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January 5, 2010

Submitted Via the Federal E-Rulemaking Portal: http://www.regulations.gov.

U.S. Department of Labor
Employee Benefits Security Administration
Office of Health Plan Standards and Compliance Assistance
Room N-5653
200 Constitution Avenue, N.W.
Washington, D.C. 20210
Attention: RIN 1210-AB27

U.S. Department of Health and Human Services
Centers for Medicare & Medicaid Services
Attention: CMS-4137-IFC
P.O. Box 8017
Baltimore, Maryland 21244-8010

U.S. Department of the Treasury
Internal Revenue Service
Attention: CC:PA:LPD:PR (REG-123829-08)
Room 5205
P.O. Box 7604
Ben Franklin Station
Washington, D.C. 20044

Re: Interim Final Rules Prohibiting Discrimination Based on Genetic Information in Health Insurance Coverage and Group Health Plans
RIN 0938-AP37

Dear Sir/Madame:

UnitedHealthcare appreciates the opportunity to submit the following comments on the Interim Final Rules Prohibiting Discrimination Based on Genetic Information in Health Insurance Coverage and Group Health Plans.

UnitedHealthcare and its affiliated companies serve more than 70 million Americans each year across the country. Partnering with more than 650,000 physicians and other care providers, 5,200 hospitals, 80,000 dentists, and 65,000 pharmacies in all 50 states, we touch nearly every aspect of health care delivery and financing.

Along with our parent company, UnitedHealth Group, we supported the enactment of the Genetic Information Nondiscrimination Act (GINA.) UnitedHealthcare continues to believe GINA was historic legislation that will protect Americans from the potential misuse of genetic information in health care and employment.

The focus of this comment is on the interim rule's expansive definition of underwriting purposes and its harmful impact on wellness programs, particularly programs that use family health information to understand health risks and prevent disease. Before we address wellness programs, however, we will discuss other provisions of the rule that allow group health plans and health insurers to collect and use genetic information when it is medically beneficial.

I. Use of Genetic Information for Claims Payment and Determinations of Medical Appropriateness

The rule provides guidance to group health plans and health insurers on when they may request genetic tests and collect genetic information necessary to make decisions regarding claims payment. Genetic tests and other genetic information, including family history information, are necessary sometimes to determine if a course of treatment or benefit is medically appropriate. The rule provides that plans and health insurers may only request the minimum necessary amount of genetic information for this purpose.

We commend the Departments for including these provisions and the accompanying examples as part of the interim rule. By providing this guidance, covered members will be assured that GINA will not disrupt their access to drug therapies and other specialized treatments that are medically appropriate to individuals with certain genetic characteristics. It is also recognition that GINA does not prevent plans and health issuers from collecting and using genetic information post-enrollment (and outside of underwriting process) when it is necessary for the provision of benefits to covered members.

II. Definition of "Underwriting Purposes" Exceeds Legislative Mandate

GINA, the statutory enactment, contains a definition of underwriting purposes that includes activities such as eligibility determinations, enrollment, computation of premiums, application of pre-existing condition exclusions, or other activities related to the creation, renewal or replacement of a contract of health insurance or health benefits.

Unfortunately, the interim rule's definition of "underwriting purposes" goes well beyond the statutory definition by adding language (the parentheticals) to sections (ii)(A) and (B) of the definition which broadly expands the definition of underwriting purposes to include many wellness program activities. [1]

The additional parenthetical language encompasses a much broader scope of activities than what was contemplated by the statute. Specifically, the inclusion of "changes in

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[1] Proposed 29 C.F.R. § 2590.702-1(d)(1)(ii)(A) and (B)

deductibles or other cost-sharing activities such as completing a health risk assessment or participating in a wellness program," as well as "discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program" result in a definition that greatly exceeds the scope of underwriting contemplated by the statute.[2]

There is no legal support in GINA, or its legislative history, for this expansion of the definition of underwriting purposes. The legislative history of Title I of GINA expressly contemplates the use of incentives by wellness programs. While the Senate Report makes clear that Congress was concerned with the use of wellness programs "as a subterfuge to discriminate in insurance premiums based on genetic information," the Report shows that Congress approved of the use of incentives by wellness programs, including the payment of "rebates" to non-smokers.[3]

The Senate Report also shows that Congress was able to distinguish between improper underwriting on the basis of genetic information and the appropriate use of incentives (e.g. payment of rebates) by wellness programs to encourage healthy behavior (non-smoking.) UnitedHealthcare respectfully requests that the Departments follow Congress' lead and make a similar distinction in the interim rule for wellness programs that use incentives. We submit that this provision could be modeled on the claims payment or medical appropriateness provisions in the interim rule that allow for the use of family history information when it is used to provide benefits to covered members.

Incentives Can Drive Favorable Health Outcomes

Wellness programs are designed to encourage individuals to modify behaviors to live healthier lifestyles, which may ultimately reduce health care costs related to unhealthy lifestyles. They have been widely adopted by employer groups. In 2008, 77 percent of employers offered health and wellness programs and more than half of those currently without programs plan to add them, many within 6 to 12 months.[4]

When used appropriately, use of incentives by wellness programs can drive employee engagement. In one recent study, it was shown that use of a $100 reward increased completion rates for a health assessment from 10% to 85%. The same study showed that a $50 reward increased participation in health coaching from 3% to 30%.[5] Wellness programs do not, however, provide instant gratification. It takes time to change an individual's behavior and instill a new healthier lifestyle. As the above data shows, use of carefully selected incentives can increase the likelihood that program participants will benefit from a wellness program.

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[2] Id.

[3] S. Rep. No. 48, 110th Cong., 1st Sess., at page 20 (2007)

[4] Optum Health, *White Paper: Best Practices for Creating Successful Wellness Programs* (2009)

[5] Id. Results from a 2007 Uniprise client study where employer groups representing nearly 40,000 members were analyzed and compared to a book of business results for health assessment and online health coach completion statistics.

III. Sound Health Policy Supports the Use of Family Medical History Information by Wellness Programs

It has been well documented that family medical history is an important factor in determining a person's risk of developing many common chronic conditions and the steps to prevent it. The Centers for Disease Control and Prevention states on its website that: "Family health history is a useful tool for understanding health risks and preventing disease in individuals and their close relatives. Family health history information may help health care providers determine which tests and screenings are recommended to help family members know their health risk." [6]

Family history is integral to not only the early identification of a need, but also for ensuring that health management programs are personalized to meet the specific health need of that individual. This plays out across a broad range of personalized health services including women's health, cancer, coronary artery disease, diabetes, mental health and substance abuse, weight management and tobacco cessation. Family history is also vitally important to children's health. Family history and early risk identification is critical to preventing chronic disease in children (oral disease is an important example), getting them needed care quickly and preventing what may potentially be a lifetime of poor health.

This type of risk factor information can be uncovered by the kinds of health risk questions used to target candidates for our preventive wellness programs or as part of health coaching. Access to family history is critical to the work we do to help people live healthier lives. It not only helps identify those who must take greater precaution, but it can also provide us with insights about the strategy and steps that should be taken to help people achieve their prevention goals.

(a) Family Medical History Informs Genetic Risk and Social Risk

Research has shown that family history informs not only physical health, but behavioral health as well. This is important because data shows that 50 percent of an individual's health status is a result of behavior, and 75 percent of health care costs may be prevented, delayed or curtailed through lifestyle modifications. [7]

Thus, family medical history does not just demonstrate genetic risk factors, but social risk factors as well. Social support is one of the most important factors in predicting the physical health and well being of everyone, from childhood through old age.[8] Nurses and wellness program professionals should be encouraged to carefully examine the social risks of disease that are such an important part of family medical histories.

[6] http://www.cdc.gov/genomics/famhistory/index.htm) (Dec. 2009)
[7] Institute For The Future, Centers for Disease Control and Prevention (Dec. 2009)
[8] *Relations between Social Support and Physical Health*, Corey Clark (Nov. 2005)

(b) Impact on Smoking Cessation and Other Behavioral Health Programs

The medical profession knows that if both parents smoke, for example, a teenager is more than twice as likely to smoke as a teen whose parents are both non-smokers. Even in households where only one parent smokes, teens are more likely to start smoking.[9] Also, when children grow up in families with poor eating habits and sedentary lifestyles, they are significantly more likely to become overweight or obese as young adults.[10]

UnitedHealthcare believes that wellness program participants are entitled to have frank discussions with dedicated nurses and other health care professionals that include all relevant health information, including their family history information. In addition, nurses and health coaches should not have to fear that they will inadvertently violate the interim rule when they discuss a family's history of smoking, drinking and obesity and use this social information to help participants make more informed health choices.

We believe that the definition of underwriting purposes in the rule must be modified so that it will not thwart the efforts of nurses and health coaches to engage in open and constructive dialogue with program participants, especially in the area of behavioral health.

(c) Impact on Program Participants with Chronic Conditions

UnitedHealthcare is concerned that the interim rule will affect the ability of plan sponsors to use family medical history information to tailor wellness programs that drive favorable health outcomes. In particular, we are concerned that the interim rule will prevent plan sponsors from designing wellness programs that seek to provide additional benefits to persons with chronic conditions to help them manage their diseases. About 133 million Americans—nearly 1 in 2 adults—live with at least one chronic illness. Chronic conditions account for as much as 75 percent of overall health care spending.[11]

Wellness programs with incentives have been designed to reward persons with chronic conditions. Our experience shows that we have been able to reduce chronic health care expenditures by as much as three times as compared to non-participants. In addition, we have seen a reduction in hospital admissions of 4 percent and a decline of emergency room visits of 7 percent among program participants.[12] These are significant savings that, if carried out on a broad scale, may have the potential to greatly reduce this nation's health care spending and improve health outcomes.

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[9] rex.nci.nih.gov/NCI_Pub_Interface/Smoking_Facts/about.html. (Dec. 2009)

[10] Teen obesity and family environment, (Aug. 15, 2005), www.medicalnewstoday.com/articles/29129.php.

[11] *Chronic Diseases: The Power to Prevent, the Call to Control*; National Center for Chronic Disease Prevention and Health Promotion, Improving Health and Quality of Life for all People, Centers For Disease Control and Prevention; (2009)

[12] *Consumerism in Health: Insights From Experience*, UnitedHealthcare (2009)

IV. The HIPAA Wellness Rule Provides a Workable Framework for Wellness Programs with Incentives

Rules governing wellness programs were proposed in Jan. 2001 and finalized in Dec. 2006. UnitedHealthcare believes that the issuance of the final "HIPAA wellness rule" appropriately encouraged the formation of wellness programs with limited incentives. [13] We believe that the HIPAA wellness rules encouraged the sponsorship of wellness program sponsorship and have led to better health and reduced spending by health plans.

The growth in wellness programs can be attributed to a range of factors. The data shows that wellness programs with HIPAA compliant incentives are effective in encouraging health and reducing health care expenditures by group health plans. Additionally, UnitedHealthcare believes that sponsorship of wellness programs increased during the last decade, in part, because the federal government provided clear regulatory guidance to plan sponsors.[14]

GINA and the interim final regulations issued by the Departments are intended to help individuals achieve better health outcomes, not harm them. UnitedHealthcare has designed and administered wellness programs with incentives covering millions of participants for more than a decade. We have measured the results of these programs in terms of employee engagement and cost reduction, particularly with respect to behavioral health and chronic conditions. Given this experience, we are convinced that by preventing wellness programs from having access to family medical history, the Departments will do far more harm than good.

We respectfully request that the Departments revise the interim rule to modify the definition of underwriting purposes to make it consistent with the statute by deleting the new "parenthetical" language that includes wellness program activities as part of the definition. This is a modest revision to the rule that will make it consistent with the statute and assure participants in wellness programs, as well as their nurses and health coaches, that they will have access to the full range of medical information, including their family medical history information, as they work to improve their health by making medically appropriate decisions with respect to their care.

V. Collection of Family Medical History Information on Application Forms

Finally, we wish to address a technical issue that arises in the context of the application forms used by health issuers. The definition of genetic information under the interim rule includes not only information about an individual's genetic tests, but also information about the manifestation of a disease or disorder in family members of the individual.

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[13] Nondiscrimination and Wellness Programs in Health Coverage in the Group Market regulations (71 Fed. Reg. 75013-75055, Dec. 13, 2006)

[14] See EBRI, *Fundamentals of Employee Benefit Programs*, 2005, indicating an 88 percent increase in wellness programs between 1995 and 2001.

As you know, health insurers routinely use application forms to obtain basic identifying information about the applicant, as well as information about diseases or disorders that have been manifested in the individual. In the case of family or dependent coverage, health insurers may obtain information about manifested diseases or disorders in the family members (or other dependents) of the individual that also have applied for coverage under the same policy.

While GINA prohibits the use of PHI that is genetic information for underwriting purposes, we do not believe that the Departments intended to broadly prohibit the use of family (or dependent) application forms by health insurers or the collection of family history information on these application forms.

We respectfully request that HHS clarify in its final regulation that the use of family/dependent application forms to collect information about manifested diseases or disorders in family members of an applicant is not prohibited by GINA, provided that such information is only used or disclosed consistent with the GINA prohibition on underwriting purposes and with HIPAA more generally. The issuance of guidance on this point would facilitate the placement and administration of health insurance policies in both the group and individual markets in a manner consistent with GINA.

Once again, UnitedHealthcare appreciates the opportunity to comment on the interim final GINA regulations. We hope this information will assist the Departments in revising its rule in a way that conforms more closely with GINA's statutory language and encourages the use of wellness programs that make appropriate use of family medical history information. Please don't hesitate to contact Kevin Maroney of UnitedHealthcare's law department at (715) 841-6085 if you have any questions about the information in this letter. We look forward to working closely with the Departments in the future.

Sincerely,

Michael Mooney
Senior Deputy General Counsel