ERIC

The ERISA Industry Committee

June 18, 2015

Submitted through the Federal eRulemaking Portal

Equal Employment Opportunity Commission
131 M Street, NE
Washington, DC 20507

Attention: RIN 3046-AB01 (Amendments to Regulations under the Americans with Disabilities Act)

Ladies and Gentlemen:

The ERISA Industry Committee ("ERIC") is pleased to submit this response to the request for comments on proposed rulemaking regarding Title I of the Americans with Disabilities Act ("ADA") as it relates to employer wellness programs. The request was published by the Equal Employment Opportunity Commission (the "Commission") in the *Federal Register* on April 20, 2015.

These proposed regulations provide an opportunity to clarify how employers can offer wellness programs that assist employees and their families to achieve better health outcomes in a manner that is compliant with the ADA. Most critically, the proposed regulations provide a much needed safe harbor that will allow wellness incentives offered in reliance on the standards set out in the Affordable Care Act ("ACA") to also comply with the voluntary wellness program exemption to the ADA's prohibition of employer medical exams. Because health risk assessments and biometric screenings are integral elements of any effective wellness program, this approach is essential to prevent the ADA from undermining the comprehensive regulatory scheme that Congress carefully crafted in enacting the ACA.

ERIC's Interest in the Proposed Rulemaking

ERIC is the only national trade association advocating solely for the employee benefit and compensation interests of the country's largest employers. ERIC supports the ability of its large employer members to tailor health, retirement, and compensation benefits for millions of employees, retirees and their families. ERIC has a strong interest in proposals that affect its members' ability to deliver high-quality, cost-effective benefits.

Over time, it has become more and more difficult for ERIC members to continue to deliver high quality health benefits to their employees due to spiraling costs and over-regulation. Given these challenges, the promotion of wellness for each and every American worker – and his or her family – has become of paramount importance, as it is one of the few efforts that demonstrably can reduce future health care costs while simultaneously providing tangible benefits to employees and employers alike.

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Employers benefit when effective workplace wellness programs improve the health of their workforce. Worksite productivity is diminished when employees are ill and unable to perform their jobs, either because they are too sick to work or because illness has hampered their productivity.[1] A healthy employee is one who can concentrate on the task at hand, without being distracted by personal and family health problems.

For employees, participation in wellness programs can offer the immediate rewards of better health and a higher quality of life.[2] Participating employees also face a brighter future when wellness programs uncover personal histories indicating predisposition towards a particular illness that – with appropriate help and guidance – may be avoided or limited in effect.

Increasing participation in wellness programs is a top priority for employers.[3] To this end, employers are seeking to change workplace cultures, increase employee awareness and improve performance. Employers are also turning to another critical tool for increasing employee achievement of wellness objectives: economic incentives.[4] Rewarding wellness improvements is an effective strategy for increasing the number of participating—and benefiting—employees.[5] ERIC strongly supports the Commission's efforts to clarify its stance on under what circumstances wellness program incentives render such a program involuntary. ERIC does not share all of the Commission's views about the effect of wellness incentives on a programs' voluntary status and, therefore, proposes certain modifications to the proposed incentive safe harbor for wellness programs as well as the need to address the existing statutory ADA bona fide benefit plan safe harbor.

Protecting the confidentiality of employee medical information is another top priority for employers. It is abundantly clear that employers both large (like ERIC members) and small do not invest millions in wellness program planning, outreach and systems in order to procure health information for purposes of making employment decisions. As a result, the Commission and ERIC members find themselves aligned in developing sound protocols to ensure that any data acquired by wellness programs is used solely for purposes of improving employee health decisions, behavior and outcomes, not for making employment decisions. However, the Commission's confidentiality proposals are needlessly duplicative and should recognize that HIPAA compliance is a permissible safe harbor.

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[1] Ross DeVol & Armen Bedroussian, An Unhealthy America 131-32 (Milken Institute Oct. 2007) (estimating $1B annually in lost employee productivity due to reduced performance and missed workdays related to chronic disease), *available at* http://www.milkeninstitute.org/pdf/chronic_disease_report.pdf.

[2] Vicki S. Conn et al., *Meta-Analysis of Workplace Physical Activity Interventions*, 37 Am. J. Preventative Med. 330, 333-34 (2009) (surveying wellness program studies and finding statistically significant improvement in fitness, diabetes risk and participant-reported quality of life and mood for certain studies), *available at* http://www.ajpmonline.org/article/S0749-3797(09)00413-9/.

[3] Aon Hewitt, 2012 Health Care Survey, 8 (2012), *available at* http://www.aon.com/attachments/human-capital-consulting/2012_Health_Care_Survey_final.pdf (70% of employers want to raise wellness program utilization).

[4] HERO, ACOEM, ACS, American Diabetes Association & AHA, *Guidance for a Reasonably Designed, Employer-Sponsored Wellness Program Using Outcomes-Based Incentives*, 54 J. Occupational & Envtl. Med. 889, 889 (July 2012), *available at* http://journals.lww.com/joem/Abstract/2012/07000; *see also* Aon Hewitt, *supra* note 6, at 33 (from 2011 to 2012, use of financial incentives increased from increase 17% to 54% in disease management programs and from 37% to 59% in health improvement programs).

[5] Soeren Mattke et al., RAND Corporation, A Review of Workplace Wellness Programs, 32 (July 2012); *see also* Employee Benefit Research Institute, Issue Brief No. 379: Findings from the 2012 EBRI/MGA Consumer Engagement in Health Care Survey, 11 (Dec. 2012), *available at* http://www.ebri.org/pdf/briefspdf/EBRI_IB_12-2012_No379_CEHCS2.pdf ("[B]etween about 60 percent and 80 percent of participants said they would participate in wellness programs if there was some type of financial incentive to do so.").

ERIC members believe that continued expansion of, and research on, incentive-based wellness programs will prove mutually beneficial to employers and their employees. We strongly encourage the Commission to continue to ensure that the wellness regulatory environment provides sufficient flexibility to permit this growth and optimization process to develop.

I. Comments on the Proposed Regulations

ERIC appreciates and strongly supports the Commission's initiative to provide a clear framework for ADA-compliant wellness programs that protects employees' (and prospective employees') rights to pursue their careers without unfair intrusion into their health and related limitations. To encourage the development of more effective wellness programs and further align the ACA and ADA regulatory regimes, ERIC suggests that the Commission incorporate the following ten modifications into the final rules:

A. Eliminate incentive limitations on wellness programs that qualify for an exemption from such limitations as "participatory" programs under the final wellness program regulations issued jointly by the Departments of Treasury, Health and Human Services, and Labor (the "Departments") on June 3, 2013 (the "ACA Regulations");
B. Align remaining proposed wellness program incentive limits with all of the ACA Regulations, including non-self coverage and tobacco cessation programs;
C. Clarify that common self-administered, non-medical measurements incorporated into wellness programs are not subject to the ADA;
D. Eliminate new notice requirements for wellness programs that are provided as part of group health plans as existing disclosure requirements are sufficient;
E. Clarify that no wellness programs will be required to separately satisfy the aggregate disclosure requirements to the extent such programs are administered in compliance with HIPAA;
F. Clarify that no wellness programs will be required to separately satisfy the breaches of confidentiality requirement to the extent such programs are administered in compliance with HIPAA;
G. Recognize that the "bona fide benefit plan" statutory safe harbor of the ADA essentially nullifies a vast portion of these proposed regulations (particularly in the jurisdiction of the United States Court of Appeals for the Eleventh Circuit); thus, provide meaningful and workable regulations addressing the underwriting, classifying, and administering risks concepts of the statutory safe harbor;
H. Eliminate the language in the proposed regulation that would prohibit the use of "gateway" plan designs;
I. Eliminate the redundant "reasonably designed" requirement of the proposed regulations; and
J. Adopt an effective date no sooner than January 1, 2017, begin with a good faith interpretation standard for the first year, and state that the final regulations contain no inference of applicability or "clarification" for any period before the effective date of the final regulations.

In addition, ERIC has identified and wishes to comment on four further compliance obstacles that were not included in the proposed regulations, but that have been identified as potential add-ons by the Commission in the preamble to its proposal, including:

K. An exception from wellness program participation for individuals that obtain a note from a medical professional indicating they are already under care;
L. An exception to the Commission's already stringent safe harbor for any incentive limits that may affect the complicated ACA "affordability analysis";

M. An additional written consent requirement to establish the voluntariness of wellness program participation;
N. An imposition of substantive criteria for a wellness program that is unnecessary to protect employees with health problems from bearing unfair costs, but that would stifle the development of wellness program design innovations; and
O. Imposing ADA limits or requirements on incentives that may be offered for wellness programs outside of a group health plan.

A. Eliminate incentive limits on "participatory" wellness programs under the ACA regulations.

Employees will not benefit from, or be further protected by, adding incentive limits to "participatory" wellness programs in addition to the other voluntary participation requirements and privacy protections established in the Commission's proposed regulations. Given the fact that participatory wellness programs such as health risk assessments are the key to identifying appropriate lifestyle and disease management programs for health plan participants, any limit on incentives in participatory programs will hamstring efforts to improve employee health and prevent disease. The ACA is consistent with, and clearly establishes a framework for, this policy position, as it clearly distinguishes such "participatory" programs from those that are "non-participatory" with regard to the incentive limit—that is, there are no incentive limits on "participatory" programs.

The ACA Regulations define participatory wellness programs as programs that either do not provide a reward that is, or do not include any conditions for obtaining a reward that are, based on an individual satisfying a standard related to a health factor. Examples in the final regulations include: A program that reimburses employees for all or part of the cost for membership in a fitness center; a program that reimburses employees for the costs of participating, or that otherwise provides a reward for participating, in a smoking cessation program without regard to whether the employee quits smoking; and a program that provides a reward to employees who complete a health risk assessment (HRA) regarding current health status, without any further action (educational or otherwise) required by the employee with regard to the health issues identified as part of the assessment.[6]

Congress and the Departments considered whether participatory wellness programs should be subject to incentive limits in drafting HIPAA, the ACA and the ACA regulations, respectively.[7] Their reasoned determination was that limitations were not needed for "participatory" wellness programs because they posed no risk of discrimination based on employees' health factors.

The Commission's conflicting decision to limit incentives offered for participatory wellness programs greatly complicates the administration of ACA-compliant wellness programs. ERIC appreciates the Commission's effort to align its proposed ADA regulations with the existing ACA regulations. Eliminating the proposed incentive limit for participatory wellness programs will vindicate this goal of alignment without deviating from the intent of the ADA's prohibition on medical exams and disability-related inquiries.

For all of these reasons, we urge the Commission to exclude participatory wellness programs (as defined in the ACA regulations) from the safe harbor incentive limit proposed in EEOC Regulation Section 1630.14(d)(3).

B. Align any proposed wellness program incentive limits with all of the ACA regulations, including non-self coverage and tobacco cessation programs.

The Commission's proposed regulations, in addition to the participatory issue noted above, fail in other

[6] Treas. Reg. §54.9802-1(f)(1)(ii) (all ERISA and PHSA references omitted for the balance of this response).

[7] Preamble to the ACA Regulations, 78 Fed. Reg. 33161 (June 3, 2013).

ways to be in accord with the ACA regulations' incentive limits. As a consequence, the proposed regulations create differences that do not reflect the well-established policy objectives of the ACA regulations and are guaranteed to create unintentional compliance problems for employers.

One of the major differences between the ACA regulations and the proposed regulations is that the Commission fails to address the design or operation of wellness programs that involve family members. In contrast, the ACA regulations provide the following:

> However, if, in addition to employees, any class of dependents (such as spouses, or spouses and dependent children) may participate in the wellness program, the reward must not exceed the applicable percentage of the total cost of the coverage in which an employee and any dependents are enrolled. For purposes of this paragraph (f)(3)(ii), the cost of coverage is determined based on the total amount of employer and employee contributions towards the cost of coverage for the benefit package under which the employee is (or the employee and any dependents are) receiving coverage.[8]

The Commission should recognize that spouses and dependent children may participate in wellness programs and set the applicable maximum incentive as a percentage of non-self coverage in such circumstances. Just as wellness programs benefit employees, families of these workers should also be incentivized to enhance their health and wellbeing through participation in worksite wellness programs.

Further, the Commission should join the Departments in equipping employers—and ultimately health care providers—with the tools necessary to combat the negative health consequences of tobacco consumption by aligning its incentive limits for tobacco cessation programs with the limits applicable under the ACA regulations.

The adverse consequences of tobacco consumption and the difficulty of successfully ending tobacco usage are unquestioned.[9] Recognizing this fact, the Departments and Congress authorized increased incentives for wellness programs that equip employees with the tools to end or avoid—or at least reduce—tobacco usage.

As the Commission implicitly recognizes in the preamble to the proposed regulations, it is rational to supplement the heightened tobacco cessation wellness program incentives with verification procedures.[10] The combination of incentives and testing can deliver better results for participating employees.

Current technologies for testing tobacco usage are considered medical examinations for ADA purposes due to the requisite medical technology and techniques involved (including collection of saliva, blood or urine). However, the ADA's prohibition on medical exams was intended to avoid employer acquisition and improper usage of knowledge about an employee or applicant's disabilities.[11] The ADA was not intended to protect

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[8] Treas. Reg. § 54.9802-1(f)(3)(ii).

[9] U.S. Dep't of HHS, The Health Consequences of Smoking—50 Years of Progress: A Report of the Office of the Surgeon General, 678, 803 (2014) (noting that approximately 2.4M additional deaths were attributable to smoking for the years 2010-14 and that the current quit rate was estimated to be 10.9% of smokers).

[10] *See* Sander R. Hilberink et al., *Validation of Smoking Cessation Self-Reported by Patients With Chronic Obstructive Pulmonary Disease*, 2011 Int'l J. of Gen. Med. 4, 85-90 (Jan. 2011) ("During the time of the biochemical validation, 12 of the 17 patients, who were classified as smokers, reported that they did not smoke…").

[11] S. Rep. No. 101-116, at 39 (1989) ("Historically, employment application forms and employment interviews requested information concerning an applicant's physical or mental condition. This information was often used to exclude applicants with disabilities-particularly those with so-called hidden disabilities...before their ability to perform the job was even evaluated. In order to assure that misconceptions do not bias the employment selection process, the legislation sets forth a process which begins with the prohibition to pre-offer medical examinations or inquiries.")

employees from restrictions on tobacco usage, which in and of itself does not constitute a disability.[12] The Commission can and should use its interpretive authority to conclude that tobacco testing does not implicate the ADA policy concerns posed by general medical examinations because tobacco consumption testing does not create any risk that employers will identify and discriminate against disabled Americans.

Imposing a lower incentive limit on medical exams related to tobacco usage also fails to mesh with the ACA underwriting guidelines associated with premium surcharges for tobacco use for insured coverage in the small employer market.[13] As a result of these ACA guidelines, insurers can charge premiums for smokers that are 50% higher than premiums for nonsmokers. It was this very difference that lead to the ACA regulation's need to adopt a 50% incentive limit for wellness programs designed to prevent or reduce tobacco use through health-contingent wellness programs. Failure of the Commission to reflect the ACA 50% standard will mean that small employers, who have the least leverage with insurers, will be caught between insurer underwriting guidelines and ADA compliance for their employees who smoke.

Finally, the ACA wellness statutory provisions recognize that the 30% limit can be increased if the Secretaries determine that such an increase is appropriate. This increase has already been exercised in the ACA regulations for programs designed to prevent or reduce tobacco use.[14] Given that the ACA regulation incentive/penalty will inevitably be increased by the Secretaries, the proposed regulations should not establish self-contained limits. The proposed regulations should, instead, merely reference the limits applicable to the ACA regulations, thus preventing the need to revise two unrelated sets of regulations under the control of different agencies when the ACA regulations change.

For all of these reasons, we urge the Commission to align the incentive limit for all wellness programs (whether involving medical examinations or not) with the incentive limits established in the ACA regulations.

C. Clarify that common self-administered, non-medical measurements incorporated into common wellness programs are not subject to the ADA.

The Commission should confirm that health measurements performed by employees themselves as part of a wellness program are not subject to ADA regulation. A common sense safe harbor to this effect will be invaluable in avoiding potential disputes that might arise due to the inherent uncertainty of the Commission's existing factor-based test for identifying medical examinations.

A number of wellness programs improve health or prevent disease by allowing employees to track and/or support each other's progress towards certain health goals relating to healthy behaviors (e.g., physical activity levels) or healthy outcomes (e.g., BMI). Structuring intervention as a shared experience among participants is a key aspect of the success of longstanding programs such as diet clubs and also new techniques like FitBit or pedometer contests.

The Commission's longstanding seven factor test[15] for identifying what constitute medical examinations provides a flexible standard that can address various types of inquiries, including new unexpected technologies.

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[12] *Doukas v. Met. Life Ins. Co.*, No. CIV. 4–478–SD, 1997 WL 833134, at *4 n.3 (D. N.H. Oct. 21, 1997); ("tobacco users cannot qualify as disabled in the absence of a physical impairment or a perceived impairment") *see* EEOC Op. Ltr. re ADA: Voluntary Wellness Programs and the ADA (Mar. 31, 1998) ("not all people who have used tobacco products in the last six months have an ADA disability"); 42 U.S.C § 12201(b) ("Nothing in this chapter shall be construed to preclude the prohibition of, or the imposition of restrictions on, smoking in places of employment…").

[13] See Section 2701(a)(1)(A)(iv) of the Public Health Service Act, as added by the ACA.

[14] See Section 2705 of the Public Health Service Act, as added by the ACA, and Treas. Reg. § 54.9802-1(f)(5).

[15] Enforcement Guidance, Q/A-2.

However, like any flexible standard, the Commission's multi-factor test inevitably results in uncertainty and disputes about its proper application.[16] By application of this multi-factor test, it is clear that the term medical examination is not intended to include any self-administered and self-reported physical testing that can be performed at home or in the workplace using widely-available consumer products (e.g., scale, pedometer, electronic activity tracker) that require no drawing of blood, urine or breath.

We urge the Commission to confirm that this self-administered and self-reported physical testing is not subject to ADA regulation.

D. Eliminate new notice requirements for wellness programs that are provided as part of group health plans as existing disclosure requirements are sufficient.

Under the proposed new 29 CFR Section 1630.14(d)(2)(iv), in order for a wellness program that includes disability-related inquiries and/or medical examinations and that is part of a group health plan to be deemed voluntary, employees must be provided with a sufficiently detailed notice. As described, this notice would need to be specific to the particular wellness program.

Under ERISA, a group health plan must provide participants with a Summary Plan Description ("SPD"). The SPD must be written in a manner calculated to be understood by the average participant and be sufficiently comprehensive to apprise participants of their rights and obligations under the plan.[17] Wellness programs are already described in SPDs, supplemental summaries and guides, and/or annual open enrollment material, and the new notice requirement in the proposed regulations would be unnecessarily duplicative.

Further, under HIPAA, a group health plan must make substantially the same and other disclosures to employees in its Notice of Privacy Practices ("NPP"). Imposing a separate and particularized notice requirement on these types of wellness programs would be redundant, given the small likelihood of raising any awareness that is not already addressed in existing disclosures, and would thus impose a disproportionate administrative burden compared to the marginal benefit such additional notice would provide. This burden would be increased significantly for employers sponsoring multiple wellness programs. It is not unusual for ERIC member employers to use multiple vendors to administer an array of wellness programs, from the simple to the complex.

As referenced in Section M below, much of the information this notice obligation imposes on employers will already be addressed in the actual description of the wellness program. Based on the program's description, employees will already know the type of medical information that a wellness program will collect, e.g., cholesterol levels, blood pressure, the third party vendors who will be administering the program, and the impact, if any, of the results of the wellness program. ERIC members, therefore, would urge the Commission to eliminate this redundant and burdensome notice obligation.

To the extent the Commission determines that it is critical to require a form of notice, ERIC would urge the Commission to adopt a more general notice requirement that could address all applicable wellness programs offered by a particular employer and to permit employers to incorporate such language into any appropriate document. For example, the new regulation could require that the group health plan add a statement to its NPP regarding uses and disclosures of information affecting wellness program participants. If, and to the extent that, different wellness programs involved different uses and disclosures, the regulation could require that the new statement in the NPP describe those material differences.

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[16] *C.f., Karraker v. Rent-a-Center, Inc.*, 316 F. Supp. 2d 675, 680 (C.D. Ill. 2004) (finding that personality test was not a medical examination as a matter of law) *rev'd*, 411 F.3d 831, 837 (7th Cir. 2005) (finding that same test could be a medical examination).

[17] See ERISA Section 102 and related regulations.

ERIC would urge the Commission not to limit this notice requirement to an insert in the NPP, but to provide employers the flexibility to include such notice separately or in plan materials describing the terms of the wellness program. ERIC members would welcome concise model language employers could use to satisfy this requirement.

E. Clarify that no wellness programs will be required to separately satisfy the aggregate disclosure requirements to the extent such programs are administered in compliance with HIPAA.

A group health plan, as a covered entity, is subject to the HIPAA Privacy Rule. Consequently, such a group health plan is already strictly limited under existing law as to what information it may disclose to the employer/plan sponsor and the circumstances in which it may do so.

Under the Commission's proposed 29 CFR Section 1630.14(d)(6), medical information collected through a wellness program could only be provided to the employer in aggregate terms that do not disclose, or are not reasonably likely to disclose, the identity of specific individuals, except (i) as needed to administer the health plan and (ii) as permitted under 29 CFR Section 1630.14(d)(4), which, with respect to disclosures to an employer, only permits disclosures to supervisors and managers to inform them regarding necessary restrictions on the work or duties of the employee and necessary accommodations.[18]

As recognized in the Commission's proposed regulations, for wellness programs that are group health plans subject to HIPAA, disclosures permitted under 29 CFR Section 1630.14(d)(4)(i) would likely not be permitted under the HIPAA Privacy Rule unless such information was de-identified health information. Arguably, de-identified information is more likely, or at least as likely, to protect an individual's confidentiality than aggregate information. Additionally, under the HIPAA Privacy Rule, a group health plan may disclose PHI to an employer/plan sponsor for "plan administration functions" but only if appropriate protections outlined in 45 CFR Section 164.504(f)(2) apply.

ERIC would like the Commission to clarify that wellness programs that are, or are part of, a group health plan, will be deemed to already satisfy the requirements of 29 CFR Section 1630.14(d)(6) to the extent they are administered in compliance with HIPAA.

ERIC would also recommend that all wellness programs, whether or not part of a group health plan subject to HIPAA, will be deemed to satisfy the "aggregate" requirement of proposed 29 CFR 1630.14(d)(6) as long as the wellness program is administered in accordance with HIPAA.

HIPAA already contains specific guidelines for determining when information has been sufficiently de-identified, such that it ceases to qualify as PHI and is no longer subject to the limitations and requirements of HIPAA. ERIC members would therefore urge the Commission to permit wellness programs that are not part of a group health plan subject to HIPAA to nevertheless apply HIPAA's rules for de-identifying information (set forth at 45 CFR Sections 164.514(a) and (b)) in order to satisfy the ADA's aggregation requirement and that, further, the Commission actually remove the proposed ADA aggregation requirement in favor of a simple cross reference to the HIPAA standards.

F. Clarify that no wellness programs will be required to separately satisfy the breaches of confidentiality requirement to the extent such programs are administered in compliance with HIPAA.

While ERIC shares the Commission's concern regarding breaches in confidentiality of its

[18] 29 CFR § 1630.14(d)(4)(i).

employees' medical information, the standard imposed by the proposed regulations, i.e., "immediately,"[19] is neither practical nor consistent with other breach notification standards to which group health plans that are covered entities are already subject, including HIPAA and state data breach notification laws. These other laws recognize that immediate notice is often impossible, and may not even be recommended, given the risk of misinforming potentially affected individuals.

ERIC members would therefore urge the Commission to permit wellness programs that are part of group health plans subject to HIPAA to be deemed to have satisfied the Commission's regulations by complying with the HIPAA data breach notification requirements. With regard to remaining wellness programs, ERIC members would further urge the Commission to merely reference the HIPAA standard and therefore require that individuals affected by a breach be notified without unreasonable delay and in no event later than a specified number of days, e.g., 60 days under HIPAA, consistent with the legitimate needs of law enforcement or any measures necessary to determine the scope of the breach.

G. Recognize that the "bona fide benefit plan" statutory safe harbor of the ADA essentially nullifies a vast portion of these proposed regulations (particularly in the jurisdiction of the United States Court of Appeals for the Eleventh Circuit) and provide meaningful and workable regulations addressing the safe harbor, underwriting, classifying and administering risks concepts of the statutory safe harbor.

Although the Commission rejected *Seff* in footnote 24 of the proposed regulations, *Seff* remains the law of the land in the Eleventh Circuit. Moreover, the *Seff* case does not represent an exercise in judicial freelancing—rather, *Seff* interprets a statutory safe harbor that may not be removed from the ADA through regulatory fiat. This statutory safe harbor states that the ADA "shall not be construed" as prohibiting a covered entity "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."[20]

Due to the ADA safe harbor, and particularly in the Eleventh Circuit, employers will continue to claim (and courts will continue to agree) that the ADA does not apply to, and, in turn, the Commission, does not have authority over, the wellness program of a bona fide benefit plan (a "BFBP"). We would strongly encourage the Commission to re-propose the regulations to align the definition of a BFBP so that it is consistent with the definition used by the Department of Labor and also address the following:

1. When a BFBP is basing its terms on underwriting associated with a wellness program;
2. How a BFBP classifies risks for purpose of the safe harbor; and
3. How a BFBP should administer the risks associated with its wellness program.

H. Eliminate the "particular benefit packages" and "extent of benefits" proposed regulations language from the definition of "voluntary".

The definition of voluntary in the proposed regulations under section 1630.14(d)(2)(ii) states that a health program is voluntary only if it "Does not deny coverage under any of its group health plans or particular benefits packages within a group health plan for non-participation, or limit the extent of benefits (except as allowed under paragraph (d)(3) of this section) for employees who do not participate".[21]

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[19] 80 Fed. Reg. 21659, 21669 (Apr. 20, 2015).

[20] See 42 U.S.C. § 12201(c)(2).

[21] 80 Fed. Reg. 21667 (Apr. 20, 2015).

Many employers routinely make a basic level of health coverage available to all employees and condition the availability of enhanced coverage on wellness program participation. The wellness program associated with these "gateway" designs may, in HIPAA terms, merely be participatory, such as requiring the completion of a HRA. Such a design is clearly permitted under the ACA regulations and prior Commission guidance as employees are eligible for a basic level of health coverage. Furthermore, as a result of the ACA Shared Responsibility requirements, basic health coverage generally reflects uniform and generous requirements associated with content and affordability.[22]

Many employees prefer these gateway designs over other incentives permitted under the proposed regulations; they can be more accepting of, and willing to participate in, a wellness program that serves as a gateway to more valuable coverage than they would be of a program incentivized by a premium differential.

Given the robust nature of today's basic level of health coverage, we do not believe that such a gateway design should be viewed as inappropriately coercive, particularly when compared to prior design approaches that refused ANY health coverage for individuals who refused to complete a HRA; employees who decline to participate in the gateway wellness program will still have access to employer-provided health coverage. In addition, as noted, many employers find such a design-based approach to be more appropriate for, and more appreciated by, employees than an approach that incentivizes employees to participate in wellness programs through monetary distinctions in premiums. Employers should be permitted to continue to offer an array of incentives that are best suited to the needs of their workforce.

I. Eliminate the redundant "reasonably designed" requirement of the proposed regulations.

The proposed regulations contain, in section 1630.14(d)(1), a requirement that is very similar to the standard under the ACA regulations for activity-only and outcome-based programs.[23] However, whenever a separate standard is enunciated but applicable to the same programs, it is inevitable that differences will creep in and complicate administration or lead to an inadvertent regulatory foot fault by an employer. As the Commission follows the ACA regulation on this topic, the Commission should adopt the ACA regulation's definition of reasonable design.

J. Adopt an effective date no sooner than January 1, 2017, begin with a good faith interpretation standard for the first year, and state that the final regulations contain no inference of applicability or a "clarification" for any period before the effective date of the final regulations.

Most ERIC members have completed, or are almost finished, with the design of their calendar 2016 wellness programs and will finish their design decisions in the next month. Final design specifications are quickly followed by (and sometimes even proceed in parallel with) drafting employee open enrollment material, programming administration and on-line enrollment systems, and training telephone representatives. It is not practical, or sometimes even possible, to change the design of wellness programs after July for the following calendar year. Given the design and administration interrelationships noted above, employers are unable to digest and respond to final regulations issued after July of 2015 for the 2016 calendar year.

As a result, ERIC requests that final regulations, when issued, apply no earlier than January 1, 2017.

Also, it has been almost 15 years since the Commission last addressed Enforcement Guidance for wellness programs under the ADA. As the proposed regulations are a significant expansion of the 2000

[22] See Treas. Reg. § 54.4980H-1 through H-6.

[23] See Treas. Reg. § 54.9802-1(f)(3)(iii) and Treas. Reg. § 54.9802-1(f)(4)(iii).

Enforcement Guidance, we urge the Commission to adopt a good faith compliance standard for the first year of the final regulations. This standard should focus on encouraging understanding of the new rules and helping employers come into compliance—not on bringing lawsuits or charges. Finally, ERIC requests that the final regulations expressly state that no inference is to be drawn from the final regulations with respect to ADA wellness program compliance before the effective date of the final regulations, although employers may rely on them at their discretion.

K. Avoid providing an exception from wellness program participation for individuals that obtain a note from a medical professional indicating they are already under care.

Employers choose to offer employees health insurance coverage to enable employees to access affordable care from a personal physician and from additional medical experts that they may need. However, this has not been enough to secure good employee health. Therefore, many employers choose also to offer employees incentives to participate in targeted wellness programs to facilitate specific health improvements. Guaranteeing payment of wellness incentives for employees under the care of a physician even if they fail to participate in the wellness program conflates the purposes of these two initiatives and will undermine the effectiveness of wellness programs.

For this reason, we do not recommend that the Commission amend the proposed regulations to deem a physician certification as sufficient to excuse employees from providing the health data required to study and improve their health.

L. Avoid providing an exception to the Commission's already stringent safe harbor for any incentive limits that may affect the complicated ACA "affordability" analysis.

The Commission should retain usage of fixed formulas for determining the maximum incentive award amount under the ADA safe harbor. Adopting a wellness program incentive limit that must be calculated on an employee-by-employee basis would be impractical. Furthermore, defining voluntariness based on the relation of an incentive to the ACA affordability threshold would provide little benefit to employees.

The ACA provides premium tax credits to certain individuals who enroll in individual coverage on a public health insurance exchange and are not offered affordable employer coverage.[24] Affordable coverage is determined as a percentage of household income.[25] Wellness program incentives are not generally scaled to household income, so they provide disproportionately greater benefits to lower income employees.

The Commission's concern about wellness incentives significantly affecting employer health plan affordability appears misplaced. The Departments have thus far excluded all wellness incentives from the affordability analysis except for tobacco cessation program incentives. As discussed above in Section I.B, we do not believe there is any policy reason under the ADA for the Commission to provide employees special protection from the prospect of tobacco usage testing.

Broad-based, fixed incentive limits like the ones described in the proposed regulations are the only viable approach for limiting incentives, and we recommend that the Commission avoid imposing a vastly complicated alternative measure based on ACA affordability.

[24] Treas. Reg. § 1.36B-2.

[25] Treas. Reg. § 1.36B-2(c)(3)(v)(A)(1).

M. Employees participating in wellness programs that include disability-related inquiries and/or medical examinations, and that are part of a group health plan, should not be required to provide prior, written, and knowing confirmation that their participation is voluntary.

ERIC recognizes the importance that wellness plans that include disability-related inquiries and/or medical examinations remain voluntary. Unfortunately, imposing a written confirmation requirement on such arrangements when they are part of a group health plan would be administratively burdensome and would not meaningfully effectuate the Commission's intent to ensure voluntariness.

Obtaining individual written confirmation would significantly increase the administrative burden associated with what are already (from an employer's perspective) complicated open enrollment procedures. In fact, it would be a step back in employer efforts to streamline enrollment processes, which are increasingly relying on simplified enrollment forms and "check the box" online enrollment mechanisms, with limited interaction between the enrollee and the employer. Asking an employee to provide an affirmative confirmation, in particular when the circumstances do not provide an opportunity to negotiate the particular terms of the program, is unlikely to be an accurate indication of voluntary participation.

Instead, a more impactful approach is to enable employees to meaningfully consider a program's terms and the consequences of choosing not to participate. ERIC members believe that wellness program communications provided to employees, such as a summary plan description, open enrollment brochure, or targeted wellness brochure, can already be expected to be sophisticated and comprehensive enough to outline all relevant issues such that employees can fully understand the scope of the wellness program and any potential impact on them should they choose not to participate. An employee's decision whether or not to participate in, or complete, the wellness program will serve as sufficient confirmation that the decision was voluntary.

N. Avoid fixing static substantive requirements for wellness program that are unnecessary to protect employees with health problems from bearing unfair costs and that would stifle wellness program design innovations.

The proposed definition of employee health program in 29 CFR Section 1630.14(d)(1) and the interpretive guidance provide a sound framework for ensuring that wellness programs do not result in unfair cost-shifting to disabled employees. As the Departments have recognized,[26] there is currently no universally agreed upon framework for successful wellness programs. Varied approaches have proven successful in varied circumstances. Limiting the development of successful designs by locking employers into any specific best practices would constrain employer flexibility to design successful choices for their workforces and would undoubtedly stymie the development of innovative designs and practices in the future. Accordingly, while we share the Commission's desire to prevent inadvertent cost-shifting to less-able employees, we recommend that the Commission not impose any further standards or requirements on wellness programs at this time.

O. Do not impose ADA limits or requirements on incentives that may be offered for wellness programs outside of a group health plan.

It is important for the Commission to understand that it will be technically difficult, if not impossible, to impose limits on wellness program incentives offered outside of a group health plan. This is

[26] Departments of Labor, HHS and Treasury, FAQs About Affordable Care Act Implementation (Part XXV), Q/A-1 (April 16, 2015) ("The determination of whether a health-contingent wellness program is reasonably designed is based on all the relevant facts and circumstances. The wellness program regulations are intended to allow experimentation in diverse and innovative ways for promoting wellness.")

due, in large part, to the impossibility of establishing the cost of the benefit associated with the wellness program and, hence, the denominator for calculating a 30% limit on the incentive. Unlike the uniform cost of a health plan, the cost of a benefit such as a gym membership varies widely by location and even within a single location. Without a uniform and consistent national denominator, it is administratively impossible to define a permissible incentive limit. As such, the Commission should not adopt limits or other financial requirements associated with wellness programs offered outside of a group health plan. If the Commission adopts such limits, they will have the practical impact of ending incentives for such wellness program components.

II. Coordination of Related Health Care Regulations

The effectiveness of these proposed regulations in spurring wellness program expansion and improvement is hampered by roadblocks that appear elsewhere in the regulatory landscape. An ongoing concern is the counterproductive restrictions that the Genetic Information Nondiscrimination Act ("GINA") places on wellness programs. Therefore, ERIC suggests that the Commission end GINA prohibitions on use of incentives in requests for family medical history information and use of family medical history in disease management outreach.

Restrictions on family medical history information under the current GINA Title I regulations unnecessarily frustrate efforts to improve and expand wellness and disease management programs. Family medical history information can be a critical tool for identifying and implementing appropriate preventive measures so that plan participants can avoid health problems that have a genetic component.

Currently, rewarding a participant's completion of a health risk assessment that requests family medical history is regarded as prohibited "underwriting" even if the genetic information is requested after enrollment and has no effect on the individual's coverage.[27] Experience has shown that without encouragement, many participants who would benefit from participation in a disease management program will never enroll.[28] Accordingly, an incentive given for the completion of a health risk assessment is among the most common types of wellness programs.[29] GINA should be interpreted to permit an employer group health plan to reward participants for providing family medical history, as long as the plan does not use this information as the basis to deny enrollment, or make any other adverse benefit-related decisions.

GINA should also be interpreted to apply to actual family medical history of the participant—and nothing else. This means that the "family medical history" of the participant refers only to information associated with lineal ascendants and blood siblings, and not to that of a spouse.

A group health plan that offers a disease management program often will be most effective if it can utilize family medical history to identify individuals who might benefit from an illness-specific program. If a plan uses family medical history, however, to determine the participant's eligibility for the disease management program, the interim final regulations under Title I of GINA treat the plan as collecting genetic information for prohibited "underwriting purposes." ERIC urges the Commission to make clear that a plan will not be deemed to collect genetic information for "underwriting purposes" when such plan uses the information to identify participants eligible for additional benefits provided on a voluntary basis.

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[27] *See* Treas. Reg. § 54.9802-3T(d)(3), Example 1.

[28] Mattke, *supra* note 10, at 20 (noting that only a third of plans achieved HRA participation rates above 50%).

[29] Kaiser Family Foundation, *supra* note 5, at 180 (noting that 63% of firms with 200 or more employees incentivize HRAs).

Preventing plans from incentivizing participants for sharing family medical history and from targeting disease management programs based on family medical history does not protect individuals from discrimination; rather, it increases the risk that preventable illnesses will fail to be detected and avoided.

ERIC appreciates the opportunity to provide these comments on the notice of proposed rulemaking. If you have any questions concerning our comments, or if we can be of further assistance, please let us know.

Sincerely,

Annette Guarisco Fildes
President & CEO
The ERISA Industry Committee