The Honorable Timothy Geithner  
U.S. Department of the Treasury  
1500 Pennsylvania Ave., NW  
Washington, DC 20220

The Honorable Kathleen Sebelius  
U.S. Department of Health and Human Services  
200 Independence Ave., SW  
Room 639 G  
Washington, DC 20201

The Honorable Hilda Solis  
U.S. Department of Labor  
200 Constitution Ave., NW  
Washington, DC 20210

The Honorable Stuart Ishimaru  
Acting Chairman  
U.S. Equal Employment Opportunity Commission  
131 M Street, NW  
Washington, DC 20507

Cc:  Robert Kocher, MD, Special Assistant to the President, National Economic Council, The White House  
Ezekial Emanuel, MD, Special Advisor for Health Policy, Office of the Director, Office of Management and Budget

RE:  Interim Final Regulations implementing the Genetic Information Nondiscrimination Act (GINA)  
DOL RIN 1210-AB27  
CMS-4137-IFC  
REG-123829-08

To Whom It May Concern:

Express Scripts appreciates the opportunity to comment on the interim final regulations implementing the Genetic Information Nondiscrimination Act (GINA). Express Scripts is one of the nation’s largest pharmacy benefit management companies with nearly 80 million lives. We are also a large employer with over 12,000 employees located throughout the United States.

We applaud the legislative intent of protecting employees from adverse consequences of having an employer know the results of direct or implicit genetic information. We believe this is a positive addition to the goal of encouraging participation in health screening and the proactive management of identifiable risk factors. Protecting the confidentiality of such data from employers fits well with those aspects of HIPAA that restrict
the sharing of personal health information (PHI) to only those parties with a defined and appropriate need for the information.

Over the past few years, an increasing number of employers have begun offering their employees a confidential health risk assessment, the employee-specific results of which are known only to those care providers who have been tasked with actively supporting and managing the identified risks. This information is held in strict compliance with HIPAA regulations and is very often made available only to specific care providers or vendors, very often actually external to the employer. Following these provisions enables employers to promote health screening, empower health advocates to support and manage identified risk factors, improve health outcomes, and simultaneously guard employee confidentiality concerns.

One example of the value brought by support for these screenings is a 46 year-old employee of our company who was found to have a very high family risk of diabetes. The screening led to a recommendation for multiple changes in her diet and increased exercise. She reports that the personalized nature of this advice is what got her to make these changes. Now, over a year later, she has lost over 25 pounds and exercises several times each week. As a result of the health risk assessment, her risk of developing diabetes with all of its complications has dropped dramatically.

I only know this story because she was so pleased with this success that she came forward and shared it with me. Otherwise, as her employer operating under current regulations such as HIPAA, I would not have had access to any of this information.

We are concerned with the provisions of the interim final regulations under which group health plans and insurers will be generally prohibited from offering any reward in return for “collection of genetic information” (defined to include family medical history through a health risk assessment (HRA). Additionally, the HRA could not be used to enroll an individual in a disease management program, regardless of whether a reward is offered in connection with an HRA. This has the potential to undermine employers’ interests in helping their employees improve their health while protecting PHI.

We have already begun to see early fall-out from just the posting of these interim final regulations. In response to these and other impending restrictions, Express Scripts’ external vendor for health risk assessments has had to alter their questions, removing anything about family history. This is true even though our process is set up to blind the employer from the results of any individual employee’s responses. As a result, our ability to tailor our interventions and offer appropriate outreach to those with elevated modifiable risks is compromised.

We urge the Administration and the various agencies to reconsider this policy and allow for incentives to encourage employees to participate in comprehensive health risk assessments, and to include questions regarding family history when appropriately shielded from identifying specific employees. The impact the regulations will have on wellness programs is contrary to the goal of improving health outcomes.

Thank you for your consideration of these important views.

Sincerely,

Edmond S. Weisbart, MD, CPE, FAAFP
Chief Medical Officer, Medical Affairs
Express Scripts, Inc.