



The
ERISA
Industry
Committee

March 8, 2011

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Re: Guidance for Voluntary Workplace Wellness Programs

Ladies and Gentlemen:

We are writing on behalf of The ERISA Industry Committee (“ERIC”) to ask the Departments of Labor, Treasury, and Health and Human Services and the Equal Opportunity Commission (the “Agencies”) to provide guidance on certain issues affecting workplace wellness programs. Congress made clear when it enacted the Patient Protection and Affordable Care Act (“ACA”) that employers should be encouraged to offer these valuable programs to their workers. Members of the Administration, including the President himself, have publicly recognized the value of wellness programs. In spite of these expressions of support, however, employers are discouraged from investing in workplace wellness programs because the regulations governing these programs are unclear and sometimes inconsistent. In particular:

- Employers need further guidance concerning the incentives they can offer their workers to participate in wellness programs.
- Employers do not have clear rules explaining how the Americans With Disabilities Act applies to workplace wellness programs.
- The regulations interpreting the Genetic Information Nondiscrimination Act (“GINA”) provide conflicting guidance about the use of family medical history to identify employees who would benefit from wellness programs.

Workplace wellness programs have a central role to play in the Administration’s efforts to reduce health care costs and improve the health of American workers. The lack of clear guidance stifles the development of new programs and threatens the continuation of existing programs. ERIC urges the Agencies to address the issues identified in this letter as soon as possible, so that

employers can design their wellness programs for 2012 based on a clear understanding of the legal constraints under which these programs must operate.

The Importance of Workplace Wellness Programs

ERIC is a nonprofit association committed to the advancement of the employee retirement, health, incentive, and welfare benefit plans of America's largest employers. ERIC's members sponsor group health plans that provide comprehensive health benefits directly to some 25 million active and retired workers and their families. ERIC members have taken the lead in developing wellness programs that are designed to improve the health of employees and their families and to reduce the health care costs that employers and employees share.

A. *Wellness programs help contain health care costs and improve workers' quality of life.*

Wellness programs target chronic diseases, which are often preventable and which are among the largest drivers of health care costs in the United States.¹ The treatment of chronic diseases accounts for more than 75 percent of our nation's health care expenditures.² Workplace wellness programs encourage employees to take care of potential health problems before they develop into chronic diseases. These programs also promote a healthy lifestyle that is less likely to lead to chronic disease. Disease management programs help employees who have developed a chronic disease to manage their care, and they provide education and preventive care to employees who are at high risk for a particular disease.

Workplace wellness programs have proved effective in containing health costs, reducing disability claims, and improving workers' productivity. The American Heart Association's Position Statement on Effective Worksite Wellness Programs cites data from a number of sources showing that workplace wellness programs produce, on average, a 26 percent reduction in health care costs; a 28 percent reduction in sick leave absenteeism; and a 30 percent average reduction in costs associated with workers' compensation and disability claims.³ In addition to these measurable benefits, wellness programs improve the quality of life for American workers and their families by promoting healthy lifestyles. Employees value these programs, and they benefit from the programs' emphasis on promoting good health and addressing health problems before the problems become more serious and more costly to treat.

¹ Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Indicators for Chronic Disease Surveillance, Morbidity and Mortality Weekly Report (Sept. 10, 2004), <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5311a1.htm>.

² Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Chronic Disease Overview, <http://www.cdc.gov/nccdphp/overview.htm>.

³ American Heart Association, Position Statement on Effective Worksite Wellness Programs, <http://www.americanheart.org/downloadable/heart/1213386784466Worksite%20Wellness%20Policy%20Position%20Statement%20to%20NPAM%20and%20EPI.pdf>. See also Yen, L., Schultz, A.B., Schaefer, C., Bloomberg, S., and Edington, D.W., Long-term Return on Investment of an Employee Health Enhancement Program at a Midwest Utility Company from 1999 to 2007, *International Journal of Workplace Health Management*, 3(2):79-96 (2010) (finding that, in one of the few longitudinal studies to cover such a length of time, wellness investments resulted in health care cost savings commensurate with an employee's degree of participation during a nine year period).

B. Congress and the Administration have recognized that wellness programs are a vital part of the health care solution.

In recent legislation, Congress has repeatedly recognized the importance of wellness programs. Congress included in Title II of GINA an exception that permits employers to offer health or genetic services as part of a wellness program. Congress believed that GINA “preserves employer-sponsored wellness programs” and “encourages employees to take advantage of genetic technologies and opportunities to improve human health.”⁴ In the American Recovery and Reinvestment Act of 2009 (the “Recovery Act”), Congress set aside \$1 billion in a “Prevention and Wellness Fund” to finance a variety of preventive care and wellness initiatives.⁵ The Department of Health and Human Services, in partnership with the Centers for Disease Control and Prevention, used a portion of the Recovery Act appropriation to develop the “Communities Putting Prevention to Work” initiative, whose goals are to reduce risk factors, prevent or delay the onset of chronic disease, and promote wellness in both children and adults.⁶

Congress again expressed strong support for wellness programs when it passed the Affordable Care Act. ACA codifies and expands the regulatory exemption for workplace wellness programs that include health-related standards.⁷ In recognition of the value and effectiveness of wellness programs, ACA includes “wellness services and chronic disease management” among the essential health benefits required for plans offered through health care exchanges.⁸ In order to promote workplace wellness programs, ACA directs the Secretary of Health and Human Services to award grants to small employers to provide their employees with access to comprehensive workplace wellness programs.⁹ ACA authorizes grants to states to provide Medicaid beneficiaries with incentives to adopt healthy behaviors.¹⁰ ACA also amends the Medicare program to provide an annual wellness visit and critical preventive screenings at no cost to Medicare beneficiaries.¹¹

Senior members of the Administration have strongly endorsed wellness programs, including programs offered through the workplace. In a speech to the Global Business Forum on January 13, Health and Human Services Secretary Sebelius explained:

Under the new health care law, we’re also helping the private sector promote better health. Private employers have long been leaders in setting up wellness programs that help workers stay healthy and out of the hospital. Now, the ACA will increase the workers’ rewards up to

⁴ H.R. Rep. No. 28, Part 1, 110th Cong., 1st Sess. 38 (2007).

⁵ American Recovery and Reinvestment Act of 2009, Title VIII. The Recovery Act funding included \$650 million “to carry out evidence-based clinical and community-based prevention and wellness strategies . . . that deliver specific, measurable health outcomes that address chronic disease rates.”

⁶ Centers for Disease Control and Prevention website, <http://www.cdc.gov/chronicdisease/recovery/>.

⁷ ACA § 1001(5), 124 Stat. 119.

⁸ ACA § 1302(b).

⁹ ACA § 10408.

¹⁰ ACA § 4108.

¹¹ ACA §§ 4104, 4105.

30 percent of their cost of health coverage for participating in a wellness program and meeting health benchmarks – a strategy with proven success. That will give businesses a little extra assistance to invest in a healthy workforce.¹²

The Surgeon General's *Vision for a Healthy and Fit Nation* promotes a number of wellness initiatives, including workplace wellness programs.¹³ First Lady Michelle Obama's "Let's Move" campaign includes wellness initiatives aimed at reducing obesity and promoting healthy habits among America's children.¹⁴ In 2009 President Obama hosted a White House discussion with workplace wellness program innovators, in which seven employers (including several ERIC member companies) showcased their efforts to reduce disease and increase quality of care.¹⁵ President Obama stated that these "best practices" should "inform[] the health care reform discussions."¹⁶ The President recently repeated his view that wellness programs can provide "better care" to American workers.¹⁷

The Administration has recognized that successful wellness programs must offer incentives to encourage participation. The Centers for Medicare and Medicaid Services ("CMS") recently solicited applications from the states for \$100 million in Affordable Care Act grants that will be used to provide incentives to Medicaid beneficiaries who adopt healthy habits such as quitting smoking or losing weight.¹⁸ In explaining the need for the program, CMS emphasized the scientific evidence demonstrating the importance of wellness incentives:

Improving participation in preventive activities will require finding methods to encourage Medicaid consumers to engage in and remain in such efforts. A significant review of the effects of economic incentives on consumers' preventive health behaviors, primarily in

¹² A copy of Secretary Sebelius's prepared remarks is available on the HHS website at <http://www.hhs.gov/secretary/about/speeches/sp20110113.html>.

¹³ "The majority of the 140 million men and women who are employed in the United States spend a significant amount of time each week at their work site. Wellness programs in the workplace are an effective way to support people's efforts to achieve and maintain a healthy weight. . . . Research has shown that health promotion programs in the workplace can be cost effective and well worth the ongoing costs of implementing these programs." *The Surgeon General's Vision for a Healthy and Fit Nation*, at 9 (Jan. 28, 2010), available at <http://www.surgeongeneral.gov/library>.

¹⁴ See <http://www.letsmove.gov/>.

¹⁵ *Innovative Workplace Practices: A Discussion with President Obama* (May 12, 2009), available at <http://www.whitehouse.gov/the-press-office/fact-sheet-innovative-workplace-practices-a-discussion-with-president-obama>.

¹⁶ Remarks by the President after Roundtable with Business Leaders to Discuss Employer Health Care Costs (May 12, 2009), available at <http://www.whitehouse.gov/the-press-office/remarks-president-after-roundtable-with-business-leaders-health-care-costs>.

¹⁷ Remarks by the President in a Backyard Discussion on Health Care Reform and the Patient's Bill of Rights, Falls Church, VA (Sept. 22, 2010), available at <http://www.whitehouse.gov/the-press-office/2010/09/22/remarks-president-a-backyard-discussion-health-care-reform-and-patients->. ("We're a lot better off if we are making sure that everybody is getting preventive care, we're encouraging wellness programs where people have access to doctors up front.")

¹⁸ Centers for Medicare and Medicaid Services, Center for Strategic Planning, *Patient Protection and Affordable Care Act Section 4108: Medicaid Incentives for Prevention of Chronic Diseases (MIPCD) Initial Announcement* (Feb. 23, 2011), available at http://www.cms.gov/MIPCD/Downloads/HHS_ACA_S4108_Solicitation.pdf.

commercial insurance program was published in 2004 in the *American Journal of Preventive Medicine*. A systematic literature review identified 111 randomized controlled trials, of which 47 (published between 1966 and 2002) were reviewed. These studies showed that financial incentives worked about 73 percent of the time. Incentives that increased the ability to purchase a preventive service worked better than more diffuse incentives, but the type matters less than the nature of the incentive. Economic incentives were assessed to be effective in the short run for simple preventive care and distinct, well-defined behavioral goals.¹⁹

The design of the CMS grant program is based on the recommendations of a panel of technical experts drawn from different disciplines, including representatives from state Medicaid programs that have attempted to implement incentive-based programs, as well as academic and industry representatives with specific expertise with incentive-based health improvement programs and the use of incentives to motivate behavior change in individuals. The report of the technical experts²⁰ includes an additional survey of scientific literature on the effectiveness of wellness incentives and a number of practical recommendations concerning the design of effective incentive-based programs.

In spite of the demonstrated success of workplace wellness programs; in spite of Congress's recognition of the value and importance of these programs in recent legislation; and in spite of public support and financial assistance from senior Administration officials for incentive-based programs, the guidance that the Agencies have provided in recent years severely restricts employers' ability to establish and maintain incentive-based wellness programs. Employers are frustrated and confused by the mixed messages they receive from the Administration, which encourages them to offer workplace wellness programs while depriving them of the tools they need to make these programs successful.

Employers Need Further Guidance on Wellness Issues

Three federal nondiscrimination statutes potentially apply to workplace wellness programs: the Health Insurance Portability and Accountability Act ("HIPAA"), 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 ("ADA"), which prohibits discrimination against a qualified individual with a disability in any aspect of employment; and the Genetic Information Nondiscrimination Act ("GINA"), which prohibits health plans, health insurers, and employers from discriminating on the basis of genetic information.

¹⁹ *Id.* at p. 5, citing Kane, Robert L., MD; Johnson, Paul E., PhD; Town, Robert J., PhD and Butler, Mary, MBA, *A Structured Review of the Effect of Economic Incentives on Consumers' Preventive Behavior*, *Am. J. Prev. Med.* 2004; 27(4):327–352).

²⁰ *Guidance Document on Preparing a Solicitation for Section 4108 of the Patient Protection and Affordability Act: Incentives for Prevention of Chronic Diseases in Medicaid* (Final Report Feb. 3, 2011), available at <http://www.cms.gov/MIPCD/Downloads/CMSMedicaidIncentivesGuidance.pdf>.

Employers struggle to design and administer their wellness programs in compliance with these three statutes. Although the Agencies have issued regulations explaining how HIPAA and GINA apply to wellness programs, important issues remain unresolved under all three statutes. Employers are reluctant to invest additional time and money in developing their wellness programs until the applicable law is clarified. In order to give effect to the intent of Congress and the Administration to support workplace wellness programs, ERIC urges the Agencies to address the points identified below.

1. Increase the Limit on Incentives for 2012.

Regulations issued in 2006 make clear that a workplace wellness program will not violate HIPAA's nondiscrimination requirement as long as the program meets certain conditions. Among other requirements, the program must ensure that the incentive for meeting a health-related standard does not exceed 20 percent of the annual cost of coverage.²¹ The incentive limit is designed to ensure that the wellness program is voluntary by prohibiting incentives so large "as to have the effect of denying coverage or creating too heavy a financial penalty on individuals who do not satisfy an initial wellness program standard that is related to a health factor."²² ACA raises the incentive limit to 30 percent of the cost of coverage and authorizes the Departments of Treasury, Labor, and HHS to raise the limit to 50 percent if they determine such an increase is appropriate.²³

The increased limit for incentives appears in a subtitle of ACA that does not become effective until 2014.²⁴ The Departments of Treasury, Labor, and HHS recently announced, however, that they will use their existing regulatory authority under HIPAA to raise the incentive limit to 30 percent before 2014.²⁵

ERIC strongly endorses the Departments' decision to implement the increased limit on incentives before 2014. As HHS has recognized,²⁶ incentives play a significant role in the success of wellness programs by encouraging participation and motivating employees to achieve their health goals. Incentives can be particularly effective when they are tied to the satisfaction of a health-related standard: Secretary Sebelius correctly identified incentive-based programs as "a strategy with proven success."²⁷ ERIC urges the Departments to make the increased incentive limit effective no later than January 1, 2012.

2. Make Clear That the Increased Limit Applies to Grandfathered Plans.

Certain provisions of ACA, including the increased limit on incentives, do not apply to a group health plan in which an individual was enrolled when ACA was enacted.²⁸ These

²¹ Treas. Reg. § 54.9802-1(f); 29 C.F.R. § 2590.702(f); 45 C.F.R. § 146.121(f).

²² 71 Fed. Reg. 75,018 (Dec. 13, 2006).

²³ ACA § 1201(2)(A), adding a new § 2705(j) to the Public Health Service Act.

²⁴ ACA § 1253.

²⁵ *FAQs About Affordable Care Act Implementation Part V and Mental Health Parity Implementation* (Dec. 22, 2010).

²⁶ See text accompanying notes 18 through 20, above.

²⁷ See text accompanying note 12, above.

²⁸ See ACA § 1251(a)(2).

“grandfathered” plans are, however, subject to the 20 percent limit on incentives under the current HIPAA regulations.

There is no reason to apply a more restrictive incentive limit to grandfathered plans. The ACA change reflects Congress’s determination that the current regulatory limit is too low, and that wellness programs will not fail to be voluntary solely because they offer an incentive up to 30 percent of the total annual cost of coverage. Because the Departments have said that they will use their existing regulatory authority to increase the incentive limit before the ACA provision becomes effective, ERIC assumes that the increased limit will apply to all plans that are subject to the current HIPAA regulations, including grandfathered plans. ERIC urges the Departments to make this point clear when they issue guidance increasing the incentive limit.

3. Make Clear That Wellness Incentives Do Not Affect a Plan’s Grandfathered Status.

Wellness programs often offer reductions in employees’ contributions or cost-sharing requirements as an incentive to meet health-related standards. For example, a group health plan might waive the deductible if the employee achieves a cholesterol count under 200 (or meets an alternative standard provided in compliance with the HIPAA regulations).

Under the Departments’ interim final regulations,²⁹ a group health plan will lose its grandfathered status if the cumulative reduction in the employer’s contribution rate or cumulative increase in employee cost-sharing requirements exceeds the amount permitted under the regulations.

The Departments have issued informal guidance indicating that grandfathered group health plans may continue to provide wellness incentives, but that penalties (such as cost-sharing surcharges) “may implicate” the standards for retaining grandfathered status “and should be examined carefully.” This guidance suggests that the application of a wellness incentive to an individual participant might affect the plan’s grandfathered status, even if the underlying design of the plan has not changed at all since March 23, 2010.

Wellness incentives do not reflect a fundamental change in the plan’s economics of the type that the grandfathered-plan definition is intended to address. We urge the Departments to make clear that a plan’s grandfathered status is determined without taking into account any incentives offered under a workplace wellness program (including any increase in the incentives adopted as a result of the increased limit), regardless of whether the incentive is structured as a penalty or as a reward. In addition, we urge the Departments to make clear that the baseline cost against which cost increases are measured is the cost of the plan to an employee who chooses not to participate in any available wellness program.

4. Issue Guidance in Time for the 2012 Plan Year.

Large employers ordinarily finalize the design of their group health plans for the next calendar year no later than June or July, so that the plans’ third-party administrators will have time to program software systems, revise administrative manuals, and train customer service

²⁹ Treas. Reg. § 54.9815-1251T; 29 C.F.R. § 2590.715; 45 C.F.R. § 147.140.

representatives to administer the benefits properly. Employers also must prepare participant communications and open enrollment materials, and must create internet-based tools, to help employees understand the new benefit options and make appropriate choices concerning their family's health coverage for the upcoming year. Many employers commence open enrollment for the upcoming year in October or earlier. ERIC urges the Departments to issue guidance this spring raising the incentive limit and addressing the other points identified above, so that employers will have sufficient time to incorporate the new limit in their wellness program designs for the 2012 plan year.

5. Make Clear that Wellness Incentives Do Not Violate the Americans With Disabilities Act.

The Americans With Disabilities Act ("ADA") imposes strict limits on the circumstances in which an employer may require medical examinations or gather medical information about current or prospective employees. The ADA permits employers to offer voluntary medical examinations or request voluntary medical histories as long as they keep the information confidential and do not use it for discriminatory purposes.³⁰ The Equal Employment Opportunity Commission issued enforcement guidance in 2000 stating that voluntary wellness programs can qualify for this exception.³¹ The enforcement guidance explains that a wellness program is "voluntary" as long as an employer neither requires participation nor "penalizes" employees who do not participate. The guidance does not explain whether withholding an incentive is viewed as a "penalty" for this purpose.

The EEOC's Office of Legal Counsel issued an opinion letter in January 2009 confirming the common-sense view that programs designed to meet the HIPAA standard for voluntary wellness programs also will meet the ADA standard. In March 2009, however, the EEOC's Office of Legal Counsel withdrew this portion of its opinion letter.³² Members of the EEOC's legal staff now warn that a workplace wellness program might violate the ADA even if the program fully complies with the 20 percent limit on incentives and other HIPAA requirements.

Congress has addressed the status of wellness incentives in ACA. The statute makes clear that a wellness program will not discriminate on the basis of health factors solely because it offers an incentive equal to 30 percent of the cost of coverage (or up to 50 percent in the discretion of the Departments of Treasury, Labor and HHS). Since Congress has determined that a 30 percent incentive does not prevent a wellness program from being voluntary for purposes of HIPAA, the EEOC should acknowledge that the same incentive does not prevent a wellness program from being voluntary for purposes of the ADA. The EEOC should issue guidance before 2012 making clear that a wellness program operated in compliance with the HIPAA standards also will satisfy the ADA.

We recognize that the EEOC's final regulation interpreting Title II of GINA uses similar language to describe an exception for voluntary wellness programs, and that the EEOC has

³⁰ 42 U.S.C. § 12112(d)(4).

³¹ EEOC Enforcement Guidance: *Disability-Related Inquiries and Medical Examinations of Employees Under the Americans With Disabilities Act*, 8 Fair Empl. Prac. Man. (BNA) 405:7701, Q&A-22 (July 27, 2000).

³² Letter dated March 6, 2009, from Peggy R. Mastroianni, Associate Legal Counsel, EEOC Office of Legal Counsel.

taken the position that this language prohibits an employer from offering *any* financial incentive for an employee to provide genetic information.³³ ERIC strongly disagrees with this interpretation of Title II of GINA, and with the Labor Department's, Treasury's, and HHS's similar interpretation of Title I of GINA.

The EEOC has offered no explanation why Title II of GINA prohibits an employer from offering an employee a reasonable incentive to provide family medical history or other genetic information that will be held in confidence and used solely for the employee's benefit, other than to say in the preamble of the regulation that this interpretation resulted from "balancing" the benefits of wellness programs "with the need to construe exceptions to the prohibition of acquisition of genetic information in a manner appropriately tailored to their specific purposes."³⁴ ERIC believes that the EEOC's interpretation will undermine the effectiveness of health risk assessments, deprive workers and their families of a valuable tool for improving their health, and contribute to health care cost inflation. ERIC urges the EEOC not to compound these problems by extending a similarly restrictive interpretation to the ADA.

ERIC also urges the Agencies to reconsider their earlier interpretation of Titles I and II of GINA. CMS has cited extensive literature demonstrating that financial incentives are necessary to encourage individuals to participate in wellness activities, even when their own health is at stake.³⁵ The Agencies' current interpretation of GINA, which prohibits an employer from offering employees a financial incentive to provide confidential family medical history in a health risk assessment, is not necessary to carry out the purposes of GINA and severely impairs the effectiveness of workplace wellness programs.

6. Make Clear That Family Medical History Provided Voluntarily May Be Used to Guide Employees Into Disease Management Programs.

Workplace wellness programs improve employees' health outcomes in part because of their ability to identify individuals who would benefit from participation. The family medical history that an employee voluntarily provides plays an important part in the success of these programs. For example, individuals who are at risk of developing heart disease might be eligible for a disease management program that seeks to prevent or delay the onset of the disease through diet, exercise, monitoring cholesterol levels, and other interventions. If a participant's voluntary health risk assessment discloses a family history of heart disease, a health professional might contact the participant, provide information about the plan's voluntary disease management program for those at risk of developing heart disease, and recommend that the individual consider participating in the program. The same disease management program would be available to employees who do not have (or who have not disclosed) a family history of heart disease, but who have clinical signs of heart disease or who are at increased risk of developing heart disease because they smoke or have high blood pressure.

³³ See 29 C.F.R. § 1635.8(b)(2)(i)(A) (describing a voluntary wellness program as one in which the employer "neither requires the individual to provide genetic information nor penalizes those who choose not to provide it") and § 1635.8(b)(2)(ii) ("Consistent with the requirements of paragraph (b)(2)(i) of this section, a covered entity may not offer a financial inducement for individuals to provide genetic information . . .").

³⁴ 75 Fed. Reg. at 68,923 (Nov. 9, 2010).

³⁵ See text accompanying notes 19 and 20, above.

The EEOC's regulation interpreting Title II of GINA makes clear that an employer may use the genetic information an employee voluntarily provides to guide the employee into an appropriate disease management program, provided that employees may also qualify for the program without providing genetic information. The regulation states:

A covered entity may offer financial inducements to encourage individuals who have voluntarily provided genetic information that indicates that they are at increased risk of acquiring a health condition in the future to participate in disease management programs or other programs that promote healthy lifestyles, and/or to meet particular health goals as part of a health or genetic service. However, to comply with Title II of GINA, these programs must also be offered to individuals with current health conditions and/or to individuals whose lifestyle choices put them at increased risk of developing a condition.³⁶

The preamble of the EEOC's regulation interpreting Title II of GINA states that Title I of GINA, which applies to group health plans, contains a parallel rule.³⁷ According to this statement, a group health plan may offer an employee incentives to participate in a disease management program based on an increased risk disclosed in the employee's voluntary family medical history, provided that the incentives to participate in the disease management program are also available "to individuals who qualify for the program but have not volunteered genetic information through a [health risk assessment]."³⁸

In fact, however, an example in the regulation interpreting Title I of GINA appears to illustrate precisely the opposite rule.³⁹ The example describes a situation in which a group health plan requests that an employee complete a health risk assessment after enrollment. The health risk assessment includes questions about the individual's family medical history, but the plan does not offer the employee any incentive to complete the health risk assessment. Employees who voluntarily provide family medical history may qualify for a disease management program based on risks disclosed in the family medical history; employees who do not provide family medical history also may qualify for the disease management program based on their own health conditions. Accordingly, family medical history is *one* basis (but not the *only* basis) for determining an employee's eligibility to participate in the disease management program.

Although the GINA Title II regulation identifies this situation as a permissible use of family medical history, the example in the Title I regulation states that the same use of family medical history constitutes impermissible underwriting. The Title I example explains:

³⁶ 29 C.F.R. § 1635.8(b)(2)(iii).

³⁷ 75 Fed. Reg. at 68,924 (Nov. 9, 2010).

³⁸ *Id.*

³⁹ Treas. Reg. § 54.9802-3T(d)(3) *Example 4*; 29 C.F.R. § 2590.702-1(d)(3) *Example 4*; 45 C.F.R. § 146.122(d)(3) *Example 4*.

[C]ertain people completing the health risk assessment may become eligible for additional benefits under the plan by being enrolled in a disease management program based on their answers to questions about family medical history. Other people may become eligible for the disease management program based solely on their answers to questions about their individual medical history.

(ii) *Conclusion.* In this Example 4, the request for information about an individual's family medical history could result in the individual being eligible for benefits for which the individual would not otherwise be eligible. Therefore, the questions about family medical history on the health risk assessment are a request for genetic information for underwriting purposes and are prohibited under this paragraph (d). Although the plan conditions eligibility for the disease management program based on determinations of medical appropriateness, the exception for determinations of medical appropriateness does not apply because the individual is not seeking benefits.

This example appears to illustrate the principle that a group health plan *may not* use voluntary family medical history to guide employees into appropriate disease management programs, and may not offer employees incentives to participate in the programs, unless the employees "seek" admission to the programs on their own initiative. Instead, the group health plan may do no more than publicize the disease management program to all participants and hope that the individuals who might benefit will identify themselves, understand on their own the importance of the program to their continued health, and apply for admission.

Nothing in Title I of GINA requires this result. As the Title I regulation recognizes, GINA permits a group health plan to use genetic information to determine whether a benefit or service is medically appropriate. Accordingly, a group health plan should be permitted to use genetic information as one way to determine whether an individual is eligible to participate in a disease management program, as long as the plan does not restrict participation to employees who provide family medical history.

The only difference between conduct prohibited and conduct permitted under the Title I regulation is a question of timing. If the plan uses genetic information on its own initiative to determine whether the participant is eligible for the disease management program, the plan's use of genetic information is prohibited. In contrast, if the plan waits until the participant applies for admission to the disease management program and then uses genetic information to determine whether the participant is eligible, the plan's use of genetic information is permitted. This artificial distinction bears no relationship to the concept of "underwriting."

Experience has shown that without the encouragement of a health professional, many participants who would benefit from participation in a disease management program will never enroll. Accordingly, the position taken in the Title I regulation is not only unnecessary, it is potentially damaging to the health of plan participants. ERIC believes that the rule stated in the Title II regulation is correct. ERIC urges the Departments of Labor, Treasury, and Health and Human Services to make clear that a plan will not be deemed to collect genetic information for "underwriting purposes" when the plan uses family medical history provided voluntarily as one

basis to identify participants eligible for a disease management program or similar voluntary program.

7. Future guidance should encourage employers to offer effective wellness and prevention programs.

A strong consensus is emerging within the Administration as well as from the plan sponsor and provider communities that workplace wellness programs are a critical component of the nation's efforts to reduce chronic health problems. Future regulatory guidance should emphasize ways in which worksite wellness programs may more successfully encourage participants and their families to pursue healthier choices and achieve healthier lifestyles. The Agencies should develop rules that will enable employers to continue their existing programs and develop new, more effective approaches.

Wellness programs are one of the few remaining tools that can help rein in spiraling healthcare costs. It would be counterproductive from a cost-containment perspective, as well as from the standpoint of improving Americans' health, if future guidance were to limit the effectiveness of workplace wellness programs. Instead, the Agencies should assist employers in their efforts to address the serious health problems of workers and their families.

Thank you for your consideration of these comments. We would be pleased to discuss this letter with you if you have any questions.

Sincerely,

Mark Ugoretz
President & CEO

Gretchen Young
Senior Vice President, Health Policy