Center for Health and Wellness Law, LLC

January/February 2018 Newsletter

The Latest and Greatest on the AARP v. EEOC Case

As many of you know, the AARP sued the EEOC in 2016 for issuing wellness incentive rules under the ADA and GINA that did not meet those laws "voluntariness" requirement. Both the ADA and GINA allow for the collection of employee health information if that information collection is part of a ***voluntary*** wellness program. In its ADA and GINA rules issued in May 2016, the EEOC created a "safe harbor" financial incentive limit of 30% of the total cost of self-only coverage; that is, employers could provide a financial incentive to employees and their spouses valued up to 30% of the total cost of self-only coverage for participating in a health risk assessment or biometric screen. Before that safe harbor amount, it was unclear what incentive amount, if any, would be permissible to encourage employers and their spouses to participate in a wellness program health screening.

The AARP won their lawsuit, and the court had asked the EEOC to propose new rules by the end of August 2018. However, the EEOC countered that the court should not require it to propose new rules in accordance with any schedule. Rather, the EEOC believes it should exercise its discretion as to if or when it decides to issue new incentive rules. The AARP did not oppose this view by the EEOC, and on January 18, 2018, the court agreed to allow the EEOC to decide if and when it will issue new incentive rules under ADA and GINA in accordance with its own timeline. The only thing that the EEOC must now do is inform the court by the end of March this year of what it thinks it might do with regard to the incentive rules and by when.

The EEOC outlined three possible options on how it might respond to the elimination of the incentive rules by the court in the AARP case. First, it may issue new rules. Second, it may decide against issuing new rules and leave the rules as they are, without the incentive safe harbor. Third, it might take a "wait-and-see" approach, choosing to study the issue further or await the resolution of potential appellate proceedings. *AARP v. EEOC*, 16-cv-2113, dkt. #56, at 7 (Jan. 18, 2018).

By the end of March 2018, we may have a better idea of which of the three options the EEOC may choose when the EEOC submits its status report to the court. But, it is probably safe to say that we won't see any new incentive limit rules for a while. This means that as of January 1st next year, the incentive safe harbors under the ADA and GINA will no longer exist. Without any new rules to replace the current 30% limit, employers will be left to guess whether any financial incentive offered in connection with a participatory wellness program health screening meets the ADA and GINA "voluntariness" requirement, which is not going away. Employers who wish to continue using financial incentives will need to rely on case law and consultations with their legal counsel to determine the risk of using certain financial incentive levels.

For example, the EEOC v. Orion Energy case may offer employers some guidance. In that case, the court found that Orion Energy's program did not violate the ADA because ultimately, the

wellness program was voluntary. The court reasons that even though employees who refused to participate in the health risk assessment had to pay 100% of their health insurance premium, it was still a choice they could make. According to the court, employers are not required to offer health insurance and therefore if an employee chooses not to participate in the wellness program and instead pay 100% of their premium, that is still offering the employee more than an employer is required to offer under the law. As stated by the court, "a hard choice is not the same as no choice." Because the employee had a choice, albeit a "hard choice," the wellness program was still voluntary and therefore not in violation of the ADA.

In addition, even in the absence of the financial incentive safe harbor, employers will still need to comply with the other provisions of the ADA and GINA rules. It is important to remember that the AARP v. EEOC case only impacted the 30% safe harbor portion of those rules. All of the other provisions from the May 2016 rule release remain intact – now and after January 1st next year. For example, these other provisions require employer wellness programs to:

- Be voluntary
- Be part of a program reasonably designed to promote health or prevent disease
- Provide employees with notice
- Not share individually identifiable employee health information with employers unless needed for administration of the health plan
- Prohibit employers from requiring employees to agree to the sale, exchange, sharing, transfer or other disclosure of their health information
- To comply with other laws affecting workplace wellness programs
- To not rely on the ADA “safe harbor” provision, even if the wellness program is part of the employer’s health plan.

29 CFR § 1630.14.

Thus, even though the AARP v. EEOC case has made the regulatory landscape uncertain in some respects, there are still rules to follow. We will continue to monitor developments and provide updates whenever possible.

Frequently Asked Workplace Wellness Compliance Questions

We offer our group health plan employees an outcomes-based program that includes an HRA and biometric screen component. In order to earn the full reward, the employees must take the HRA and biometric screen. Because our wellness program is tied to our group health plan, the ACA/HIPAA incentive rules apply. Will our program be affected by the AARP v. EEOC case and the repeal of the ADA incentive rules?

Yes. If there is an HRA or biometric screen component to your outcomes-based program, then the change to the ADA and GINA rules would apply, particularly if your incentive is tied to the HRA and/or biometric screen. You will want to consult with legal counsel to evaluate your risk.

Our organization employs a lot of family members. Do we violate the Genetic Information Nondiscrimination Act (GINA) if we offer health risk assessments (HRAs) to all employees and some of those employees' family members, who are also employees, take the HRA?

No. Under GINA, 29 CFR § 1635.8(c)(1), an employer does not violate GINA when it requests information about the manifestation of a disease or disorder of an individual's family member who is also an employee for the same employer.

Listen to Jen Arnold from Redesigning Wellness Interview Barbara Zabawa about the AARP v. EEOC Case!

Recorded on January 24, 2018, you can listen to the podcast here.

WELCOA Health Promotion Legal Updates to continue into 2018!!

The Center for Health and Wellness Law, LLC is happy to announce that its founder, Barbara J. Zabawa, JD, MPH, will continue her monthly webinar series for WELCOA in 2018. Topics to be covered in 2018 will include sexual harassment in the workplace, COBRA and workplace wellness, onsite clinics and workplace wellness, FTC Act, tiered incentives, use of genetic information, among others. The one-hour webinar will occur on the third Wednesday of each month, starting in January 2018. We hope you can join us! Visit https://www.welcoa.org/training/webinars-current-events/ to learn more.

UPDATE on FDA Regulation of mHealth and Wellness Devices

After publishing the article "FDA Regulation of mHealth and Wellness Devices: What You Need to Know" in the American Bar Association December 2017 issue of *The Health Lawyer* (hereinafter "December article"), the FDA issued "Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act" on December 8, 2017 (hereinafter

"Draft Guidance").[1] Although the document is "draft guidance" for purposes of comment only, we believe it is important to alert readers of possible changes to the information provided in the December article.

The December article differentiates between "mobile medical apps" (which are medical devices regulated by the FDA), "mobile apps" (which are medical devices that fall within the FDA's "enforcement discretion") and "low risk wellness devices" (which are not medical devices at all and therefore not subject to FDA regulation, discretionary or otherwise).

To fall within the category of "low risk wellness device," the device had to meet several requirements:

1. Its intended use relates to maintaining or encouraging a general state of health or a healthy activity; or
2. Its intended use associates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions; and
3. The device presents a very low risk to the user's safety.[2]

The Draft Guidance appears to address an inconsistency within the definition of low risk wellness device. This inconsistency is that a low risk wellness device should not be related to the diagnosis, cure, mitigation, prevention or treatment of a disease or condition. Yet, the second category of low risk wellness device identified above references "chronic diseases or conditions." According to the FDA, wellness devices that relate to the mitigation or prevention of a disease or condition should not be excluded from the definition of "medical device."[3] As a result, the FDA plans to recognize wellness devices in that second category as medical devices, but subject to enforcement discretion as long as the device also presents a low risk to the user's safety.

Likewise, the Draft Guidance moves some mobile apps from the "enforcement discretion" category to "not a medical device" category. The mobile apps the FDA is moving to "not a medical device category" (and therefore not subject to FDA regulation include:

Mobile apps that are intended for individuals to log, record, track, evaluate, or make decisions or behavioral suggestions related to developing or maintaining general fitness, health or wellness, such as those that:

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[1] FDA Draft Guidance for Industry and Food and Drug Administration Staff, Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act, Dec. 8, 2017 (hereinafter "Draft Guidance"), available at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM587820.pdf.

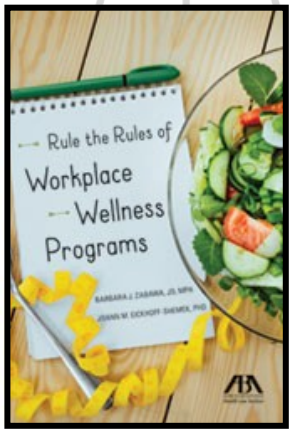
[2] December article, at 43.

[3] Draft Guidance, at 8.

- Provide tools to promote or encourage healthy eating, exercise, weight loss or other activities generally related to a healthy lifestyle or wellness;
- Provide dietary logs, calorie counters or make dietary suggestions;
- Provide meal planners and recipes;
- Track general daily activities or make exercise or posture suggestions;
- Track a normal baby's sleeping and feeding habits;
- Actively monitor and trend exercise activity;
- Help healthy people track the quantity or quality of their normal sleep patterns;
- Provide and track scores from mind-challenging games or generic "brain age" tests;
- Provide daily motivational tips (e.g., via text or other types of messaging) to reduce stress and promote a positive mental outlook;
- Use social gaming to encourage healthy lifestyle habits;
- Calculate calories burned in a workout.[4]

Contact www.wellnesslaw.com to learn more.

Have you ordered Rule the Rules of Workplace Wellness Programs yet?



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[4] Draft Guidance, at 9.