The ERISA Industry Committee

April 8, 2011

Submitted through the Labor Department's eRulemaking Portal:
http://www.dol.gov/regulations/regreview.htm

e. christi cunningham
Associate Assistant Secretary for Regulatory Policy
U.S. Department of Labor
200 Constitution Avenue, NW
Room S-2312
Washington, DC 20210

Re: Retrospective Review under Executive Order 13536

Dear Ms. cunningham:

We are writing on behalf of The ERISA Industry Committee ("ERIC") to respond to the Department of Labor's request for information on ways in which the Department can reduce the burden associated with its regulations. The Department's request reflects the President's Executive Order 13536, "Improving Regulation and Regulatory Review," which requires federal agencies to review existing regulations to determine how they can be made more effective or less burdensome.

ERIC's Interest in the Retrospective Review

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 provide comprehensive retirement, health, and other benefits directly to tens of millions of active and retired workers and their families. These benefit plans are extensively regulated by the Department of Labor's Employee Benefits Security Administration, as well as by other federal agencies.

ERIC's members strongly support the goal of protecting workers' benefits. In order to compete in a global economy, however, ERIC's members must limit the resources they spend on their benefit programs.

As federal regulations become more complex and pervasive, ERIC's members spend a larger and larger portion of their available time, effort, and financial resources complying with federal requirements. ERIC's members believe that these resources often would be better spent preserving and enhancing workers' benefits. Accordingly, ERIC's members have a vital interest in proposals that would reduce this regulatory burden and its associated costs.

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The Department's request for information originally gave the public only nine business days in which to respond. The Department subsequently extended the comment deadline by an additional six business days, to April 8. ERIC has not had sufficient time to review the request with its members and to develop a comprehensive response. ERIC hopes that the comments provided in this letter will be helpful as the Department undertakes its retrospective review. ERIC reserves the right to submit additional comments in the future.

Comments on Regulations

ERIC's comments relate to regulations and other guidance under 29 C.F.R. Subtitle B, Chapter XXV.

1. Permit electronic disclosure without affirmative consent (29 C.F.R. § 2520.104b-1).

If an individual does not have access to an employer's electronic systems as an integral part of the individual's duties, the employer may provide required disclosures electronically only if the individual affirmatively consents. It is not practical for large employers to obtain, store, and administer electronic consents from tens of thousands of workers, retirees, alternate payees, COBRA beneficiaries, and other individuals. Accordingly, the Department's restrictions make electronic disclosure effectively unavailable to large employers.

On April 7 the Department published a separate request for information soliciting comments on ways to make the conditions for electronic disclosure less burdensome. ERIC strongly supports this initiative. Any effort to streamline regulatory disclosure requirements must make efficient use of modern technology. Electronic disclosure should not require affirmative consent: instead, participants should be permitted to opt out of electronic disclosure if they wish to receive paper copies of disclosure. ERIC expects to have specific comments in response to the request for information on electronic disclosure requirements.

2. Clarify that most employee assistance programs are not group health plans.

Many employers offer employee assistance programs in addition to their comprehensive group health plans. The Department has never provided formal guidance concerning the status of these programs, but it has issued advisory opinions indicating that the programs will be treated as group health plans if they offer limited counseling benefits.

Employee assistance programs are not designed to offer comprehensive medical benefits. It is not possible for these programs to meet the extensive new mandates for

group health plans under the mental health parity rules, the Affordable Care Act, and other recent legislation. The Department should make clear that most employee assistance programs will not be treated as group health plans.

3. Resolve the conflict between the fee disclosure requirement for participant-directed plans and the SEC's summary prospectus requirement (29 C.F.R. § 2550.404a-5(d)(1)(iv)(A)*(3)*).

The Department's fee disclosure requirements for participant-directed plans require the plan administrator to disclose a designated investment alternative's total annual operating expenses expressed as a dollar amount for a $1,000 investment, assuming no returns. In contrast, the Securities and Exchange Commission's summary prospectus rules for mutual funds require the fund to disclose annual operating expenses expressed as a dollar amount for a $10,000 investment, assuming a 5% annual return.

Many participant-directed individual account plans offer mutual funds as investment options and must provide disclosure that satisfies the prospectus requirements. It is confusing to plan participants and burdensome for plan administrators to disclose operating expenses in two different ways for the same funds. The Labor Department should conform its disclosure requirement to the Securities and Exchange Commission's prospectus rules, so that the same disclosure will satisfy both rules.

4. Increase the Form 5500 reporting thresholds for non-monetary compensation (Instructions to Form 5500 Schedule C).

Plan administrators are required to report non-monetary compensation received by plan service providers unless an individual gift is valued at less than $50 and the aggregate value of gifts from one source is less than $100. No gift may be ignored unless its value is less than $10. These reporting thresholds should be increased substantially. The burden of collecting and reporting information for business meals and other incidental forms of non-monetary compensation far exceeds any possible benefit associated with the reporting requirement.

5. Coordinate regulations affecting workplace wellness programs under Titles I and II of GINA.

Although the Departments of Labor, Treasury, and HHS, as well as the EEOC, have issued regulations explaining how the Health Insurance Portability and Accountability Act ("HIPAA"), and/or Genetic Information Nondiscrimination Act ("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 that regulations under Title I (issued by the Departments of Labor, Treasury, and HHS) and Title II of GINA (issued by the EEOC) be coordinated to 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.

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 under Title I, however, appears to apply 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.

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 Department of Labor to make clear that a plan will not be deemed to collect genetic information for "underwriting purposes" when the plan uses family medical history as one basis to identify participants eligible for a disease management program or similar voluntary program.

6. Change the regulations under Title I of GINA to permit employers to give a financial incentive to workers and their families to complete a health risk assessment that requests family medical history.

Congress has addressed the status of wellness incentives in the Affordable Care Act. 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). This significant increase in the level of permitted incentives is a clear acknowledgment of the valuable role that incentives play in encouraging employees and their families to participate in wellness programs and work toward achieving their wellness goals.

Under the GINA Title I regulation, however, the Department of Labor (along with Treasury and HHS) has taken the position that an employer is prohibited from offering *any* financial incentive for an employee to provide genetic information, including family medical history. ERIC strongly disagrees with this interpretation of Title I of GINA.

ERIC further believes that the Department'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 Department to reconsider its interpretation of Title I and to permit employers to give a financial incentive to workers and their families to complete a health risk assessment that requests family medical history.

7. The preventive services regulation under the Affordable Care Act must be coordinated with the regulations under the MHPAEA so that a plan that does not otherwise cover mental health and substance use disorder benefits does not become subject to the MHPAEA merely because it provides mental health or substance use disorder benefits in accordance with the preventive services regulation.

Under the Affordable Care Act, non-grandfathered group health plans must provide preventive benefits for evidence-based items or services in three categories. One of these categories is preventive benefits that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force (the "Task Force"). Many of the Task Force recommendations require plans to provide counseling for various conditions, including alcohol misuse, tobacco use, obesity, and sexually transmitted diseases. We assume that some of these counseling services would be considered mental health or substance use disorder benefits under the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (the "MHPAEA").

For example, alcohol abuse is considered a substance use disorder under the current version of the International Classification of Diseases, with the result that counseling for alcohol misuse is a substance use disorder benefit subject to the parity requirements of the MHPAEA. The statutory provisions amended by MHPAEA specifically provide that they do not require group health plans to offer mental health or substance use disorder benefits. If a plan sponsor chooses to offer these benefits, however, then the plan must ensure that any limitations imposed on the mental health

or substance use disorder benefits are no more restrictive than the predominant treatment limitation applied to substantially all medical and surgical benefits in the same classification.

Compliance with these parity requirements is a significant and costly administrative burden and often entails a substantial redesign of the plan itself. Nothing in ACA suggests that Congress intended to overturn the provision of the MHPAEA that gives employers the freedom to choose whether to offer mental health or substance use disorder benefits and, thus, whether they will be subject to the parity restrictions of MHPAEA. If the preventive care provisions of ACA require plans to provide coverage for any mental health or substance use disorders, however, plan sponsors will no longer be able to choose whether they wish to subject their plans to the parity requirements. Instead, the plan sponsors will be forced not merely to cover substance use disorder benefits that are classified as preventive, but also to provide these benefits on a basis that is in parity with the plan's medical and surgical benefits.

We request that the Department issue guidance to provide that a plan will not become subject to the parity requirements of MHPAEA merely because it provides a mental health or substance use disorder benefit in compliance with the regulation's recommended preventive services. This exclusion would preserve the MHPAEA's intent not to force employers to provide benefits that will be subject to the parity requirements.

8. The Department should encourage the United States Preventive Services Task Force to accept representatives from the employer benefits community as members and/or should create an advisory task force that will give group health plans a voice in delineating the recommended preventive care mandates.

As noted above, under the Affordable Care Act, non-grandfathered group health plans must provide preventive benefits for evidence-based items or services in three categories. One of these categories is preventive benefits that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force (the "Task Force").

This Task Force consists mainly of health care providers and other professionals concerned with the delivery of health care. The Task Force does not include representatives of the employer group health plans that must cover these services. ERIC has nominated four individuals who have significant expertise with employer benefits to serve on this Task Force. We urge the Department to work with us to ensure that individuals with employer expertise are in fact able to play a formal role on this Task Force.

If membership in the Task Force itself is not possible, it would be extremely helpful if representatives of group health plans could have a voice in the process that will identify new items and services that must be covered as "recommended preventive services" and that will determine when items and services should be removed from the mandated coverage list on an ongoing basis. These representatives could help translate the provider recommendations into terms that plan sponsors can understand with respect to the precise benefits that must be offered. In addition, the employer plan representatives have insights into participant behavior and plan administrative issues that would be helpful to the providers as they develop the preventive care recommendations.

Accordingly, we urge the Department either to help the plan sponsor community achieve formal representation on the Task Force or to create an advisory task force or other forum through which group health plan representatives can participate – on an ongoing basis - in the process of identifying and delineating the items and services that will be included in the recommendations for preventive care.

9. Two standards in the "Interim Final Regulations Relating to Internal Claims and Appeals and External Review Processes" do not comply with Executive Order 13563; they should be changed in this regulation and should be significantly modified before being included in upcoming regulations. These two standards are the "culturally and linguistically appropriate" rule and the "strict adherence" standard.

Executive Order 13563 directs federal departments and agencies to develop and submit a preliminary plan under which they will periodically review their existing significant regulations. This Executive Order outlines several "guiding principles", including:

- Agencies must consider costs and benefits of its regulations and choose the least burdensome path;
- Agencies must attempt to coordinate, simplify, and harmonize regulations to reduce costs and promote certainty for businesses and the public; and
- Agencies must consider approaches that maintain freedom of choice and flexibility.

The strict adherence standard: The interim final regulation on claims and appeals states that if a plan fails to *strictly* adhere to *all* requirements of the internal claims and appeals process, the claimant is deemed to have exhausted his or her right to internal review. In this circumstance, the claimant may proceed straight to external review or to court, regardless of whether the plan administrator has substantially complied with the internal claims and appeals procedure, and regardless of the magnitude of the error. If the claimant chooses to bypass further review and proceed straight to court, the regulations, contrary to well settled existing law, direct the court

to give no deference to the plan administrator's decision, but to assume instead that the claim has been denied on review "without the exercise of discretion by an appropriate fiduciary."

We urge the Departments to moderate this "strict compliance" rule, which otherwise will substantially undermine the internal claims and appeals process, and not to incorporate such a rule in future regulations. The interim final regulations impose standards for internal claims and appeals that are so demanding that it is highly unlikely that even large group health plans will satisfy the standards without some small and inconsequential error, such as a typographical error. Such a high bar would be similarly inappropriate for rules in other areas affecting employee benefits.

A strict adherence standard violates nearly all of the guiding principles set forth in Executive Order 13563. Such a standard does not represent the "least burdensome path", nor does it reduce costs or promote certainty. And it certainly by no means is an approach that maintains freedom of choice and flexibility for plan sponsors.

We urge the Department instead to establish a compliance standard in the claims and appeals regulation, as well as in any future regulations, that is reasonable and where the consequences of a violation are appropriate to the transgression. A severe penalty should never be applied to a de minimis error, especially when no participant has been harmed in the process. We instead would encourage the Department to set a compliance bar that would apply severe penalties (including the $100/day excise tax) only where there has been a material violation of the rule or where a participant's rights have been significantly compromised by a plan's failure to comply with a regulation.

The "culturally or linguistically appropriate" standard: The claims and appeals interim final regulation requires plans to provide relevant notices in a culturally or linguistically appropriate manner if at least a threshold number of participants are literate only in the same non-English language. For plans with 100 or more participants, the threshold is the lesser of 500 participants or 10 percent of participants. If the applicable threshold is met, the plan must (1) include a statement in the English versions of all notices offering to provide the notice in the non-English language, (2) provide the notice in the non-English language upon request by any claimant and automatically provide any subsequent notices to that claimant in the non-English language, and (3) to the extent that plans provide a customer assistance process, provide this assistance in the non-English language.

These requirements will impose extraordinary costs and administrative burdens on group health plans that will generally far exceed the benefits they will confer on non-English-speaking participants. In some cases, the requirements will have the unintended effect of reducing the services available to all participants. At a minimum,

this standard does not follow the least burdensome path to inform non-English-speaking plan participants of their benefit rights, nor can it even remotely be categorized as an approach that maintains freedom of choice and flexibility.

ERIC recommends that these requirements be changed to achieve a better balance between the needs of plan participants and the costs and practical realities of plan administration. First, ERIC recommends changes in the threshold tests to make them more understandable and workable. Second, ERIC strongly recommends that plans not be required to issue individualized benefit notices in non-English languages. Third, ERIC urges the Department to eliminate the requirement that plans provide customer assistance in non-English languages.

ERIC also recommends that any future regulations incorporating a "culturally or linguistically appropriate" standard follow these suggested modifications.

10. Except in rare and unusual circumstances, regulations should initially be published only in proposed form, not as interim final regulations. Further, regulations should be effective on a prospective basis only, and the effective date should be no earlier than at least a year after they are published in final form.

All employers, and large employers in particular, face a number of significant administrative and practical challenges as they modify their plans to comply with new rules and regulations. Further, in some cases employers may potentially face an excise tax of $100 per day for each covered individual until the plan may be brought into compliance.

Complying with new rules and regulations affecting employee plans is an inordinately difficult and time-consuming process involving strategic design issues, payroll and benefits systems modifications, administrative procedures overhaul, and significant and fundamental communications challenges. Many of these necessary modifications may not be addressed before others have been put in place. In the case of large plans, significant changes require many months to implement in an efficient and effective fashion.

In recognition of these difficulties, ERIC recommends that, as a rule, regulations be initially issued in proposed form so that the Department may realize the benefit of public comment, particularly from those entities that will bear the burden of implementing (and paying the cost of) the new rules.

ERIC also urges the Department to provide a reasonable period of time for plans to come into compliance with new rules and regulations as well as for plans to comply with final versions of, or changes to, previously proposed regulations.

At the very least, regulations that encompass a rule that is more restrictive than an earlier version should be effective no earlier than the first plan year that begins at least 12 months after the interpretation is published in final form, following a period for public comment. For any period before the new interpretation becomes effective, the Department should make clear that good-faith compliance is sufficient. Such an approach, in accordance with Executive Order 13563, would most effectively balance regulatory goals with the needs of plan sponsors, choosing the least burdensome path between realizing the benefits of the regulations with the costs and other burdens to those who actually provide the benefits.

11. The Department should create a regulatory review group consisting of large employers and other interested parties that would meet on an ongoing basis to periodically assess regulations published by the Department.

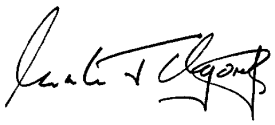
In its March 21, 2011 RFI, the Department states that as a first step in developing its regulatory review plan, it is requesting public comment on how the Department can increase the effectiveness of its significant regulations while minimizing the burden on regulated entities.

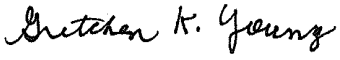
ERIC believes that much could be gained if large employers, and other interested parties, were engaged on an ongoing basis in the Department's regulatory review process. We recommend that a group representing large employers and others be constituted to meet on a regular and periodic basis to review regulations that have been published during the previous period, perhaps on a quarterly basis. The point of the review would be to assess how the regulations published during this period comport with the stated goals of Executive Order 13563.

ERIC will make a similar recommendation in response to the RFIs published by other Departments. In addition, ERIC believes that the regulatory review process could be greatly enhanced, and many inter-Department complications minimized, if there were a larger regulatory review group – consisting of members from each of the individual Departmental review groups – that was charged with the responsibility for determining the need for coordination across Departments and for assessing the overall ongoing compliance with, and suitability of, the goals set forth in the Executive Order. This umbrella group might best be associated with OMB, which already has responsibility for reviewing Departmental regulations.

ERIC appreciates the opportunity to provide comments on the retrospective review of the Department's regulations. If the Department has any questions concerning our comments, or if we can be of further assistance, please let us know.

Sincerely,





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