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EEOC Issues Final Wellness Program Amendments to ADA and GINA Regulations

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On May 17, 2016, the Equal Employment Opportunity Commission ("EEOC") published in the *Federal Register* its final rule setting forth the EEOC's interpretation of the extent to which employers may use incentives to encourage employees to participate in wellness programs that ask them to respond to disability-related inquiries and/or undergo medical examinations that employers otherwise could not require under the Americans with Disabilities Act ("ADA").[1] At the same time, the EEOC also published its final rule regarding the extent to which an employer may offer incentives for an employee's spouse to participate in a wellness program under the Genetic Information Nondiscrimination Act ("GINA").[2] The final ADA and GINA rules, applicable to plan years beginning on or after January 1, 2017, apply to all wellness programs that ask employees to respond to disability related inquiries and/or undergo medical examinations, whether the program is participatory or health-contingent, and regardless of whether the program is offered (i) only to employees enrolled in an employer-sponsored group health plan; (ii) to all employees, regardless of whether they are enrolled; or (iii) by employers that do not sponsor a group health plan. The final ADA and GINA rules do not apply, however, to wellness programs that do not include such inquiries.

The final rules still largely attempt to mandate a fix where no real problem was ever identified. While certain groups decry wellness programs as supposedly posing great risks for employees, there is no documented record that employers have obtained and misused information gathered in connection with wellness programs. The final ADA and GINA rules still tend to undercut the full promise of wellness programs, which are a vital tool in reaching the goal of the Affordable Care Act ("ACA") to improve the health of American employees and to reduce spiraling health care cost increases.

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[1] EEOC, Regulations Under the Americans With Disabilities Act, 81 Fed. Reg. 31125 (May 17, 2016), *available at* https://www.federalregister.gov/articles/2016/05/17/2016-11558/regulations-under-the-americans-with-disabilities-act.

[2] EEOC, Genetic Information Nondiscrimination Act, 81 FR 31143 (May 17, 2016), *available at* https://www.federalregister.gov/articles/2016/05/17/2016-11557/genetic-information-nondiscrimination-act.

The final ADA rule largely follows proposed regulations in a Notice of Proposed Rule Making ("NPRM") published in April 2015,[3] particularly as to the amount of incentive that can be offered for both participatory and health-contingent wellness programs, but adds additional provisions regarding when a wellness program meets the requirement of being "reasonably designed to promote health or prevent disease," plus additional confidentiality protections. The EEOC refused to modify the NPRM's limitation on incentives to 30 percent of the self-only premium to allow an incentive of 30 percent of the premium for family or dependent coverage, as do the tri-agency regulations issued in 2013 by the U.S. Departments of Labor, Health and Human Services, and the Treasury under the ACA ("Tri-Agency Regulations").[4]

The EEOC in the NPRM had requested comments as to whether the final ADA rule should provide employees an exemption from completing a risk assessment or having a medical exam if they instead provided a doctor's certification that they were under medical care. The final ADA rule fortunately does not adopt this idea, which would undercut the effectiveness of wellness programs.

The final GINA rule also largely follows proposed regulations published in October 2015,[5] again in particular as to the amount of incentive that can be offered, but with added provisions regarding when a wellness program is "reasonably designed to promote health or prevent disease." As discussed below, however, the final GINA rule prevents incentives for employees' children who participate in wellness programs.

Notably, the final ADA rule continues to contain provisions that conflict with the Tri-Agency Regulations, particularly a provision that allows a wellness program incentive of 50 percent of the full cost of coverage for tobacco cessation programs, which the final ADA rule limits to 30 percent if there is a biometric screening or other medical examination that tests for the presence of nicotine or tobacco. This has already met with opposition from Congress. On May 16 2015, Senate Health and Labor Committee Chairman Lamar Alexander said that the rules "contradict the law and continue the confusion the agency has caused . . . ."[6] The EEOC's more restrictive provisions are likely to reduce participation in tobacco cessation wellness programs.

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[3] *See* Epstein Becker Green Health Care and Life Sciences Client Alert, "EEOC Issues Proposed Wellness Program Amendments to ADA Regulations" (April 17, 2015), *available at* http://www.ebglaw.com/news/eeoc-issues-proposed-wellness-program-amendments-to-ada-regulations/.

[4] 26 C.F.R. § 54-9802-1(f); 29 C.F.R § 2590.702(f); and 45 C.F.R. § 146.121(f).

[5] EEOC, Genetic Information Nondiscrimination Act of 2008, 80 Fed. Reg. 66853 (Oct. 30, 2015), *available at* https://www.federalregister.gov/articles/2015/10/30/2015-27734/genetic-information-nondiscrimination-act-of-2008.

[6] L. Alexander, Press Release, "Alexander: EEOC Workplace 'Wellness' Rules Will Make it Harder for Employees to Choose Healthy Lifestyles and Save Money" (May 16, 2016), *available at* http://www.alexander.senate.gov/public/index.cfm/pressreleases?ID=DE681569-0ED5-4563-A1FA-8BEB2BB6A17D.

Major Provisions of the Final Rules

The final ADA rule expressly permits employers to offer limited incentives of up to a maximum of 30 percent of the total cost of *employee-only coverage,* whether in the form of a reward or penalty, to promote an employee's participation in a qualifying wellness program that includes disability-related inquiries (usually through a Health Risk Assessment ("HRA")) or biometric examinations, as long as the participation is voluntary.[7] Notably, the calculation of incentives under the final ADA rule must include both financial and in-kind incentives, as well as "de minimis" incentives.[8] In this regard, the EEOC rejected proposals by various commenters to exclude in-kind and de minimis incentives. Under the final GINA rule, no such inducement can be offered to provide genetic information but may be offered for completion of HRAs that include questions about family medical history or other genetic information, provided it is made clear that the inducement is available whether or not the questions regarding genetic information are answered.[9]

Similarly, the final GINA rule expressly permits employers to offer the same incentives to an employee whose spouse provides information about the spouse's manifestation of disease or disorder as part of an HRA, but not for the spouse's providing his or her own genetic information, including results of his or her genetic tests, or for information about the manifestation of disease or disorder in an employee's children or for genetic information about an employee's children, including adult children.[10] In addition, a covered entity may not deny access to health insurance benefits due to a spouse's refusal to provide information to an employer-sponsored wellness program about his or her manifestation of disease or disorder.[11]

Under the final ADA rule, "voluntary" means that an ADA covered entity does not (i) require employees to participate, (ii) deny coverage under any of its group health plans or limit the extent of such coverage for an employee who refuses to participate in a wellness program, and (iii) take any adverse employment action or retaliate against, interfere with, coerce, intimidate, or threaten employees who do not participate.[12]

Further, the final ADA rule provides that to insure that participation in a wellness program that includes disability-related inquiries or medical examinations and is part of a group health plan is truly voluntary, an employer must provide an employee with a detailed notice clearly explaining (i) what medical information will be obtained, (ii) who will receive the medical information, (iii) how the medical information will be used, (iv) the restriction on such information's disclosure, and (v) the methods that the covered

[7] 29 C.F.R. § 1630.14(d)(3). There are special formulas for calculating the 30 percent where participation is offered even if an employee is not enrolled in a health plan, where the employer offers more than one health plan but the employee is not enrolled, or where no group health plan is offered. 29 C.F.R. § 1635.8(d)(3)(i)-(iv).
[8] 29 C.F.R. §1630.14(d)(3).
[9] 29 C.F.R. § 1635.8(b)(2)(ii).
[10] 29 C.F.R. § 1635.8(b)(2)(iii).
[11] 29 C.F.R. § 1635.8(b)(2)(iv).
[12] 29 C.F.R. § 1630.14(d)(2)(i)-(iii).

entity will employ to prevent improper disclosure.[13] Within 30 days after publication of the final ADA rule, the EEOC intends to provide on its website an example of a notice that complies with this rule.

Both the final ADA and GINA rules require that a qualifying wellness program be "reasonably designed to promote health or prevent disease." The program must have "a reasonable chance of improving the health of, or preventing disease in, participating employees"; must not be "overly burdensome"; may not be a subterfuge for violating the ADA, GINA, or other employment discrimination laws; and may not be "highly suspect in the method chosen to promote health or prevent disease." Whether a program meets this standard is to be evaluated in light of all the relevant facts and circumstances.[14] Despite many comments that the EEOC should not be determining the merits of the design of wellness programs, the final rules continue to give this authority to the EEOC. It is quite possible that this provision could retard the development of novel wellness programs that respond to the health issues and needs of particular employers' workforces.

Both final rules state that the collection of information without providing results, follow-up information, or advice would not qualify "unless the collected information actually is used to design a program that addresses at least a subset of the conditions evaluated."[15] This does raise some concern about the permissibility of data collection that may assist in the design of more effective future plans even if not fully utilized in the current plan year. The final ADA rule also states that a program that "exists mainly to shift costs to targeted employees based on their health or simply to give an employer information to estimate future health costs" would not qualify,[16] but no evidence of such plans has been observed. Similarly, the final GINA rule also states that a program that 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 achieving a certain health outcome is not "reasonably designed."[17]

The final ADA rule also addresses confidentiality of medical information. Although it makes no changes to the current ADA confidentiality rules, it rule adds two new subsections. The first new subsection generally requires that medical information collected through a wellness program may be provided to the ADA covered entity *only* 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 plan.[18] In accompanying guidance, the EEOC states that a covered entity likely will be able to comply with this obligation by complying with the Health Insurance Portability and Accountability Act ("HIPAA") Privacy Rule.[19]

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[13] 29 C.F.R. § 1630.14(d)(2)(iv).
[14] 29 C.F.R. § 1630.14(d)(1); 29 C.F.R. § 1635.8(b)(2)(i)(A).
[15] 29 C.F.R. § 1630.14(d)(1); 29 C.F.R. § 1635.8(b)(2)(i)(A).
[16] 29 C.F.R. § 1630.14(d)(1).
[17] 29 C.F.R. § 1635.8(b)(2)(i)(A).
[18] 29 C.F.R. § 1630.14(d)(4)(iii).
[19] Appendix to Part 1630, *Section 630.14(d)(4)(i) through (v): Confidentiality*.

The second new subsection, added in response to comments suggesting that participation might result in employees inadvertently waiving critical confidentiality protections, provides that an ADA covered entity may not require an employee to agree to the sale, exchange, sharing, transfer, or other disclosure of medical information (except to the extent permitted to carry out specific activities related to the wellness program), or to waive confidentiality protections available under the ADA, as a condition for participating in a wellness program or receiving a wellness program incentive.[20] The final GINA rule contains a similar provision with respect to genetic information, including information about the manifestation of disease or disorder of an employee's family member.[21] The final GINA rule does not, however, adopt any other new protections addressing confidentiality of genetic information.

Notably, despite two well-reasoned court decisions to the contrary,[22] the final ADA rule expressly states that the statutory "safe harbor" provision set forth in 42 U.S.C. § 12201(c), which, in relevant part, states that an insurer or entity that administers benefit plans is not prohibited 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," does not apply to wellness programs, even if such plans are part of a covered entity's health plan.[23] The EEOC has already begun to use this new regulation as a sword in pending litigation, arguing that its regulation is due substantial deference and therefore the defendant's safe harbor defense should be dismissed.[24] The basis for deference here seems highly questionable under applicable administrative law standards. Moreover, the legal interpretation of the courts seems more correct than the position of the final ADA rule.

Lastly, the final ADA rule explicitly notes that it does not relieve a covered entity from the obligation to comply with the nondiscrimination provisions of Title VII of the Civil Rights Act of 1964 ("Title VII"), the Equal Pay Act, the Age Discrimination in Employment Act, GINA, or other sections of Title I of the ADA.[25] The final GINA rule similarly restates a prior provision that it does not limit the rights of individuals under the ADA, other applicable civil rights laws, or under HIPAA.[26] Significantly, the EEOC's guidance accompanying the final ADA rule explicitly notes that discrimination on the basis of sex includes pregnancy, gender identity, transgender status, and sexual orientation—the latter two of which are the subject of ongoing litigation as to whether

[20] 29 C.F.R. § 1630.14(d)(4)(iv).
[21] 29 C.F.R. § 1635.8(b)(2)(vii).
[22] *Seff v. Broward County*, 788 F. Supp. 2d 1370 (S.D. Fla. 2011), *aff'd*, 691 F.3d 1221 (11th Cir. 2010); *EEOC v. Flambeau, Inc*., No. 14-cv-638-bbc, 2015 U.S. Dist. LEXIS 173482 (W.D. Wis. Dec. 30, 2015), *appeal filed*, No. 16-1402 (7th Cir. Feb. 25, 2016).
[23] 29 C.F.R. § 1630.14(d)(6).
[24] *EEOC v. Orion Energy Systems*, No. 1:14-cv-01019, *Notice of Supplemental Authority* (D.E. 47-1) (E.D. Wis. filed May 17, 2016).
[25] 29 C.F.R. § 1630.14(d)(5).
[26] 29 C.F.R. 1635.8(b)(2)(vii).

they are covered by Title VII. [27]The final ADA rule also provides that an employer may be able to avoid a disparate impact claim regarding a wellness program requirement by offering and providing a reasonable alternative standard when a health contingent wellness program would require meeting a particular standard.[28]

Continued Conflict Between the Final Rules and the ACA Tri-Agency Regulations

The 2013 ACA Tri-Agency Regulations increased the maximum total health-contingent wellness program incentive to 30 percent of the total cost of coverage under the group health plan (including 30 percent of the family or dependent coverage costs where applicable) and to 50 percent for tobacco cessation programs. The EEOC's final rules depart from the Tri-Agency Regulations by extending the 30 percent incentive limit under health-contingent wellness program to participatory programs, which the Tri-Agency Regulations do not limit. Participatory wellness program do not include any condition for obtaining a reward-based incentive that turns on an individual satisfying a standard related to health. A health-contingent wellness program requires an individual to satisfy a standard related to a health factor to obtain a reward. The EEOC's inclusion of participatory wellness programs is unnecessary and reduces the available incentive to participate in such programs.

In addition, the final ADA rule excludes the additional 20 percent incentive available under the Tri-Agency Regulations for wellness programs related to tobacco cessation if the program includes biometric screening or other medical examinations that test for the presence of nicotine or tobacco. The EEOC states, however, that a tobacco smoking cessation program that merely asks employees whether or not they use tobacco (or whether or not they ceased using tobacco upon completion of a program) does not include disability-related inquiries or a medical examination and thus could qualify for the 50 percent incentive.[29] The EEOC's 30 percent exclusion is significant because it could affect affordability as well as reduce incentives for participation. Moreover, verification is particularly essential to incentivize the difficult task of tobacco cessation.

Further and of great importance is that the final rules still calculate the 30 percent incentive based only on the total cost of self-only coverage, while the Tri-Agency Regulations base the calculation on the total cost of coverage for the individual and any spouse or dependents to whom the wellness programs are available where family or dependent coverage is selected. Again, this reduces the incentive to participate.

What Employers Should Do Now

Employers should review their existing wellness programs and related incentives and begin making any changes necessary to comply with the final ADA and GINA rules in advance of the requirement to implement them for new plan years beginning on or after

[27] Appendix to Part 1630, *Section 1630.14(d)(5): Compliance With Other Employment Nondiscrimination Laws*.
[28] 29 C.F.R. § 1630.14(d)(5).
[29] Appendix to Part 1630, *Application of Section 1630.14(d)(3) to Smoking Cessation Programs.*

January 1, 2017. More specifically, employers should do the following:

1) Evaluate the extent to which the 30 percent limit on incentives must be extended to any participatory wellness programs.
2) Evaluate the extent to which any current 30 percent incentives are based on the total cost of coverage for family or dependent coverage and whether to apply the new limit of 30 percent of the total cost of employee-only coverage for both employees and for spouses who participate in a wellness program.

3) Determine whether affordability is affected if the incentive is lowered for employees currently enjoying a tobacco cessation incentive above 30 percent consistent with the ACA rule and, if so, begin weighing the options on whether and how to adjust it accordingly.

4) Make sure a wellness program cannot reasonably be read to require employee participation or to deny or limit group health plan coverage as a consequence for nonparticipation.

5) Prepare draft notices that comply with the above-mentioned requirements regarding the obtaining, receipt, use, restrictions on disclosure, and methods employed to prevent improper disclosure of medical information; watch for the EEOC to publish its model notice; and then adjust draft notices accordingly.

6) Confirm wellness program compliance with the HIPAA Privacy Rule, and, if the wellness program is not governed by HIPAA, consider implementing a HIPAA-compliant confidentiality policy. Make sure that all employees who handle confidential health information are properly trained.

7) Consider whether, notwithstanding the final ADA rule, it makes sense to make a wellness program part of your health benefit plan, thus, potentially meeting the ADA bona fide benefit plan safe harbor as endorsed by the U.S. Court of Appeals for the Eleventh Circuit in *Seff v. Broward County* and currently on appeal before the Seventh Circuit in *EEOC v. Flambeau, Inc.*

8) Keep in mind that compliance with the final ADA and GINA rules concerning wellness programs will not relieve you and other covered entities of the obligation to comply with other portions of the ADA, as well as other employment discrimination laws in connection with wellness programs.

In light of the EEOC's sometimes conflicting interpretation of wellness program requirements with the Tri-Agency Regulations, conferring with legal counsel may be appropriate.

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For additional information about the issues discussed in this Advisory, or if you have any questions concerning the final ADA and GINA rules, or on wellness programs in

general, please contact the Epstein Becker Green attorney who regularly handles your legal matters or one of the authors:

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