

February 27, 2009

Office of Health Plan Standards and Compliance Assistance
Employee Benefits Security Administration
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210
ATTN: GINA Comments

Re: Impact of GINA on Preventive Prognostic Tests in Stand-Alone Dental Plans

To Whom It May Concern:

I am writing on behalf of the Delta Dental Plans Association ("DDPA") in response to an interagency request for information by the Internal Revenue Service of the Department of the Treasury, the Employee Benefits Security Administration of the Department of Labor, and the Centers for Medicare & Medicaid Services, and Office of Civil Rights of the Department of Health and Human Services, regarding issues in connection with the implementation of the Genetic Information Non-discrimination Act of 2008 ("GINA").

DDPA represents the nation's largest and most experienced dental benefit plans consisting of 39 independent dental service corporations that operate in all 50 states, the District of Columbia, and Puerto Rico. Most of our plans are offered separately from medical coverage as stand-alone coverage from group health plans. We provide coverage to over 50 million people, enrolled in 88,000 dental plan groups that are administered locally or nationally for employers. In 2006, DDPA members processed over 73 million dental claims with an accuracy rate of over 99 percent.

Preventive Prognostic Features

Some dental insurance plans are considering adding prognostic ("predictive") features to plan designs that test for susceptibility to dental decay and periodontal diseases. These tests will improve coverage and individual health outcomes and could lower premium costs. Plans would provide enrolled persons that test "positive" with additional plan benefits that supplement a standard benefit design to prevent future disease. No coverage or benefits are denied for tested individuals.

One test examines specific genetic material for the presence of a specific "genotype." If a person tests positive they are predisposed to more severe periodontal diseases and require more aggressive preventive treatment than those without these genetic variants.

Another test examines specific components of saliva for sugar complexes to predict who will get cavities and in which specific teeth. Specific combinations of proteins and carbohydrates are

supportive of a group of organisms that are "bad" and cause cavities while other groups are "good" and protective. Individuals with "bad" sugar complexes would be given more aggressive preventive services.

With both tests, personalized aggressive preventive care would lower overall plan costs by precluding the onset of disease or diminishing the severity of the disease and lead to improved health outcomes and quality of care.

Dental Plans as Excepted Benefits

GINA's requirements for health insurance practices do not apply to supplemental insurance products that are classified as "excepted benefits" such as most of DDPA's dental plan arrangements because they are "limited scope dental plans." As a result, GINA would not generally prohibit the use of these preventive prognostic features for these dental plans.

The intent of GINA's requirements is to prohibit the use of predictive genetic information in an adversely "discriminatory" manner such as denying coverage based on predictive genetic information, or raising premiums on the basis of predictive genetic information. Neither of these concerns is at issue with respect to the described preventive prognostic features for dental insurance plans.

Privacy Rule Raises Underwriting Issue

GINA's amendments to the Social Security Act's Privacy Rule apply to any "group health plan" (as defined in ERISA) or "health insurance issuer" and there is no "excepted benefits" exception.

The Privacy Rule explicitly prohibits the "use or disclosure" of genetic information for purposes of "underwriting" defined broadly to mean: (1) determination of eligibility for benefits, coverage, or the policy; (2) computation of premium or contribution amounts (3) application of any pre-existing condition exclusion; and (4) other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.

Impact on Prognostic Tests in Dental Plans

Because the tests are used to determine if additional benefits are provided, which may result in premium costs being adjusted for lower overall plan costs, these preventive care prognostic features appear to be included in the very broad definition of "underwriting" under the Privacy Rule (and the GINA rules but for the "excepted benefits" exception).

As a result, these beneficial preventive measures would be prohibited even though they are not intended to be used to reject applicants, raise premiums, or otherwise adversely "discriminate" against individuals, but rather to improve and expand coverage policies, improve individual health outcomes, and reduce overall plan costs.

Possible Safe Harbor

DDPA believes that these preventive prognostic features are not the kinds of practices that GINA was intended to prohibit because these tests are not used to deny eligibility for coverage, or to deny benefits under the plan. Instead, these tests are applied to plan enrollees for the purpose of expanding and improving coverage, plan benefits, and the quality of health.

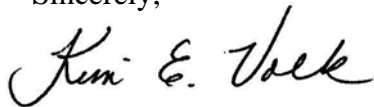
To address this unintended consequence of GINA, DDPA respectfully requests the agencies to consider perhaps defining what "is not" underwriting under the statutory definition, and to specifically provide exception for the use of a genetic test that is offered to currently enrolled individuals for the purpose of preventive care and the provision of additional benefits under the plan.

Alternately, under the Privacy Rule, this same exception could apply by not treating preventive prognostic tests as health care operations "underwriting" but rather as a permissible health care operations activity for either the improvement of methods of payment or coverage policies under the plan, or that it is a quality assessment and improvement activity.

Importantly, the provision of these or other "safe harbors" will give our plans the use of genetic information to benefit the care of plan enrollees while also preventing instances of harmful discrimination.

We very much appreciate the opportunity to provide these comments for your considering in issuing guidance under GINA. Please feel free to contact us if you have any questions or comments.

Sincerely,

A handwritten signature in black ink that reads "Kim E. Volk". The signature is written in a cursive, flowing style.

Kim Volk
President and CEO