THE EMERGING CONTOURS OF THE RULES GOVERNING WELLNESS PROGRAMS

ALDEN J. BIANCHI is the Practice Group Leader of the Employee Benefits & Executive Compensation Practice Group of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. He advises corporate, not-for-profit, governmental, and individual clients on a broad range of executive compensation and employee benefits issues, including qualified and nonqualified retirement plans, stock and stock-based compensation arrangements, ERISA fiduciary and prohibited transaction issues, benefit-related aspects of mergers and acquisitions, and health and welfare plans. Alden is nationally renowned for his advice on the Affordable Care Act's impact on employers. He represented the Romney administration in connection with the historic 2006 Massachusetts health care reform act, which laid the foundation for the "Affordable Care Act." He has testified before the Senate Finance Committee on the subject of health care reform. His many published works include the Bloomberg/Bureau of National Affairs Health Care Reform Advisor, a comprehensive work on the impact of the Affordable Care Act on employers and employer-sponsored group health plans. Alden also provides a regular installment on the Affordable Care Act on Mintz Levin's Employment Matters Blog.

As the costs of providing health insurance continue to rise, employers have sought—with limited success—to find options to hold down costs. One of the few promising approaches in an otherwise bleak cost-containment landscape is the workplace wellness program. While the evidence supporting of the efficacy of workplace wellness programs is mixed, U.S. employers,[1] large employers in particular,[2] have embraced these arrangements. The consensus seems to be that workplace wellness programs improve workforce health, thereby diminishing the demand for services at the margins.

Wellness programs come in all shapes and sizes. They may be (or be or integrated with) group health plans, or not. A wellness program that simply offers discounts on gym memberships, for example, is not a group health plan; a wellness program under which an employee qualifies for discounted group health plan premiums is integrated with a group health plan; and an arrangement where the employer simply provides biometric screenings and health coaching but offers no other major medical coverage is its own standalone group health plan. Whatever the form, these programs share a common need to navigate a shockingly complex legal and regulatory environment.

While a host of Federal laws impact the maintenance and operation of workplace wellness programs, three in particular are currently at the epicenter of wellness program design:

- The Health Insurance Portability and Accountability Act ("HIPAA"),[3] which prohibits employer-sponsored group health plans from discriminating against an employee on the basis of the employee's (or a family member's) adverse health factors;
- The Americans with Disabilities Act, as amended by the ADA Amendments Act of 2008 ("ADA"),[4] which prohibits discrimination against a qualified individual with a disability in any aspect of employment; and
- Title II of the Genetic Information Nondiscrimination Act ("GINA"),[5] which protects job applicants, current and former employees, labor union members, and apprentices and trainees from employment discrimination based on their genetic information.

Another Federal law, the Patient Protection and Affordable Care Act of 2010 ("ACA")[6] also figures prominently. The ACA codified and expanded on a set of 2006 HIPAA regulations establishing the basis for the regulation of wellness programs under the Internal Revenue Code (the "Code"), the Employee Retirement Income Security Act of 1974 ("ERISA"),[7] and the Public Health Service ("PHS") Act.[8]

With the issuance of final regulations under the ACA in June 2013, employers thought that they understood the legal and regulatory environment in which they must operate. This is not to say that they were unaware that the ADA also could impact wellness plan design. They did. But the apparent early lack of interest on the part of the Equal Opportunity Employment Commission

("EEOC"), the agency with the authority to interpret the ADA, followed by contradictory signals from that agency, imparted what ultimately proved to be a false sense of security. As one commentator aptly put it, the EEOC was "late to the party."[9] That changed with a flurry of recent cases and an even more recent bout of regulatory activity by the EEOC. Overnight the question became, do wellness incentives violate the ADA?

Employers also started to worry about the impact of GINA following the issuance of final regulations in October 2009 (relating to GINA Title I, barring the use of genetic information for group health plan underwriting purposes)[10] and November 2010 (relating to GINA Title II, barring the use genetic information for employment purposes).[11] The GINA Title I regulations, which interpreted the term "underwriting" broadly, proved particularly irksome to employers. The rule all but barred incentives aimed at obtaining family medical histories, thereby impairing the usefulness of health risk assessments. Separately, a narrow issue arose under GINA Title II relating to the participation of spouses in health risk assessments. This issue was addressed in a recent notice of proposed rulemaking.[12]

Commentators may differ on the reasons why workplace wellness programs have had to travel such a torturous route. Some claim that the fault lies with Congress for failing to enunciate clear priorities. Others demur and instead place the blame at the feet of overzealous regulators. Or it may simply be that the goal of the ACA is to keep people healthy, while the goal of the ADA is to prevent employers from gaining access to medical information about employees that could be used to discriminate against their employees. Whatever the cause, a basic structure for the regulation of wellness programs is still emerging. And the final EEOC rules, once they emerge, will almost certainly include some limitations with which employers disagree.

There is also the matter of how wellness programs are implemented. For a combination of reasons, employers have come to rely on independent, third-party vendors to deliver wellness services. This approach is all but mandated under the EEOC's view of the ADA. The use of third-parties in this context introduces an additional layer of regulatory complexity as vendors must coordinate their compliance efforts with their employer-clients.

This article traces the development of the regulation of workplace wellness program design. Section I examines the regulation of wellness programs under HIPAA and the ACA, with respect to which final regulations are in place. Sections II and III provide background on the ADA and GINA, respectively, as they affect wellness program design and operation. Section IV surveys EEOC enforcement actions prior to its recent proposed rules. Section V offers a look at two recent proposed EEOC rules, relating to voluntary wellness programs under the ADA and spousal participation in wellness programs under GINA. Section VI shifts the focus to the emerging trends in third-party wellness programs and vendors, with a particular emphasis on service agreements. Finally, Section VII offers some predictions concerning the eventual content of the final EEOC rules on the subject.

I. HIPAA AND THE ACA

The regulation of employer-sponsored group health plans is governed by a patchwork of overlapping Federal laws:

- Title I of ERISA regulates group health plans other than those maintained by churches[13] and state and local governments. While ERISA is primarily enforced by the Department of Labor, its civil enforcement scheme also provides plan participants and beneficiaries with private rights of action to recover benefits, clarify rights, and obtain other relief;

- Group health plans are also subject to parallel provisions set out in group health provisions in the Code, which apply to all group health plans (including church plans) but not to governmental plans or health insurance issuers. The Treasury Department, acting by and through the Internal Revenue Service, promulgates regulations under and otherwise enforces the Code.[14] These rules are enforced through the imposition of excise taxes;[15] and

- The PHS Act imposes requirements on health insurance issuers in the individual and group markets and on self-funded non-federal governmental group plans. While the Secretary of Health and Human Services is the primary enforcer of the PHS Act as it applies to governmental plans, with respect to health insurance issuers, the Department of Health and Human Services (HHS) generally defers to the states for enforcement.[16]

This scheme took form following the enactment of the Consolidated Omnibus Budget Reconciliation Act of 1995 ("COBRA"). By including parallel amendments to ERISA, the Code and the PHS Act, most, but not all, Federal insurance mandates are made to apply to group health plans (whether sponsored by private sector companies, churches, or instrumentalities of government) and to state-licensed health insurance issuers or carriers. At the direction of Congress, the arrangement was memorialized in a memorandum of understanding by and among the Department of the Treasury, the Department of Labor, and the Department of Health and Human Services (the "Departments") effective April 21, 1999.[17] The ACA's insurance market reforms followed this approach by amending the PHS Act and incorporating these amendments into the Code and ERISA. Specifically, the ACA incorporated the provisions of PHS Act § 2705 by reference into ERISA § 715(a)(1) and Code § 9815(a)(1).

HIPAA added Code § 9802, ERISA § 702, and PHS Act § 2702 imposing non- discrimination requirements on group health plans and health insurance issuers. These non- discrimination requirements generally prohibit group health plans from charging similarly situated individuals different premiums or contributions or imposing different deductible, copayment or other cost sharing requirements based on a health factor. "Health factors" included health status, medical condition (including both physical and mental illnesses), claims experience, receipt of health care, medical history, genetic information, evidence of insurability, and disability. An exception to this rule is found in the case of wellness programs.

In 2006, the Departments published final regulations[18] implementing the HIPAA nondiscrimination standards and fleshing out the wellness exception. The regulations permit group health plans to vary benefits, including cost-sharing mechanisms (such as a deductible, copayment, or coinsurance), based on whether an individual has met the requirements of a wellness program that satisfies the various requirements enumerated in the rule.[19] The regulations classify wellness programs into two basic types:

Participatory Wellness Programs

Wellness programs that do not provide a reward and wellness programs that provide incentives based solely on participation are referred to as "participatory wellness program."[20] Examples in the regulations include a fitness center reimbursement program, a diagnostic testing program that does not base rewards on test outcomes, a program that waives cost-sharing for prenatal or well-baby visits, a program that reimburses employees for the cost of smoking cessation aids regardless of whether the employee quits smoking, and a program that provides rewards for attending health education seminars.[21]

Importantly for purposes of later developments, a participatory wellness program also includes a program that rewards employees who complete a health risk assessment ("HRA") regarding current health status, without any further action required by the employee with regard to the health issues identified as part of the assessment. Participatory wellness programs are permissible under the HIPAA nondiscrimination requirements without any additional standards or limits, provided they are made available to all similarly situated individuals.[22] This is not the case, however, under the EEOC rules, as proposed.

Health-Contingent Wellness Programs

Health-contingent wellness programs require individuals to satisfy a standard related to a health factor in order to obtain a reward. A reward can take the form of a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism (e.g., deductibles, copayments, or coinsurance), the absence of a surcharge, or the value of a benefit that would otherwise not be provided under the plan (e.g., a prize).[23] Examples include a program that requires an individual to obtain or maintain a certain health outcome in order to obtain a reward (such as being a non-smoker, attaining certain results on biometric screenings, or exercising a certain amount).

Health-contingent wellness programs may be either activity-only or outcome-based. In either case, the program requires individuals to satisfy a standard related to a health factor to obtain a reward (or require an individual to undertake more than a similarly situated individual based on a health factor in order to obtain the same reward). Activity-only programs require individuals to perform or complete an activity related to a health factor in order to obtain a reward, but do not effect cost of coverage under the plan. Outcome-based programs, in contrast, require individuals to attain or maintain a specific health outcome (such as

not smoking or attaining certain results on biometric screenings) in order to obtain a reward.

The 2006 final wellness regulations established the following five requirements for health-contingent wellness programs:

- The total reward for such wellness programs offered by a plan sponsor is limited to 20 percent of the total cost of employee-only coverage under the plan. (However, if any class of dependents can participate in the program, the limit on the reward is modified so that the 20 percent is calculated with respect to the total cost of coverage in which the employee and any dependents are enrolled.)[24]
- The program must be reasonably designed to promote health or prevent disease. For this purpose, it must: have a reasonable chance of improving health or preventing disease, not be overly burdensome, not be a subterfuge for discriminating based on a health factor, and not be highly suspect in method. While the preamble to the final regulations explains that "bizarre, extreme, or illegal requirements" in a wellness program would be prohibited, it also states that there does not need to be a scientific record that the method used in the program promotes wellness. Thus, the "reasonably designed" standard is intended to allow diversity and experimentation in promoting wellness.[25]
- The program must give eligible individuals an opportunity to qualify for the reward at least once per year.[26]
- The reward must be available to all similarly situated individuals. For this purpose, a reasonable alternative standard (or waiver of the original standard) must be made available to individuals for whom it is unreasonably difficult due to a medical condition to satisfy the original standard during that period (or for whom a health factor makes it unreasonably difficult or medically inadvisable to try to satisfy the original standard).[27]
- In all plan materials describing the terms of the program, the availability of a reasonable alternative standard (or waiver of the original standard) must be disclosed.[28]

The ACA added the PHS Act § 2705, effective for plan years beginning on or after January 1, 2014, which codified and expanded on the 2006 final wellness regulations. The ACA generally codifies the HIPAA wellness program regulations. Under both sets of rules, wellness programs that do not require the satisfaction of a standard relating to a health factor and are made available to all similarly situated individuals are not considered discriminatory. But if a wellness program conditions receiving a reward (such as a premium rebate) on meeting a health factor- related standard, the program must meet the above-enumerated requirements, except that the available reward is capped at 30 percent rather than 20 percent. The ACA further empowered the regulators to increase this reward to up to 50%.

The HIPAA nondiscrimination requirements, as amended by ACA, apply only if the program is offered as part of a group health plan or through an insurer that provides group health coverage. Thus, programs offered outside of a group health plan as a separate employment policy are not subject to the HIPAA/ACA requirements. Of course, other federal laws (e.g., the ADA) may still apply.

Final regulations under the PHS Act § 2705 were issued in June 2013.[29] These regulations also included five requirements for health-contingent wellness programs, but the order was changed and there were some important modifications:

- The total reward offered to an individual under all health-contingent wellness programs with respect to a plan cannot exceed 30 percent of the total cost of employee- only coverage under the plan, including both employee and employer contributions towards the cost of coverage (or 50 percent to the extent that the additional percentage is attributed to tobacco prevention or reduction);
- Health-contingent wellness programs must be reasonably designed to promote health or prevent disease;
- The full reward under a health-contingent wellness program must be available to all similarly situated individuals. For this purpose, an activity-only program must allow a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is unreasonably difficult due to a medical condition to satisfy the otherwise applicable standard, and for any individual for whom, for that period, it is medically inadvisable to attempt

> to satisfy the otherwise applicable standard. An outcome-based program must allow a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward to any individual who does not meet the initial standard based on a measurement, test, or screening; and Plans and issuers must disclose the availability of a reasonable alternative.[30]

The 2013 PHS Act final wellness regulations also explicitly recognize that compliance with HIPAA nondiscrimination rules, including the wellness program requirements, is not determinative of compliance with any other provision of any other state or federal law, including, but not limited to, the ADA, GINA, and Title VII of the Civil Rights Act of 1964 ("Title VII").[31]

II. THE AMERICANS WITH DISABILITIES ACT

Congress enacted the ADA in 1990 to prohibit discrimination against individuals with disabilities. The ADA generally makes it unlawful for employers, employment agencies, labor organizations, and joint labor management committees to discriminate on the basis of disability against a qualified individual with a disability in regard to "job application procedures, the hiring, advancement, or discharge of employees, employee compensation, job training, and other terms, conditions, and privileges of employment."[32] Implementing regulations further provide, in pertinent part, that it is unlawful for an employer to discriminate on the basis of disability against a qualified individual with a disability in regard to "[f]ringe benefits available by virtue of employment, whether or not administered by the [employer]."[33] The ADA separately requires employers to provide reasonable accommodations (modifications or adjustments) to enable individuals with disabilities to have equal access to the fringe benefits offered to individuals without disabilities.[34] It also generally prohibits employers from making disability-related inquiries or requiring medical examinations.[35]

Employee Health Programs

In the EEOC's view, wellness programs are "employee health programs." A wellness program may be part of a group health plan or may be offered outside of a group health plan. The term "group health plan" includes both insured and self-insured group health plans. According to the EEOC:

> [W]ellness programs include nutrition classes, onsite exercise facilities, weight loss and smoking cessation programs, and/or coaching to help employees meet health goals. Wellness programs also may incorporate health risk assessments and biometric screenings that measure an employee's health risk factors, such as body weight and cholesterol, blood glucose, and blood pressure levels. Some employers offer incentives to encourage employees simply to participate in a wellness program, while others offer incentives based on whether employees achieve certain health outcomes. Incentives can be framed as rewards or penalties and often take the form of prizes, cash, or a reduction or increase in health care premiums or cost sharing.[36]

Employee health programs offered by employers must comply with laws enforced by the EEOC, including Title I of the ADA which restricts the medical information employers may obtain from applicants and employees and makes it illegal to discriminate against individuals based on disability. They also must comply with other laws that prohibit discrimination based on race, color, sex (including pregnancy), national origin, religion, age, or genetic information.

The Voluntary Wellness Program Exception

To the general rule barring discrimination against individuals with disabilities, the ADA provides an exception that permits "voluntary medical examinations, including voluntary medical histories, which are part of an employee health program available to employees at that work site."[37] The law's legislative history provides some additional gloss. According to the House Education and Labor Committee:

> A growing number of employers today are offering voluntary wellness programs in the workplace. These programs often include medical screening for high blood pressure, weight control, cancer detection, and the like. As long as the programs are voluntary and the medical records are maintained in a confidential manner and not used for the purpose of limiting health insurance eligibility or of preventing occupational advancement, these activities would fall within the purview of accepted activities.[38]

Thus Congress pretty clearly intended to equate voluntary wellness programs under the ADA with the sort

of workplace wellness programs that are the subject of this paper. As a consequence, an employer may make disability-related inquiries or conduct medical examinations as a part of a voluntary wellness program. In its interpretive guidance, the EEOC concedes as much but also adds some gloss of its own. According to the EEOC, "a wellness program is 'voluntary' as long as an employer neither requires participation nor penalizes employees who do not participate."[39] The EEOC did not further elaborate on the meaning of "voluntary" in its regulations.

The Bona Fide Insurance Plan Safe Harbor Provision

The ADA establishes a separate safe harbor provision for bona fide insurance plans:

> [The ADA] shall not be construed to prohibit or restrict . . . a person or organization covered by this chapter from establishing, sponsoring, observing or administering the terms of a *bona fide benefit plan* that are based on underwriting risks, classifying risks, or administering such risks that are based on or not inconsistent with State law (emphasis added).[40]

To qualify for this safe harbor protection, the arrangement "must not be used as a subterfuge to evade the purposes of law."[41]

In Seff v. Broward County,[42] the 11th Circuit was called upon to interpret the ADA's bona fide insurance plan safe harbor provision. The case involved a wellness program maintained by the Broward County, Florida, which required employees submit to biometric screening and complete an online health risk assessment. The County's group health plan used the information from the screening and questionnaire to identify employees who had certain diseases to offer them the opportunity to participate in a disease management coaching program and obtain co-pay waivers for certain medications. The County imposed a $20-per-pay-period surcharge on health plan premiums for those who did not participate in the wellness program. The plaintiff filed a class action lawsuit alleging that the employee wellness program's biometric screening and online health risk assessment questionnaire violated the ADA's prohibition on non-voluntary medical examinations and disability-related inquiries.

The district court[43] held that the County's wellness program fit squarely within the ADA's bona fide benefit plan safe harbor provision. In reaching its conclusion, the district court found that the employee wellness program qualified as a bona fide benefit plan within the meaning of the safe harbor provision because the employee wellness program constituted a "term" of Broward's group health plan. The court also determined that the program was based on underwriting, classifying, or administering risk and that it "was designed to develop and administer present and future benefit plans using accepted principles of risk assessment." Lastly, the district court observed that "the program is enormously beneficial to all employees of Broward County—disabled and non-disabled alike." Therefore, said the court, there is no subterfuge.

On appeal,[44] the plaintiff disputed the lower court's determination that the wellness program was part of a bona fide benefit plan based on testimony to the effect that the wellness program was not mentioned in the group health plan. The Eleventh Circuit was unpersuaded, noting that the County's insurer sponsored the wellness program as part of its contract with the County to provide a group health plan; the program was only available to group plan enrollees; and the County presented the wellness program as part of its group plan in at least two employee handouts. The Court also said that the written terms of the plan were not necessarily material to the applicability of the safe harbor provision.

While Seff appears well reasoned, the EEOC disagrees with the decision. Its reasoning is set out in the following footnote in the preamble to its 2015 proposed wellness program regulations.[45]

> The Commission does not believe that the ADA's "safe harbor" provision applicable to insurance, as interpreted by the court in Seff v. Broward County, 778 F. Supp. 2d 1370 (S.D. Fla. 2011), affirmed, 691 F.3d 1221 (11th Cir. 2012), is the proper basis for finding wellness program incentives permissible. The ADA contains a clear ''safe harbor'' for wellness programs—the "voluntary" provision at 42 U.S.C. 12112(d)(4)(B). See H.R. Rep. 101-485, pt. 2, at 51 ("A growing number of employers today are offering voluntary wellness programs in the workplace. These programs often include medical screening for high blood pressure, weight control, cancer detection, and the like. As long as the programs are voluntary and the medical records are maintained in a confidential manner and not used for

the purpose of limiting health insurance eligibility or of preventing occupational advancement, these activities would fall within the purview of accepted activities."). Reading the insurance safe harbor as exempting these programs from coverage would render the "voluntary" provision superfluous.

The EEOC's position is, however, suspect. Some wellness programs are based on "underwriting, classifying, or administering risks," others are not. The latter are unable to meet the requirements of the bona fide insurance plan safe harbor provision. Congress provided these plans with an alternative; they can instead qualify as voluntary wellness programs. In addition, the EEOC seems to miss that the ADA's voluntariness requirement would still apply to employer wellness programs that are not a part of a group health plan.

III. THE GENETIC INFORMATION NONDISCLOSURE ACT OF 2008

GINA protects individuals against discrimination in health coverage and in employment based on their genetic information.[46] GINA generally prohibits the use of genetic information in employment decisions, including hiring, firing, job assignments, and promotions by employers, labor unions, employment agencies, and labor-management training programs.[47] In addition, an employer, employment agency, labor union, or training program may not "request, require or purchase genetic information" with respect to the employee, individual, union member, or family member.[48] There are statutory exceptions to the prohibition on the acquisition of genetic information for employers, employment agencies, labor unions, and training programs.[49] But even where an exception applies, genetic information may not be used in a manner that violates nondiscrimination or confidentiality requirements of GINA.

For the purpose of Title II of GINA, "genetic information" means:

(A) In general. The term "genetic information means, with respect to any individual, information about —

(I) such individual's genetic tests,

(II) the genetic tests of family members of such individual, and

(III) the manifestation of a disease or disorder in family members of such individual. Such term includes, with respect to any individual, any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by such individual or any family member of such individual.[50]

A "family member" of an individual includes someone who is "a dependent of an individual through *marriage*, birth, adoption, or placement for adoption and any other individual who is a first-, second-, third-, or fourth-degree relative of the individual.[51] (emphasis added). It's not hard to see the problem here: information about the manifest disease of a spouse qualifies as genetic information as to the employee. Thus, GINA appears to prohibit offering incentives to an employee's spouse to participate in a wellness plan, since the disclosure by the spouse of a manifest health condition would result in the disclosure of genetic information. The preamble to the proposed regulations under GINA Title II explains the conundrum: Read in one way, conditioning all or part of an inducement on the provision of the spouse's current or past health information could be read to violate the [ ] prohibition on providing financial inducements in return for an employee's protected genetic information. When an employer seeks information from a spouse (who is a ''family member'' under GINA as set forth at 29 C.F.R. § 1635.3(a)(1)) about his or her current or past health status, the employer is also treated under GINA as requesting genetic information about the employee.[52]

GINA is organized in two titles. Title I of GINA prohibits discrimination based on genetic information in health coverage; and Title II of GINA prohibits discrimination based on genetic information in employment. Participation in a wellness program almost always involves the provision of medical information—which may include genetic information—by the participant (e.g., the employee, the employee's spouse) to the employer. As a consequence, wellness programs that are part of a group health plan must contend with both Titles.

The interpretive challenge is complicated by the nature of Title II of GINA, which broadly prohibits employers from using genetic information in employment decisions in all circumstances. There are, however, six very limited circumstances in which an employer may request, require, or purchase genetic information

about an applicant or employee.[53] One of the six narrow exceptions to GINA's acquisition prohibition permits employers that offer health or genetic services, including such services offered as part of voluntary wellness programs, to request genetic information as part of these programs only if they meet three specific requirements:

- The employee must provide prior, knowing, voluntary, and written authorization;
- Only the employee 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
- Any individually identifiable genetic information provided in connection with the health or genetic services provided under this exception is only available for the 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. [54]

Final regulations[55] interpreting Title I of GINA limit the use of health risk assessments that ask for information relating to family medical history. Under these rules, an employer may offer an incentive to an employee for completing a health risk assessment that includes family history only if receipt of the incentive is paid irrespective of whether the employee provides answers to the family history questions. For example, if Company A offers a premium discount under its group health plan in return for completion of health risk assessment that includes five questions, the last of which involves family medical history, the employee must be able to qualify for the premium discount by completing only the first four questions.

Final regulations[56] interpreting Title II require that a health risk assessment (HRA)—the survey often given to participants in wellness programs to collect their health information—must clearly and understandably indicate that the provision of any genetic information asked for on the HRA is not linked to any incentive. Specifically, the final rule explains that an employer:

> may not offer a financial inducement for individuals to provide genetic information, but may offer financial inducements for completion of health risk assessments that include questions about family medical history or other genetic information, provided the covered entity makes clear ... that the inducement will be made available whether or not the participant answers questions regarding genetic information.[57]

IV. ANTECEDENT EEOC ENFORCEMENT EFFORTS

Before the issuance of the proposed rules referred to above, the EEOC's view of the wellness programs was little known or understood. A series of conflicting informal EEOC letters did not help.[58] Whether as a consequence of, or despite, the EEOC's oscillations in the matter, employers generally took little notice of the EEOC's views as it designed and adopted wellness programs. This changed abruptly once the EEOC started to enforce the proposed rules, without warning and without first issuing interpretive regulations.

EEOC v. Orion Energy Sys.

In EEOC v. Orion Energy Sys.,[59] the EEOC challenged a wellness program maintained by Wisconsin-based Orion Energy Systems alleging that the program violated the ADA. According to the EEOC, when an employee declined to participate in Orion's wellness program, Orion required the employee to pay 100% of the premiums for employee health benefits. Shortly thereafter, Orion fired the employee. The EEOC claimed that this Orion's wellness program violated the ADA, and that Orion retaliated against the employee because of her good-faith objections to the program. The EEOC further asserted that Orion interfered with the employee's exercise of her federally- protected ADA right to not be subjected to unlawful medical exams and disability-related inquiries, in violation of 42 U.S.C. § 12112(d)(4)(A).

On September 19, 2016, Judge Griesbach granted summary judgment for the on the ADA claim, but denied Orion's requested dismissal of the ADA anti- retaliation/interference claim.[60] Notably, the court declined to find that an employer's wellness program fell within the ADA's safe harbor provision, 42 U.S.C. § 12201(c)(2).[61]

The court not only deferred to the EEOC's regulations but even with casting aside the regulation, the court found that the wellness program "was not used to underwrite, classify, or administer risk," i.e. the basic tenet and purpose behind the safe harbor provision could not be furthered as Orion did not use the information provided to determine premiums or coverage

under its health plan.[62] However, the court did find that the wellness program was "voluntary," thereby allowing Orion to escape liability on the ADA claim.[63] The court rejected the EEOC's position that shifting 100% of the premiums cost to the employee for failure to participate in the program rendered the program involuntary.[64] The court called the decision to enroll "may have been difficult, but…a choice nonetheless," and thus, "a medical examination or inquiry that is 'voluntary' and part of a health program does not violate the ADA."[65] And finally, the court denied summary judgment on the ADA ant-retaliation/interference claim, reasoning in part that the employee's sincere, good faith belief of a violation constituted sufficient protected activity to state a claim.[66]

EEOC v. Flambeau, Inc.

The EEOC's Chicago District Office sued defendant Flambeau, Inc., a plastic manufacturing company, alleging that it violated the ADA by requiring employees to participate in a wellness program that required them submission to biometric testing and completion of a health risk assessment, or face cancellation of medical insurance, unspecified disciplinary action for failing to attend the scheduled testing, and a requirement to pay the full premium in order to stay covered.[67] When charging party did not complete the biometric testing and health risk assessment, Flambeau cancelled his medical insurance and shifted responsibility for payment of the entire premium cost to him. The EEOC said employees who had taken the biometric testing and health risk assessment, by comparison, did not have their coverage cancelled involuntarily, and were only required to pay 25% of their premium cost. The EEOC contended that the biometric testing and health risk assessment constituted "disability-related inquiries and medical examinations" that were not job-related and consistent with business necessity as defined by the ADA.

Flambeau argued that the testing and assessment requirements of its wellness program fell within ADA's safe harbor provision.[68] They also argued the requirements were not prohibited by 42 U.S.C. § 12112(d)(4)(A) because an employee's completion the health assessment and biometric test were "entirely voluntary." In other words, employee only had to complete the assessment and test if he or she wanted to participate in Flambeau's insurance plan.

On December 30, 2015, the court granted Flambeau's motion for summary judgment.[69] In a decision wholly contrary to the EEOC's position and its proposed ADA regulations, the court held:

- The ADA's safe harbor provision applies to wellness programs that are part of an employer's insurance benefit plan;
- Flambeau's wellness program requirement was a "term" of its insurance benefit plan since "employees were required to complete the wellness program before they could enroll in the plan."[70]
- Flambeau's wellness program requirement was "based on underwriting risks, classifying risks, or administering risks."[71]
- There was no subterfuge involved because Flambeau's "wellness program clearly did not involve such a [disability-based] distinction or relate to discrimination in any way. Regardless of their disability status, all employees that wanted insurance had to complete the wellness program before enrolling in [Flambeau]'s plan. Furthermore, there is no evidence that [Flambeau] used the information gathered…to make disability-related distinctions with respect to employees' benefits."[72]

On January 25, 2017, the U.S. Court of Appeals for the Seventh Circuit affirmed the district court's holding, but not on the merits.[73] The Seventh Circuit chose not to address the statutory issue as to whether wellness programs fall within the ADA's safe harbor provision, but not before commenting "cases raising [this issue] can be counted on one hand."[74] Instead, the court affirmed because the EEOC's claim for injunctive relief was moot and the undisputed facts established failed to establish a claim for compensatory or punitive damages.[75]

EEOC v. Honeywell International, Inc.

On October 27, 2014, the EEOC moved for a preliminary injunction against Honeywell asserting that Honeywell violated the ADA by requiring participation in medical exams associated with Honeywell's group health plan and wellness program.[76] The group health plan and wellness program at issue included a self-funded health reimbursement arrangement, and it provided financial inducements to incentivize participation. The wellness program that was the subject of the suit was pretty straightforward. Honeywell imposed

a surcharge on an employee in instances in which the employee or the employee's spouse declined to undergo limited biometric testing associated with the wellness program. The EEOC claimed that the financial inducements violated both the ADA and, by including spouses, GINA. On November 3, 2014, the court denied the EEOC's motion based on the EEOC's failure to show any irreparable harm.

The first two cases, Orion and Flambeau, did not worry most employers. The cases appeared to be outliers, and the wellness programs that they involved seemed excessive. Even so, the district court in Flambeau, in contrast to the court in Orion, held that the employer's wellness program that required employees to participate in health assessments and biometric tests was protected by the ADA's safe harbor provision and thus did not violate the ADA—even though an employee could not obtain medical insurance benefits if he or she chose not to participate in the program. Honeywell's wellness program, in contrast, was considered by most commentators to be "mainstream." The ruling in Honeywell's favor involved a temporary order, so the EEOC faced a high evidentiary bar. It provided little comfort other than (one might imagine) a few "high fives" by the litigants and their counsel at the EEOC's expense. Left unresolved were two substantive issues: (i) Can wellness programs qualify as bona fide insurance plan?, and (ii) Do wellness programs violate GINA Title II with respect to spouses? In its 2016 GINA regulations, the EEOC conceded the latter. But in the 2016 ADA regulations, the agency doubled down on the former.

V. FINAL EEOC REGULATIONS UNDER THE ADA AND GINA TITLE II

On May 18, 2016, the EEOC released its regulations concerning employer wellness programs. These regulations became effective July 18, 2016 but began applying to plans that started on January 1, 2017. In the preamble to their proposed regulations interpreting the ADA voluntariness standards, the EEOC makes the following important observations and concession:

> The Interaction of Title I of the ADA and HIPAA's Nondiscrimination Provisions, as Amended by the Affordable Care Act. The Commission's interpretation of the term "voluntary" in the ADA's disability-related inquiries and medical examinations provision is central to the interaction between the ADA and HIPAA's wellness program provisions, as amended by the Affordable Care Act. A plausible reading of "voluntary" in isolation is that covered entities can only offer de minimis rewards or penalties to employees for their participation (or nonparticipation) in wellness programs that include disability-related inquiries and medical examinations. That reading, however, would make many wellness program incentives tied to the disclosure of health information or the completion of medical examinations expressly permitted by HIPAA impermissible under the ADA. *Although it is clear that compliance with the standards in HIPAA is not determinative of compliance with the ADA, the Commission believes that it has a responsibility to interpret the ADA in a manner that reflects both the ADA's goal of limiting employer access to medical information and HIPAA's and the Affordable Care Act's provisions promoting wellness programs.* Accordingly, the Commission concludes that allowing certain incentives related to wellness programs, while limiting them to prevent economic coercion that could render provision of medical information involuntary, is the best way to effectuate the purposes of the wellness program provisions of both laws. (emphasis added).[77]

The EEOC's final regulations reaffirms this central theme: "Although the Commission recognizes that compliance with the standards in HIPAA, as amended by the Affordable Care Act, is not determinative of compliance with the ADA, we believe that the final rule interprets the ADA in a manner that reflects the ADA's goal of limiting employer access to medical information and is consistent with HIPAA's provisions promoting wellness programs."[78] Thus, EEOC will not stand in the way of wellness plans as envisioned by HIPAA/ACA wellness regulations.[79] It does not mean, however, that the two sets of rules will coordinate perfectly. At the end of the regulatory process, the design features and parameters of workplace wellness programs will be based on the lowest common denominators under the final HIPAA/ACA rules issued by the Departments of Health and Human Services, Labor, and Treasury/IRS, and the ADA/GINA rules once issued in final form by the EEOC.

Amendments to the ADA Regulations[80]

The May 2016 final regulations made good on the EEOC's stated intention to "interpret the ADA in a manner that reflects both the ADA's goal of limiting employer access to medical information and HIPAA's

and the Affordable Care Act's provisions promoting wellness programs."[81] The final regulations reiterate the EEOC Commission's view of its regulatory mandate, as explained in the preamble to the proposed regulations: "employee health programs that include disability related inquiries or medical examinations (including inquiries or medical examinations that are part of a HRA or medical history) must be voluntary."[82] Thus in the EEOC's view, wellness programs fall under the ADA and squarely within its jurisdiction.

The regulations, which apply to "employee health programs"[83] that are part of an insured or self-insured group health plan, establish the following requirements for the program to be voluntary:[84]

- Generally, an employee health program, including any disability-related inquiries and medical examinations that are part of such a program, must be reasonably designed to promote health or prevent disease. This standard is similar to the standard under the HIPAA/ACA regulations applicable to health contingent wellness programs. In order to meet the standard, the program must have a reasonable chance of improving the health of, or preventing disease in, participating employees, and must not be overly burdensome, a subterfuge for violating the ADA or other laws prohibiting employment discrimination, or highly suspect in the method chosen to promote health or prevent disease. This requirement appears to apply irrespective of whether the program relies on or provides an incentive.[85]
- For a program to be considered voluntary, an employer may not require an employee to participate in such a program, may not deny coverage under any of its group health plans or particular benefits packages within a group health plan, generally may not limit the extent of such coverage, and may not take any other adverse action against employees who refuse to participate in an employee health program or fail to achieve certain health outcomes.[86] Nor may an employer may retaliate against, interfere with, coerce, intimidate, or threaten employees (e.g., by coercing an employee to participate in an employee health program or threatening to discipline an employee who does not participate).[87] For example, a program that gathers health-related information from employees through biometric screening but does not provide employees with the results or offer any programs to mitigate health-related conditions would not be a valid wellness program. This requirement will end the not uncommon practice of denying participation in a particular group health plan or health plan coverage to employees who fail to complete a health risk assessment.
- For a wellness program *that is part of a group health plan* to be deemed voluntary, the employer must provide a notice clearly explaining what medical information will be obtained, how the medical information will be used, who will receive the medical information, the restrictions on its disclosure, and the methods the covered entity uses to prevent improper disclosure of medical information.[88]
- While an offer of limited incentives to participate in wellness programs that are part of a group health plan and that include disability-related inquiries and/or medical examinations will not render the program involuntary, the total allowable incentive available under all programs, both participatory programs and health-contingent programs, may not exceed 30 percent of the total cost of employee-only coverage.[89] With respect to its treatment of participatory wellness programs, the EEOC "decided that by extending the 30 percent limit set under HIPAA and the Affordable Care Act to include participatory wellness programs that ask an employee to respond to a disability-related inquiry or undergo a medical examination, this rule promotes the ADA's interest in ensuring that incentive limits are not so high as to make participation in a wellness program involuntary."[90] And while the EEOC had previously taken the position that any penalty is impermissible, the regulations would permit employers to offer incentives in the form of rewards or penalties.

While the 30 percent limit is similar to the HIPAA/ACA rules, the EEOC's proposal applies the limit differently. The HIPAA/ACA standards apply the 30 percent to the selected coverage, e.g., self-only, employee-plus-one, family, etc. The EEOC rule applies the 30 percent limit to the cost of employee-only coverage. Similarly, while the HIPAA/ACA regulations permit incentives of up to 50 percent of the cost of coverage for health-contingent wellness programs that contain tobacco prevention or reduction initiatives, the EEOC regulations do not. The EEOC retained a distinction it made

in its proposed rules: smoking cessation programs that merely encourage employees to participate in a smoking cessation program without asking whether they actually quit are not subject to the ADA.[91] However, the ADA would apply in this instance if the program required a test for nicotine or tobacco, which triggered an incentive (reward or penalty).[92]

- The EEOC added a new rule concerning the confidentiality and use of medical information gathered in the course of providing voluntary health services to employees, including information collected as part of an employee's participation in an employee health program. Medical information collected through an employee health program only may be provided to a covered entity under the ADA in aggregate terms that do not disclose, or are not reasonably likely to disclose, the identity of specific individuals, except as needed to administer the health plan.[93] The EEOC reminds employers that, where a wellness program is part of a group health plan, the individually identifiable health information collected from or created about participants as part of the wellness program is protected health information under the HIPAA Privacy, Security, and Breach Notification Rules. The consequences of this in the case third-party wellness vendors are explored in Section VI below.
- Compliance with the proposed ADA wellness rules does not relieve an employer of its obligation to comply with other employment nondiscrimination laws.[94] Thus, for example, even if an employer's wellness program complies with the incentive limits set forth in the ADA regulations, the employer would violate Title VII or the Age Discrimination in Employment Act ("ADEA") if that program discriminates on the basis of race, sex, national origin, or age, or any other grounds prohibited by those statutes.

The EEOC's rules also include governing the interaction between the ADA and the HIPAA privacy (and related) rules as they apply to wellness programs that are a part of an employer's group health plan. The information elicited by health risk assessment and biometric screenings is protected health information or "PHI" for HIPAA purposes. Thus, a wellness program that provides incentives for completing a health risk assessment and/or participating in biometric screenings is subject to the HIPAA privacy, security, and breach notification rules.[95] Such a program can piggyback on the group health plan's compliance, but this approach may not be available if the group health plan is fully insured and receives only summary health information.[96] (The wellness program in this latter instance is a separate, self-funded arrangement.)According to the EEOC's interpretative guidance, where a wellness program is part of a group health plan and required to comply with HIPAA, its obligations concerning the confidentiality and use of medical information may be satisfied by adhering to the HIPAA privacy and related rules.[97] Thus, when an employer has a health plan sponsor perform plan administration and receive individually identifiable health information from or on behalf of the group health plan, as permitted by HIPAA, the plan generally satisfies its confidentiality obligations under the ACA. Importantly, where the employer performs no administration on behalf of the group health plan, then the aggregate information that the employer may receive from the wellness program must be de-identified.[98] Thus, and as the preamble to the EEOC's notice of rulemaking proposal notes:

> [O]ther disclosures of protected health information from the wellness program may only be made in accordance with the Privacy Rule. Thus, certain disclosures that are otherwise permitted under [the ACA] for employee health programs generally may not be permissible under the Privacy Rule for wellness programs that are part of a group health plan without the written authorization of the individual.[99]

While it's not clear whether the EEOC had any particular HIPAA compliance issue or challenge in mind here, there is one issue that jumps out. Simply because an employer outsources wellness program administration to an unrelated third party does not mean that it can avoid having to comply with HIPAA. The biggest challenges arise in instances (alluded to above) in which an employer's group health plan is fully-insured but the wellness program is self-funded. Here, the wellness program would be required to separately comply with all of the HIPAA administrative simplification rules. That the employer relies on a third party does not change this result.

Amendments to GINA Regulations[100]

Through regulations, the EEOC recently addressed the issue of providing incentives for the collection of a spouse's current and past health status as part of a wellness program. The EEOC's new rule allows the

employer to incentivize the spouse—but not the employee—to provide information about his or her own current or past health status (e.g., blood pressure, diabetes).[101] It does not, however, allow for the employer to incentivize the spouse to provide his or her own genetic information (e.g., results of a genetic test, family medical history).[102] The proposal does not extend to the practice of providing an incentive in exchange for an employee's children's current or past health status.[103]

The incentive permitted under the rule caps the incentive to both the spouse and the employee at 30 percent of the total annual cost of family health insurance coverage.[104] While the EEOC claims that this limit is consistent with limits for inducements established by the ACA,[105] this claim is modestly disingenuous. Under the EEOC's approach, the maximum inducement that an employer can offer for an employee's provision of information on himself or herself is 30 percent of the cost of sole-employee coverage. The maximum inducement that an employer can offer for spousal provision of information is 30 percent of the cost of family coverage minus 30 percent of the cost of sole-employee coverage. Thus, the rule does not align with the HIPAA/ACA incentives.

Under the rule, employers will be able to offer wellness programs that include inducements, whether in the form of rewards or penalties, for participation by spouses of covered employees. The term "inducements" includes both financial and in-kind inducements, such as time-off awards, prizes, or other items of value, in the form of either rewards or penalties.[106] A group health plan would be able to furnish an inducement to a spouse who provides information in response to an HRA about his or her current or past manifest health conditions. The HRA may include a medical questionnaire, a medical examination (e.g., to detect high blood pressure or high cholesterol), or both,[107] provided the following procedural safeguards are adhered to:

- Employers may request, require, or purchase genetic information as part of health or genetic services *only* when those services, including any acquisition of genetic information that is part of those services, "are reasonably designed to promote health or prevent disease." In order to meet this standard, the program must have "a reasonable chance of improving the health of, or preventing disease in, participating individuals, and it is not overly burdensome, is not a subterfuge for violating Title II of GINA or other laws prohibiting employment discrimination, and is not highly suspect in the method chosen to promote health or prevent disease. A program is not reasonably designed to promote health or prevent disease if it imposes a penalty or disadvantage on an individual because a spouse's manifestation of disease or disorder prevents or inhibits the spouse from participating or from achieving a certain health outcome. . . ."[108]

- No inducement may be offered in return for the spouse providing his or her own genetic information, including results of his or her genetic tests. The HRA, which may, however, include a medical questionnaire, a medical examination (e.g., to detect high blood pressure or high cholesterol), or both, must otherwise comply with ADA requirements that would otherwise apply to the employee, including the requirement that the spouse provide prior knowing, voluntary, and written authorization when the spouse is providing his or her own genetic information, and the requirement that the authorization form describe the confidentiality protections and restrictions on the disclosure of genetic information.[109] The employer also must obtain authorization from the spouse when collecting information about the spouse's past or current health status.

A separate authorization for the acquisition of this information from the employee is not necessary.[110]

- The total inducement to the employee and spouse may not exceed 30 percent of the total annual cost of coverage under plan.[111]

- An employer is barred from conditioning participation in a wellness program or an inducement on an employee, or the employee's spouse or other covered dependent, agreeing to the sale of genetic information or waiving protections provided elsewhere in the law.[112]

- The employer must satisfy all of the requirements for seeking genetic information as part of a voluntary health or genetic service, including the rules on authorization and inducements.[113]

VI. DEALING WITH THIRD-PARTY WELLNESS VENDORS

The phrase "wellness plan design" means different things to employers and to third-party wellness plan vendors. While the former are principally concerned with the regulatory issues that occupy much of this paper, the latter are concerned principally with providing an integrated set of administrative services, contracting with health care providers, and otherwise organizing and aggregating services. Wellness programs can take many forms. Although there is no commercially available "canonical" workplace wellness program (at least not yet), many such programs include an HRA, employer-paid immunizations (e.g., flu shots), employer-paid biometric screenings (e.g., blood pressure screening, BMI, etc.), a "blood draw" (sometimes done on-site), a health coaching feature, and other advice and counseling. Commercially available wellness programs range from passive, i.e., technology based "self-help" arrangements, to more robust health management programs that emphasize person centered coaching models. These latter programs take a comprehensive approach that includes understanding the various factors impacting participants' health and overall lifestyle choices. Ultimately, the goal is affect meaningful and permanent change to participants' lifestyles. However structured, these programs are almost universally made a part of an employer's group health plan. For the balance of this Section VI, references to wellness programs will mean and refer to this typical form of comprehensive program, unless otherwise specified.

As a consequence of the general requirement in the proposed ADA rules that employers be provided only with aggregate medical information collected through a wellness program, and as consequence of the HIPAA privacy and security rules, it would be difficult for an employer to operate a typical wellness program without the engaging a third-party vendor. Use of third-party vendors by employers to administer wellness programs will, as a result, become the norm—to the extent that it has not already become so.

A comprehensive overview of all of the laws that affect the employer-wellness vendor relationships is beyond the scope of this article.[114] There are however (in the authors' experience) three recurring issues that merit special attention

ERISA

ERISA § 733(a)[115] defines the term "group health plan" as follows:

> (1) In general
>
> The term "group health plan" means an employee welfare benefit plan [as defined in section 3(1) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1002 (1))] to the extent that the plan provides medical care (as defined in paragraph (2) and including items and services paid for as medical care) to employees or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise.
>
> (2) Medical care
>
> The term "medical care" means 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 subparagraph (A), and
>
> (C) amounts paid for insurance covering medical care referred to in subparagraphs (A) and (B).

Wellness programs that identify risks, provide coaching and support, and help participants to manage diagnosed conditions and/or prevent the occurrence of future health problems, are—and are regulated as—group health plans for ERISA purposes. Thus, these programs generally must be described in a plan document, the material terms of which must be communicate in a summary plan description. There must also be a formal claims procedure and the program must file annual reports. To the extent the plan is made a part of an employer's group health plan, such a wellness program can piggyback on the latter's compliance. While this is often the case, the particulars of the wellness program often are not included in the plan's summary plan description. Not a fatal omission, to be sure, but an omission nonetheless. In the case of stand-alone wellness program, however, the ERISA obligations loom large.

ERISA Title I, Subtitle B, Section 7 also imposes health care continuation (or COBRA) requirements on group

health plans. To the extent the plan is made a part of an employer's group health plan, COBRA compliance can be integrated pretty much seamlessly. Not so in the case of a stand-alone wellness program or a wellness program that is available to all employees regardless of enrollment in the health plan. Here, the not insubstantial COBRA notice and administrative requirements would apply separately.

The ACA

ACA § 1301(b)(3) provides that the term group health plan "has the meaning given such term by section 2791(a) of the Public Health Service Act." The PHS Act section 2791(a) provides as follows:

> (3) DEFINITION. — The term ''group health plan'' means an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income Security Act of 1974) to the extent that the plan provides medical care (as defined in paragraph (2)) and including items and services paid for as medical care) to employees or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise.
>
> (4) MEDICAL CARE. — The term "medical care" means 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 subparagraph (A), and
>
> (C) amounts paid for insurance covering medical care referred to in subparagraphs (A) and (B).

Section 3(1) of ERISA defines the term "employee welfare benefit plan" broadly to mean:

> [A]ny plan, fund, or program…established or [ ] maintained for the purpose of providing for its participants or their beneficiaries, through the purchase of insurance or otherwise,…medical, surgical, or hospital care or benefits, or benefits in the event of sickness,….

A wellness program is, as a consequence, also a group health plan for ACA purposes. This means among many other things that the ACA insurance market reforms apply. (At a minimum, the plan would need to cover in-network preventive services without cost sharing.) As was the case with ERISA, to the extent the wellness plan is made a part of an employer's group health plan, such a wellness program can piggy back on the latter's ACA compliance. But a stand-alone wellness program cannot, unless the program can fit with a handful of very narrow exceptions for on-site clinics, grandfathered plans, or excepted-benefit employee assistance programs.

HIPAA Administrative Simplification

Perhaps the most daunting compliance challenge for wellness programs administered by third parties arise under the HIPAA "administrative simplification" rules, i.e., the HIPAA privacy, security, and breach-notice rules.[116] These rules govern covered entities and their business associates. Group health plans are covered entities, but the employers that sponsor them are not. Entities that assist covered entities with the performance of coverage functions are referred to business associates. Third-party wellness vendors are business associates. Business associates are subject to the security and breach notices rules and some but not the entire privacy rule.

If a wellness program provided *only* for employer-paid immunizations and biometric screenings (e.g., blood pressure screening, BMI, etc.),[117] there would be little need for a business associate agreement, since there would be no covered function for the vendor to assist with. This is similar to the plight of a group health plan that does not get a business associate agreement with provider hospitals, since the providing of clinical services is not a covered function of a group health plan. The provider in this case would likely insist on a duly executed HIPAA authorization that would, if properly drafted, indicate that summary or aggregate information would be provided to the employer. But once the health coaching component is added, the third- party vendor is assisting with a covered function, so a business associate agreement is necessary.

Unless integrated into a duly-licensed, fully-insured group health plan, a stand-alone wellness program, or a wellness component of an employer's fully-insured group health plan, is itself a separate, self-funded group

health plan—or in the parlance of HIPAA, a separate "covered entity." This invokes the full panoply of HIPAA requirements, including among other things the need for privacy and security policies and procedures; the appointment of privacy official; workforce training and management; the adoption of mitigation protocols; the adoption of data safeguards; a formal complaint process; a ban on retaliations and waivers; additional documentation and record retention requirements; and establishing a firewall between the wellness plan and the employer. And because the wellness program is in all likelihood self-funded, it cannot avail itself or the rules that apply in the case of fully-insured plans relating to the receipt of summary information.

VII. WHAT THE FUTURE HOLDS

Predicting what the final EEOC regulations will hold, or how the Federal Courts will rule in the current wellness plan cases is in all likelihood a fool's errand. But is does make for interesting reading. So here are three high-level wellness program-related predictions for the near term:

The Federal Courts Will (Again) Reject the EEOC's View on Bona Fide Wellness Plans

The courts will hold that the EEOC's rational for its rejection of the outcome in Seff v. Broward County[118] is unpersuasive. A fundamental rule of statutory construction provides that effect must be given, to the extent possible, to every word, clause and sentence.[119] The thrust of the EEOC's position, i.e., exempting wellness programs that qualify as bona fide wellness programs from coverage would render the "voluntary" provision superfluous, would violate this basic standard of construction. It would have the effect of reading the bona fide wellness program exception out of the statue. The words "bona fide wellness program" mean *something*. That they are used in the same statute alongside "voluntary wellness program" signals that Congress intended to establish two different standards. If the case ever gets heard on the merits, Honeywell will prevail.

The statute does not seem all that complicated in our view: an employer wellness program will qualify for the insurance safe harbor if the employer sponsors, observes or administers a "bona fide benefit plan," which is based on "underwriting risks, classifying risks, or administering such risks," and satisfies certain other requirements not relevant here. But what does "underwriting risks, classifying risks, or administering such risks" mean, exactly? There is some legislative history on the subject. Congress included the safe harbor provision:

> to make it clear that this legislation [ADA] will not disrupt the current nature of [health status] insurance underwriting or the current regulatory structure for self-insured employers or of the insurance industry in sales, underwriting, [and] pricing.[120]

Congress further opined that:

> benefit plans (whether insured or not) need to be able to continue business practices in the way they underwrite, classify, and administer risks, so long as they carry out those functions in accordance with accepted principles of insurance risk classification.[121]

Both the Flambeau and Seff trial courts disagreed with the EEOC's views that the "ADA's 'safe harbor' provision applicable to insurance…is [not] the proper basis for finding wellness program incentives permissible" and that "[r]eading the insurance safe harbor as exempting these programs from coverage would render the 'voluntary' provision superfluous." So which is it? Who has it right? To find out, it helps to take a closer look at the boundaries of each exception:

- Wellness programs that are covered by the voluntary plan exception allow employers to make disability-related inquiries or require medical examinations so long as employee participation in such inquiries and examinations is *voluntary*. The EEOC's 2015 notice of proposed rulemaking endeavors to establish rules for determining what "voluntary" means in this context. The wellness programs under this exception may, but are not required to, be part of an employer's group health plan. Thus, while an employer without a group health plan would be unable to apply the insurance safe harbor, it could still establish and maintain a voluntary wellness program.
- Wellness programs that are covered by the insurance safe harbor are those that are (i) based on "underwriting, classifying, or administering risks," and (ii) a term or part of a "bona fide benefit plan."

As the Flambeau court readily acknowledged, these sets overlap. They are not the same, however. (In the parlance of set theory, the set consisting of the

differences is not a null set.) For example, an employer that adopts a wellness program that is risk-based and is part of its group health plan would appear to be able to avail itself of either exception. But if that same employer wants to establish a wellness plan separate and apart from its group health plan, it would be required to adhere to the standards that the EEOC establishes under the voluntary plan exception. The same would be true if the employer sought to establish a wellness program as part of its group health plan but did not want to take risk into account.

The EEOC's position in the matter is suspect. Some wellness programs are based on "underwriting, classifying, or administering risks," others are not. The latter are unable to meet the requirements of the bona fide insurance plan safe harbor exception.

Congress, it would seem, provided these plans with an alternative: they can instead choose to qualify as voluntary wellness programs. In addition, the ADA's voluntariness requirement would still apply to employer wellness programs that are not a part of a group health plan.

The EEOC Will Coordinate Its Final ADA Rule with the Final HIPAA/ACA Wellness Rules

To the largest extent possible, employers would prefer that the incentives under HIPAA/ACA rules and the EEOC's ADA rule align perfectly. This is not going to happen. Under the former, participatory wellness programs are permitted without limits provided they are made available to all similarly situated individuals; under the proposed EEOC rules, participatory wellness are subject to the same 30 percent limit that applies to health contingent programs. While employers will be less than pleased, we expect the EEOC will hold firm on the former (imposing limits on participatory wellness programs where there are none under the HIPAA/ACA rules), but they will relent on the latter.

In the EEOC's view, the scope of the HIPAA/ACA rules is far narrower than that the ADA. As they explain in the preamble to the proposed ADA rule, "HIPAA and Affordable Care Act wellness program provisions are limited to regulating what constitutes discrimination based on a health factor."[122] In contrast, the ADA rules broadly govern disability-related inquiries and medical examinations of employees. As the EEOC sees it, the ADA places strict limits on the circumstances under which employers a may obtain medical information from employees and the type of information that may be sought. While the EEOC has not said as much, one gets the sense that their decision to even attempt to align their rule with HIPAA and the ACA is a major concession. We do not expect them to budge on this issue.

The differing application of the percentage limits are another matter. The EEOC will be under a great deal of pressure to line the ADA wellness incentives with those of the final HIPAA/ACA rules, at least as to the 30 percent limitation. The limits that the EEOC is endeavoring to navigate are no longer the mere creature of regulation. With the enactment of ACA, they take on the mantle of a Congressional directive. In the preamble to the proposed ADA rule, the EEOC casually observes that the 30 percent limit on self- only coverage is "that which generally is the maximum allowable incentive available under HIPAA and the Affordable Care Act for health-contingent wellness programs."[123] But that is not the rule under the ACA as applied to participatory wellness programs. The EEOC's cramped reading of the applicable limits seems to us unnecessary and perhaps even petty. We expect the EEOC to relent on this score, though we do not expect them to go so far as to include the HIPAA/ACA final rule's treatment of smoking cessation programs.

We base this prediction on what we view as the EEOC's misplaced worries about affordability. In the preamble to the proposed wellness rule, the EEOC invited comments on a handful of items relating to the impact on wellness programs on the affordability of coverage for ACA purposes. It strikes us that affordability is an ACA concept with respect to which Congress variously delegated regulatory authority to the Departments of Health and Human Services, Labor and Treasury.[124] These agencies have already issued a rule that is employee-friendly in the extreme: affordability (other than in the case of smoking cessation) is determined assuming employee *fails* to earn incentive.[125] It therefore appears to us that the EEOC's concerns on this score are unfounded.

The Proposed Final GINA Title II Rules Relating To Participation by Spouses in Wellness Plans Will Become Final

The proposed rules on the impact of GINA Title II on wellness programs that include spousal incentives generally strike the right balance in our view. To sure, the notice requirements under both the proposed

ADA rule and the GINA Title II rules are burdensome, but we don't see the EEOC relenting on this issue. So we would expect the proposed rules to be adopted with little change, other than a better alignment of incentives with the HIPAA/ACA final rules (with the exception of smoking cessation) for the reasons set out immediately above.

If our first prediction is correct, the others may not matter; and either way, the matter will not end with this case. Sooner or later we expect that the Supreme Court will be called on to settle the matter. If we are wrong about the first prediction, and the second and third predictions prove accurate, then participatory wellness programs will be subject to the same limits as health-contingent wellness programs. Further, separate smoking cessation adjustments, at least for programs that require the employee satisfy some standard, will not be allowed. All these features will ultimately form a part of lowest-common denominator of workplace wellness programs.

Notes

1 The Kaiser Family Foundation and Health Research & Educational Trust, Employer Health Benefits 2014 Annual Survey 6 (2014) (51 percent of firms with 200 workers or more offer incentives for employees to complete health risk assessments; and 36 percent of firms with more than 200 workers, and 18 percent of firms over all, use financial incentives tied to health objectives like weight loss and smoking cessation). See also Rand Corporation, Do Workplace Wellness Programs Save Employers Money? (2014), available at http://www.rand.org/content/dam/rand/pubs/research_briefs/RB9700/RB9744/RAND_RB9744.pdf.

2 Id.

3 Pub. L. No. 104-191, 110 Stat. 1936 (1996).

4 42 U.S.C. § 12101 (1990) (amended 2008).

5 Pub. L. No. 110–233, 122 Stat. 881 (2008).

6 Pub. L. No. 111-148 (2010), amended by Health Care and Education Reconciliation Act of 2010 (HCERA), Pub. L. No. 111-152 (2010). The ACA and the Internal Revenue Code sections added by it also have been amended by the TRICARE Affirmation Act, Pub. L. No. 111-159, Pub. L. No. 111-173 (2010); the Medicare and Medicaid Extenders Act of 2010, Pub. L. No. 111-309 (2010); the Comprehensive 1099 Taxpayer Protection and Repayment of Exchange Subsidy Overpayments Act of 2011, Pub. L. No. 112-9 (2011); the Department of Defense and Full- Year Continuing Appropriations Act, 2011, Pub. L. No. 112-10 (2011); and the 3% Withholding Repeal and Job Creation Act, Pub. L. No. 112-56 (2011).

7 Pub. L. No. 93-406, 80 Stat. 830 (1974) (codified as amended at 29 U.S.C Chapter 18).

8 Pub. L. No. 78-410, 58 Stat. 682 (1944) (codified at 42 U.S.C. Chapter 6A).

9 Sally Doubet King, Late to the Party: EEOC Proposes Wellness Program Regulations, McGuirewoods Healthcare Reform Guide: Installment No. 50, May 28, 2015, available at https://www.mcguirewoods.com/Client-Resources/Alerts/2015/5/EEOC-Proposes-Wellness-Program- Regulations.aspx.

10 74 Fed. Reg. 51,664 (Oct. 7, 2009) (to be codified at 26 C.F.R. pt. 54; 29 C.F.R. pt. 2590; 45 C.F.R. pt. 144, 146, 148).

11 75 Fed. Reg. 68,912 (Nov. 9, 2010) (to be codified at 29 C.F.R. pt. 1635).

12 80 Fed. Reg. 66,853 (proposed Oct. 30, 2015) (to be codified at 29 C.F.R. pt. 1635).

13 9 U.S.C. § 1003 (b); I.R.C. § 414(e).

14 See I.R.C. § 7805 (giving Secretary of the Treasury the power to create the necessary rules and regulations for enforcing the Internal Revenue Code).

15 I.R.C. § 4980D.

16 42 U.S.C. § 300gg-22(a)(1).

17 See HIPAA § 104 (directing the Departments to enter into an interagency MOU, the purpose of which is to ensure that regulations, rulings, and interpretations relating to the changes made by HIPAA "over which two or more Secretaries have responsibility" are administered so as to have the same effect at all times). Pub. L. No. 104-191, 110 Stat. 1936, 1978.

18 Nondiscrimination and Wellness Programs in Health Coverage in the Group Market, 71 Fed. Reg. 75,014 (Dec. 13, 2006) (to be codified at 29 C.F.R. pt. 54; 29 C.F.R. pt. 2590; 45 C.F.R. pt. 146).

19 29 C.F.R. § 2590.702(b)(1)(ii); 45 C.F.R. § 146.121(b)(1)(ii); 26 C.F.R. § 54.9802-1(b)(1)(ii).

20 29 C.F.R. § 2590.702(f)(1); 45 C.F.R. § 146.121(f)(1); 26 C.F.R. § 54.9802-1(f)(1).

21 29 C.F.R. § 2590.702(f)(2)(i); 45 C.F.R. § 146.121(f)(2)(i); 26 C.F.R. § 54.9802-1(f)(2)(i).

22 29 C.F.R. § 2590.702(f)(1); 45 C.F.R. § 146.121(f)(1); 26 C.F.R. § 54.9802-1(f)(1).

23 29 C.F.R. § 2590.702(f)(2)(i); 45 C.F.R. § 146.121(f)(2)(i); 26 C.F.R. § 54.9802-1(f)(2)(i).

24 29 C.F.R. § 2590.702(f)(i); 45 C.F.R. § 146.121(f)(i); 26 C.F.R. § 54.9802-1(f)(i).

25 29 C.F.R. § 2590.702(f)(2)(ii); 45 C.F.R. § 146.121(f)(2)(ii); 26 C.F.R. § 54.9802-1(f)(2)(ii); 71 Fed. Reg. 75,014, 75,018.

26 29 C.F.R. § 2590.702(f)(2)(iii); 45 C.F.R. § 146.121(f)(2)(iii); 26 C.F.R. § 54.9802-1(f)(2)(iii).

27 29 C.F.R. § 2590.702(f)(2)(iv); 45 C.F.R. § 146.121(f)(2)(iv); 26 C.F.R. § 54.9802-1(f)(2)(iv).

28 29 C.F.R. § 2590.702(f)(2)(v); 45 C.F.R. § 146.121(f)(2)(v); 26 C.F.R. § 54.9802-1(f)(2)(v).

29 Incentives for Nondiscriminatory Wellness Programs in Group Health Plans, 78 Fed. Reg. 33,158 (June 3, 2013) (to be codified at 26 C.F.R. pt. 24; 29 C.F.R. pt. 2590; 45 C.F.R. pt. 146, 147). Because the ACA incorporates the PHS Act § 2705 into the Code and ERISA, the final HIPAA/ACA wellness rule was issued concurrently by the All individuals eligible for a health-contingent wellness program must be given the opportunity to qualify for the reward at least once per year;

30 Id.at 33,162.

31 Id. at 33,168.

32 42 U.S.C. § 12112(a).

33 29 C.F.R. § 1630.4(f).

34 42 U.S.C. § 12112(b)(5)(A) and 29 C.F.R. § 1630.9 (prohibiting covered entity from failing to provide reasonable accommodations absent undue hardship); 29 C.F.R. § 1630.2(o)(1)(iii) (reasonable accommodation includes modifications and adjustments that enable a covered entity's employees to enjoy ''equal benefits and privileges of employment.'').

35 42 U.S.C. § 12112(d)(4)(A). However, "[a] covered entity may make inquiries about the ability of an employee to perform job-related functions." 42 U.S.C. § 12112(d)(4)(B).

36 Amendments to Regulations under the American Disabilities Act, 80 Fed. Reg. 21,659 (proposed April 20, 2015) (to be codified at 29 C.F.R. pt. 1630).

37 42 U.S.C. § 12112(d)(4)(B).

38 H. Rep. No. 101-485, at 75 (1990).

39 29 C.F.R. §§ 1630.13, 1630.14.

40 42 U.S.C. § 12201(c)(2).

41 42 U.S.C. § 12201(c).

42 778 F. Supp. 2d 1370 (S.D. Fla. 2011), aff'd, 691 F.3d 1221 (11th Cir. 2012).

43 778 F. Supp. 2d at 1375.

44 691 F.3d 1221 (11th Cir. 2012).

45 80 Fed Reg. 21,660, 21,664 n. 24.

46 Pub. L. No. 110–233, 122 Stat. 881, 882.

47 Pub. L. No. 110–233, 122 Stat. 881, 905.

48 42 U.S.C. § 2000ff-1(a)-(b)(employers); 42 U.S.C. § 2000 ff-2(a)-(b) (employment agencies); 42 U.S.C. § 2000ff- 3(a)-(b) (labor organizations); 42 U.S.C. § 2000ff-4(a)(b) (training programs).

49 42 U.S.C. § 2000ff-1(b) (employers); 42 U.S.C. § 2000ff-2(b) (employment agencies); 42 U.S.C. § 2000ff-3(b) (labor organizations); 42 U.S.C. § 2000ff-4(b) (training programs).

50 42 U.S.C. § 2000ff (4).

51 See 42 U.S.C. § 2000ff (3)(A) (defining family member for purposes of GINA to include a dependent within the meaning of section 701(f)(2) of ERISA; see also 29 C.F.R. § 1635.3(a).

52 80 Fed. Reg. 66,853, 66,855.

53 42 U.S.C. § 2000ff-1(b); 29 C.F.R. § 1635.8 (acquisition of genetic information).

54 42 U.S.C. § 2000ff-1(b)(2); 29 C.F.R. § 1635.8(b)(2).

55 Infra note 10.

56 Infra note 11.

57 75 Fed. Reg. 68,912 68,935.

58 See EEOC Office of Legal Counsel, Informal Discussion Letter, ADA: Health Risk Assessments (Aug. 10, 2009) (stating that the "the Commission has not taken a formal position on the question [of incentives to complete health risk assessments]"); but cf., EEOC Office of Legal Counsel, Informal Discussion Letter, ADA: Voluntary Wellness Programs & Reasonable Accommodation Obligations (Jan. 18, 2013) (implying that incentives are permitted provided that the employer offers reasonable accommodations).

59 Complaint, No. 1:14-cv-1019 (E.D. Wis. Aug. 20, 2014).

60 EEOC v. Orion Energy Sys., No. 14-CV-1019, 2016 U.S. Dist. LEXIS 127292 (E.D. Wis. Sep. 19, 2016).

61 Id. at *12-26.

62 Id. at *22-24.

63 Id. at *27-28.

64 Id.

65 Id. at *26-28.

66 Id. at *29-31.

67 See generally EEOC v. Flambeau, Inc., 131 F. Supp. 3d 849, (W.D. Wis. 2015).

68 See infra. Section II, discussion of safe harbor for bona fide insurance plan.

69 Flambeau, Inc., 131 F. Supp. 3d at 853-57.

70 Id. at *855.

71 See 42 U.S.C. § 12201(c)(2).

72 Flambeau, Inc., 131 F. Supp. 3d at 857.

73 EEOC v. Flambeau, Inc., No. 16-1402, 2017 U.S. App. LEXIS 1289 (7th Cir. Jan. 25, 2017).

74 2017 U.S. App. LEXIS 1289, at *10.

75 Id. at *6.

76 EEOC v. Honeywell Int›l, Inc., No. 14-4517, 2014 U.S. Dist. LEXIS 157945 (D. Minn. Nov. 6, 2014).

77 80 Fed. Reg. 21,659, 21,662 (footnotes omitted).

78 81 Fed. Reg. 31,129.

79 26 C.F.R. § 54.9802–1(f)(1)(i); 29 C.F.R. § 2590.702(f)(1)(i); 45 C.F.R. §146.121(f)(1)(i).

80 81 Fed. Reg. 31,126.

81 80 Fed. Reg 21,662.

82 Id. at 21,663; 81 Fed. Reg. 31130.

83 42 U.S.C. § 12112(d)(4)(B).

84 29 C.F.R. § 1630.14(d)(2).

85 Id. at § 1630.14(d)(1).

86 Id. at § 1630.14(d)(2)(i)–(iii).

87 Id. at § 1630.14(d)(2)(iii).

88 Id. at § 1630.14(d)(2)(iv).

89 Id. at § 1630.14(d)(3).

90 81 Fed. Reg. 31,132.

91 *Id.* at 31,136; 80 Fed. Reg. 21,668.

92 *Id.* at 31,136; 80 Fed. Reg. 21,669.

93 29 C.F.R. § 1630.14(d)(4)(iii).

94 Id. at § 1630.14(d)(5).

95 81 Fed. Reg. 31,126-27;45 C.F.R. pt. 160, 164.

96 45 C.F.R. § 164.530(k).

97 81 Fed. Reg. 31,138.

98 Id.

99 80 Fed. Reg. at 21,664.

100 81 Fed. Reg. 31,143.

101 Id. at 31,144-46.

102 Id. at 31, 144.

103 Id. at 31, 145.

104 Id. at 31, 146, 31, 154.

105 80 Fed. Reg. 66, 857.

106 81 Fed. Reg. 31,155.

107 Id.; 29 C.F.R. § 1635.8(b)(2)(iii)).

108 29 C.F.R. § 1635.8(b)(2)(i) (A).

109 Id. at § 1635.8(b)(2)(iii).

110 81 Fed. Reg. 31,155.

111 29 C.F.R. §1635.8(b)(2)(iii).

112 Id. at. §1635.8(b)(2)(iv).

113 81 Fed. Reg. 31,155-56.

114 See Kate Ulrich Saracene & Steven C. Mindy, Wellness programs after the Affordable Care Act (Part I), Nixon Peabody Benefits Alert, August 8, 2013 Benefits Alert; Kate Ulrich Saracene & Darcie A. Falsioni, Wellness programs after the Affordable Care Act (Part II), Nixon Peabody Benefits Alert, July 14, 2014 (explaining in comprehensive and highly readable fashion the laws that apply to employer workplace wellness programs).

115 29 U.S.C. § 1191b.

116 45 C.F.R. pts. 160 through 164.

117 But see 80 Fed. Reg. 21,659, 21667 (to be codified at 29 C.F.R. § 1630.14(d)(1)). Such a program would likely fail the EEOC's proposed requirement that the program must be reasonably designed to promote health or prevent disease.

118 Infra notes 42-44.

119 See Norman J. Singer & Shambie Singer, Sutherland Statutes and Statutory Construction 46:6 (7th ed. 2007); see also 78 Fed. Reg. at 231. Practitioners and others familiar with the ACA employer's shared responsibility rules will recognize this reference as that used by the Treasury and the Internal Revenue Service in the proposed regulations issued under Code § 4980H to reject commenters suggestion to not require employers to extend coverage to dependents.

120 S. Rep. No. 101-116, at 84-85.

121 H.R. Rep. 101-485, at 138.

122 80 Fed. Reg. 21,659, 21,663.

123 Id.

124 See infra Section I.

125 Treas. Reg. § 1.36B-2(c)(5).

More **CLE** = More **Savings**

ALI CLE offers fully customizable course bundles, with an increased discount for every addition.

Choose from any of our high-quality continuing legal education courses that are accredited in your state.

Start your custom online CLE bundle now at www.ali-cle.org.

Save up to 50% when you add multiple CLE credits to your bundle.

Purchase

- **4⁺ credits = 10% off**
- **8⁺ credits = 20% off**
- **10⁺ credits = 30% off**
- **12⁺ credits = 50% off**

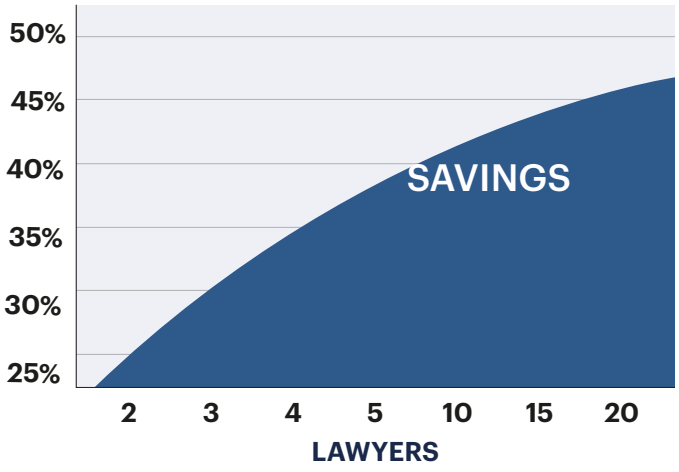
American Law Institute
CONTINUING LEGAL EDUCATION

Progressive Savings

ALI CLE offers progressive savings when two or more lawyers register for in-person or distance courses.

The more attorneys from your firm who register, the cheaper it gets per attorney, and the more you get out of your CLE spend: group interaction and those "aha" learning moments shared among a team of attorneys studying the same issue together.

In-Person Courses



Distance Courses

15%

2-4 LAWYERS

25%

5 + LAWYERS

Group registration is fast and easy. Simply click on the "Group Rates" option when registering for any ALI CLE course at www.ali-cle.org.

American Law Institute
CONTINUING LEGAL EDUCATION