supra* in Section IV on Types of Wellness Programs.

other standards that are stricter than for other medical conditions. Non-medical care offerings, such as smoking cessation classes and materials should not, however, invite scrutiny under the MHPAEA.

*5) Are wellness plans subject to the Affordable Care Act's mandated benefit requirements, such as the requirement to allow children up to age 26 to participate?*

For wellness programs that constitute a group health plan (e.g., certain onsite clinics), they may be subject to mandated plan benefit requirements under the Affordable Care Act, which includes, for example, a requirement to include the dependent children, up to the age 26, of employees, and to offer essential health benefits.

In some instances, employers are able to meet this requirement by incorporating the wellness program into an existing group health benefit plan that complies with these ACA requirements (or as the courts note above and per Department of Labor (DOL) guidance) solely to medical plan participants. However, for stand-alone programs, employers may avoid these requirements by offering a wellness program limited to "excepted benefits" that do not include "significant benefits in the nature of medical care" and meet certain other criteria (e.g., there is no cost-sharing obligation or employee contributions).

The IRS offered the following illustrations to clarify the scope of significant benefits in connection with an onsite health clinic:[64]

- *Significant Benefit: "*A hospital permits its employees to receive care at its facilities for all of their medical needs. For employees without health insurance, the hospital provides medical care at no charge. For employees who have health insurance, the hospital waives all deductibles and co-pays."
- *Not a Significant Benefit:* "A manufacturing plant operates an on-site clinic that provides the following free health care for employees: (1) physicals and immunizations; (2) injecting antigens provided by employees (*e.g.*, performing allergy injections); (3) a variety of aspirin and other nonprescription pain relievers; and (4) treatment for injuries caused by accidents at the plant."[65]

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64 IRS Internal Revenue Bulletin, 2008-29 (July 21, 2008), *available at* https://www.irs.gov/irb/2008-29_IRB.

65 *Id*.

*6) How can an onsite health clinic be offered to employees with HSAs or high deductible plans?*

For employers and program vendors that offer onsite clinics, they should take into account their employees' ability to maintain eligibility for Health Savings Accounts (HSAs), which requires that the employee be covered by a high-deductible health plan (HDHP) and disqualifies them if they have coverage from any other, non-HDHP health plan coverage that is not otherwise exempt. As noted above, an onsite clinic may constitute a group health plan if its offerings extend beyond simply treating minor injuries or illness (e.g., headaches) or providing first aid for workplace accidents.

According to IRS guidance, an employee's access to free or discounted health care services at a clinic will not disqualify the employee from contributing to an HSA unless the clinic provides "significant benefits in the nature of medical care" that extends beyond preventive care, and dental and vision care.[66] Nevertheless, even if the clinic offers significant benefits, the IRS guidance offered a strategy for a clinic benefit that could still preserve an employee's HSA eligibility. Specifically, the employer or vendor must determine the fair market value of the clinic services that are not preventive in nature and require the employees to pay for such services out-of-pocket, typically up to the deductible under the HDHP.

## VIII. OTHER REGULATORY CONSIDERATIONS FOR WELLNESS PROGRAM VENDORS

### *Fraud & Abuse Laws*

Employer-sponsored wellness programs should not typically implicate federal or state false claims act laws, since payments for such services are made directly by employers and not pursuant to federal health care programs such as Medicare and Medicaid. Moreover, because wellness programs do not typically involve the types of referral arrangements that invite scrutiny under the federal Anti-Kickback Statute and Stark Law, regulator risk under federal fraud and abuse laws should be minimal. Nevertheless, due to some state fraud and abuse statutes that may be implicated even when no government payer program is involved, it remains prudent to review relevant state law requirements.

### *Licensure & Accreditation*

Wellness programs have yet to be subject to federal or state licensing or registration requirements. That said, for wellness programs engaged in the

[66] IRS Internal Revenue Bulletin, 2008-29 (July 21, 2008), *available at* https://www.irs.gov/irb/2008-29_IRB.

provision of licensed health care services, such as the administration of flu vaccinations and engaging in activities that constitute "medical services," vendors should ensure that they engage appropriately licensed and qualified personnel and that they perform services within their respective scopes of practice. In particular, for vendors that operate in multiple states, additional care should be taken to confirm that their personnel hold all required licenses and permits in the applicable jurisdictions.

As with other participants in the health care industry, wellness programs are seeking out accreditation, now offered by national accrediting bodies such as the National Committee for Quality Assurance (NCQA).[67] Because accreditations constitute a seal of approval and signal compliance with industry standards, obtaining them can allow vendors to stand out from their competitors and enhance their marketing efforts.

### *Corporate Practice of Medicine*

Several states prohibit or restrict the ability of lay, non-professional entities from employing or contracting with licensed health care practitioners for the provision of licensed medical and related health care professional services. The specific prohibitions and availability of exceptions vary from state to state, and are often based on decades old case law, attorney general opinions, and agency guidelines. Qualified health care counsel should be consulted to review the potential restrictions and options available in the applicable state or states.

### *Risk-Bearing Organization Registration*

Although wellness program vendors are not traditionally subject to regulatory oversight by state insurance departments, the emergence of alternative payment models has triggered new scrutiny of arrangements involving health care providers, particularly when payments are made for health care services where the provider is subject to financial risk. Depending on the state, providers who assume financial risk for the delivery of health care services may be subject to state insurance department registration and compliance obligations.

## IX. KEY CONSIDERATIONS FOR VENDORS DESIGNING WELLNESS PROGRAMS FOR EMPLOYERS

- Will the program:
  1. Be limited to group health plan enrollees or include all employees?
  2. Involve the provision of medical services?

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[67] Wellness and Health Promotion Accreditation, Nat'l Comm. for Quality Assurance, *available at* http://www.ncqa.org/programs/accreditation/whp-accreditation.

3. Involve health risk assessments or biometric screenings?
4. Involve disability-related inquiries?
5. Involve genetic information (e.g., will the HRA collect family medical histories)?

- Will the program include incentives?
  1. What types of incentives?
  2. What is the potential for disparate impact for protected classes of employees of applicable anti-discrimination laws?
  3. Are they taxable under IRS standards?
- Are the program goals and activities reasonable?
- What types of reasonable alternatives and accommodations are required?

In summation, the legal and compliance obligations for a wellness program will vary depending on its elements and characteristics. The following table offers a high-level overview of how these requirements can apply:

| | **Educational only & non-group health plan participatory/activity only programs** | **Group health plan participatory/activity only** | **Group health plan outcomes-based** |
|---|---|---|---|
| **ACA** | No | Yes | Yes |
| **ERISA** | No | Yes, if it furnishes significant medical benefit (e.g., clinic) | |
| **HIPAA** | No | Yes | Yes |
| **MHPAEA** | No | Yes | Yes |
| **ADEA** | Yes | | |
| **Title VII** | Yes | | |
| **ADA** | Yes, if there is a disability-related inquiry or examination | | |
| **GINA** | Yes, if spouse HRA or biometric examination | | |

So, for example, a wellness program that includes premium and cost-sharing incentives for weight loss or reducing blood pressure would constitute a group health plan outcomes-based program. As a result, although it may be structured to avoid scrutiny under ERISA, the ADA or GINA, employers and vendors must take care to ensure compliance with the ACA, HIPAA, MHPAEA, ADEA and Title VII.

## X. CONCLUSION

The trend toward greater proliferation of wellness programs as an expected employee benefit and as an additional means to tame rising health care expenditures and improve employee health is not likely to change in the

foreseeable future. As wellness programs become more prevalent, they are assuming a wider variety of forms, each with its unique mix of regulatory and compliance challenges. Employers, vendors, and their attorneys must be sensitive to these factors as they design and implement wellness programs to ensure that their goals are achieved while minimizing their legal and compliance risks. Wellness programs have great potential to improve health and reduce costs for employer and employee alike, but given the regulatory complexity and their current, fluid state, care should be taken in pursuing or expanding such programs.

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