Baum, Beth - EBSA

From: Jodrey, Darrel [JJCUS] [DJodrey@its.jnj.com]
Sent: Tuesday, January 05, 2010 3:40 PM
To: EBSA, E-OHPSCA - EBSA
Cc: Jodrey, Darrel [JJCUS]
Subject: RIN 1210-AB27 (Submitting Comments from Johnson & Johnson)
Attachments: GINATitleI-1 5 10.pdf; GINA Title I Comments Letter(Final).pdf; HHS Letter to American Heart Association-12-01-09.pdf

Attached please find comments submitted by Johnson & Johnson to RIN 1210-AB27. The submission has three parts: a letter dated January 5, 2010 and two attachments: a letter from Johnson & Johnson dated November 25, 2009 and a letter from HHS dated December 1, 2009.

Please contact me if there is any problem with this submission.

Thank you.

Darrel C. Jodrey
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ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, N.J. 08933

January 5, 2010

Timothy Geithner
Secretary
U.S. Department of Treasury
1500 Pennsylvania Avenue NW
Washington, DC 20220

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

Hilda Solis
Secretary
U.S. Department of Labor
200 Constitution Avenue NW
Washington, DC 20210

Re: *REG-123829-08, CMS-4137-IFC, RIN 1210-AB27 – Interim Final Rules Prohibiting Discrimination Based on Genetic Information in Health Insurance Coverage and Group Health Plans (Vol. 74, No. 193) (October 7, 2009)*

Dear Secretaries Geithner, Sebelius, and Solis:

Johnson & Johnson submits this letter in follow up to our letter dated November 25, 2009 (attached). We would like to express our support for the "bifurcated" Health Risk Assessment ("HRA") concept addressed in the interim final rules implementing sections 101 through 103 of the Genetic Information Nondiscrimination Act of 2008 (“GINA”) (the “Interim Final Rules”) and as described in Secretary Sebelius' letter dated December 1, 2009 to the American Heart Association (attached).

As stated in our prior letter, Health Risk Assessments and health coaching programs are powerful ways to help people understand their personal health risks, including risks related to family medical history. We believe the bifurcated HRA approach is an effective way to ensure that family medical

history information is given voluntarily and is not used to discriminate in employment or health insurance coverage, while at the same time giving people the opportunity and incentive to identify and address health risks.

In Secretary Sebelius' letter to AHA, it is stated:

> "Specifically, as part of the implementation of Title I, bifurcated HRAs will permit issuers and plans to continue wellness programs with minimal disruption. For example, under GINA a plan can continue to use financial incentives to encourage employees to complete an HRA, if the section of the form seeking family medical history includes a notice that completing that section is optional and that the reward will be received whether that section is completed or not."

We recommend that the above example be included in the Final Rules and that the Final Rules clarify that such a bifurcated HRA would not be in violation of paragraph (d) (1) – the underwriting rule or paragraph (d)(2) – the enrollment rule. We also recommend that Example 5 of paragraph (d) in the Interim Final Rules be clarified such that the bifurcated HRA in that example would likewise not be in violation of paragraph (d)(2) – the enrollment rule.

"Open enrollment" is the period of time prior to the effective date of coverage that employers commonly give individuals to select, and enroll in, a health plan. It is also the period of time that is commonly used to offer HRAs to individuals, for several reasons: (1) for the convenience of the individuals who wish to participate in an HRA so that they may do so at the same time as completing enrollment forms; (2) to provide individuals the tools to identify and address health risks as soon as possible; (3) to increase participation that may drop off after open enrollment; and (4) to create efficiencies and avoid the increased cost of conducting an HRA after open enrollment. As long as the provision of family medical history is voluntary and does not affect an individual's eligibility to participate in a health plan, its collection in an HRA during open enrollment should not be restricted. For these reasons, we request the clarification that properly structured bifurcated HRAs as described above do not violate paragraph (d) – the enrollment rule.

The clarifications recommended above, if adopted, would ensure highly effective incentive programs remain intact and would allow the collection of information critical to providing a high-quality and effective coaching experience, while at the same time protecting employees' genetic information from being inappropriately used. Our goal is to ensure that individuals continue to be able to receive important information based on family medical history that could help improve their health and save lives.

Please contact either of us if you have any questions or would like to discuss our concerns or suggestions in more detail. Johnson & Johnson and HealthMedia are prepared to actively participate in the crafting of the Final Rules. Please feel free to call on us.

Kathy Buto can be reached at 202-589-1010; Dr. Fikry Isaac can be reached at 732-524-3404.

Sincerely,

Kathy Buto
Vice President, Health Policy

Fikry W. Isaac, MD
Executive Director, Global Health Services

Attachments:

November 25, 2009 Letter to Secretaries Geithner, Sebelius and Solis from Johnson & Johnson

December 1, 2009 Letter to the American Heart Association from Secretary Sebelius, Department of Health and Human Services

cc: Robert P. Kocher, MD, Special Assistant to the President, National Economic Council, The White House; Ezekiel Emanuel, MD, Special Advisor for Health Policy, Office of the Director, Office of Management and Budget

ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, N.J. 08933

November 25, 2009

Timothy Geithner
Secretary
U.S. Department of Treasury
1500 Pennsylvania Avenue NW
Washington, DC 20220

Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
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Re: *REG-123829-08, CMS-4137-IFC, RIN 1210-AB27 – Interim Final Rules Prohibiting Discrimination Based on Genetic Information in Health Insurance Coverage and Group Health Plans (Vol. 74, No. 193) (October 7, 2009)*

Dear Secretaries Geithner, Sebelius and Solis:

Johnson & Johnson is a health care company that brings innovative ideas, products and services to advance the health and well-being of people around the world. Our more than 250 Johnson & Johnson companies work with partners in health care to touch the lives of over a billion people every day. Johnson & Johnson is committed to offering employees effective wellness, prevention, and disease management programs. Over the past 10 years, we have successfully reduced risk factors among employees through our programs and, in doing so, have improved the health and productivity of our workforce. Our HealthMedia, Inc., business is an industry pioneer in developing digital health coaching interventions that help organizations reduce health care costs by cost-effectively enhancing the health and wellness of their employees and members. We appreciate the opportunity to comment on the interim final rules implementing sections 101 through 103 of the Genetic Information Nondiscrimination Act of 2008 ("GINA") (the "Interim Final Rules").

Johnson & Johnson fully supports GINA's intended purpose of prohibiting discrimination on the basis of genetic information with respect to health insurance and employment. However, we

believe that the overly broad definition of "underwriting" in the Interim Final Rules far exceeds the original intent of the law and will have significant and unfortunate consequences on wellness, prevention and disease management programs, and, ultimately, health care costs. Specifically, we are concerned that the Interim Final Rules prohibit (i) the collection of family medical history as part of a valid Health Risk Assessment ("HRA") that provides an incentive or is completed during an open enrollment period, and (ii) the use of HRAs that collect family medical history to match individuals with appropriate disease management programs. We believe that rather than apply absolute prohibitions against the use of these tools, there are other appropriate ways to ensure the protections provided under GINA are realized, and we believe the Agencies should take the appropriate time to evaluate these options.

Health risk assessments and health coaching programs are powerful ways to help people understand their personal health risks, including risks related to family medical history. These important tools help motivate healthier lifestyles and drive appropriate preventive behavior. Family medical history is a vital piece of the HRA. Answers to a few key family medical history questions can provide a participant critical information about his or her health risks. For example:

- The U.S. Preventive Services Task Force recommends that people at normal risk of colorectal cancer start screening at 50 years of age. Some people with a family history of colorectal cancer are at increased risk of developing this cancer at a young age, and should begin screening before 50 years. If this information is not collected in an HRA, the participant may not be advised to speak to his or her doctor about the best time to initiate screening.

- The U.S. Preventive Services Task Force does not recommend cholesterol screening for men under 35 years old who are at low risk or for women at any age who are low risk. Family history of premature heart disease (<55 years old in first-degree male relative, <65 years old in first-degree female relative) is a major risk factor for coronary heart disease. If that is the only risk factor that a woman or young man has for coronary heart disease, the participant will not be advised to get screened for high cholesterol and they may not take advantage of interventions that could lower their risk of heart attack and stroke.

These are just a few examples of how important family medical history questions are in helping individuals receive accurate risk information and motivating healthier lifestyles and appropriate preventive behavior.

It is important to note as well that, in general, employers today neither request nor receive individually identifiable family medical history information about their employees from the third parties who administer HRAs and other health coaching programs. Common industry practice is that third parties hold this information confidential from employers.

The option presented by the Interim Final Rules of removing incentives related to the completion of HRAs that contain family history questions will significantly decrease participation in HRAs. Incentives have been a key driver in encouraging people to take an HRA and to participate in health coaching programs. A CDC-sponsored employer health and productivity management benchmarking study identified "meaningful incentives," such as insurance premium discounts for completing an HRA, as a promising practice.[i] Incentives can serve as powerful motivators: A $25 cash incentive can generally spur a 50 percent HRA participation rate compared with a 10 percent to 15 percent rate in programs without incentives.[ii] At Johnson & Johnson, we have offered an annual incentive for completing an HRA and typically have over 80% of our employees participate, which we believe has a positive impact on the health and wellbeing of our workforce. The rules implementing GINA should not restrict incentive programs connected with valid HRAs that include family medical history questions where the family history information is used appropriately to help individuals identify and respond to important health risks.

We believe that there are ways to ensure family medical history information is not used to discriminate in employment or health coverage, while at the same time helping people identify and address health risks through the use of HRAs and health coaching tools. Therefore, we request a delay in the implementation and enforcement of the Interim Final Rules in order for affected parties to explore ways to ensure we protect genetic information, while also encouraging healthier lifestyles through use of valid and effective wellness and prevention tools.

Please contact either of us if you have any questions or would like to discuss our concerns in more detail. Kathy Buto can be reached at 202-589-1010; Dr. Fikry Isaac can be reached at 732-524-3404.

Sincerely,

Kathy Buto
Vice President, Health Policy

Fikry W. Isaac, MD
Executive Director, Global Health Services

[i] Goetzel RZ, Shechter D, Ozminkowski RJ, Marmet PF, Tabrizi MJ, Roemer EC. Promising practices in employer health and productivity management efforts: findings from a benchmarking study. J Occup Environ Med. 2007; 49(2):111-30.
[ii] Hunnicutt, D; Leffelman, B. (2006). *WELCOA's 7 Benchmarks.* WELCOA's Absolute Advantage Magazine, 6(1), 2-29.

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

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

December 1, 2009

Mr. Derek Scholes
Government Relations Manager
American Heart Association
1150 Connecticut Ave., NW, Suite 300
Washington, DC 20036

Dear Mr. Scholes:

Thank you for your letter regarding the Genetic Information Nondiscrimination Act of 2008 (GINA). Please share this response with the organizations who signed on to the letter.

As you know, the Departments of Labor, Health and Human Services, and the Treasury (the Departments) published an interim final rule implementing GINA's health coverage provisions on October 7, 2009 to help ensure that genetic information is not used adversely in determining health care coverage and to encourage more individuals to participate in genetic testing, which can help better identify and prevent certain illnesses.

The Departments recognize that concern exists about the potential impact of these regulations on certain wellness and disease management programs (in particular, health risk assessments (HRAs)). The Departments seriously considered these issues before promulgating the interim final rules. In fact, the Departments had earlier published, on October 10, 2008, a request for information soliciting comments on, among other things, this precise issue.

The statutory language of GINA clearly states that a group health plan (or health insurance issuer) cannot collect genetic information (including family medical history) for underwriting purposes. The term "underwriting purposes" is broadly defined by the statute to include any effect on eligibility, benefits, or premiums for coverage. A legal analysis of this provision of the statute is discussed in detail in the preamble to the regulations at 74 FR 51668 (published October 7, 2009).

The Departments are aware of the success of certain wellness programs in obtaining improved health outcomes. That is why the regulations provide illustrations of how plans and issuers can continue to collect family medical history as part of wellness programs in a way consistent with GINA's important new protections. Specifically, as part of the implementation of Title I, bifurcated HRAs will permit issuers and plans to continue wellness programs with minimal disruption. For example, under GINA a plan can continue to use financial incentives to encourage employees to complete an HRA, if the section of the form seeking family medical history includes a notice that completing that section is optional and that the reward will be received whether that section is completed or not. This approach preserves the voluntary nature of the disclosure. Ultimately, GINA's protections should encourage more employees to

participate in wellness programs since they will be able to do so without concerns about the use of their genetic information. The preamble to the regulations invited comments on ways in which participation in HRAs can be encouraged while complying with the statutory prohibition on using genetic information for underwriting purposes.
Today's genetic technologies yield data that are vital to helping Americans make personal, medical decisions. The GINA statute and the Departments' regulations protect individuals against unwarranted use of information related to their personal health because no one should have to fear that disclosure of their medical data will put their job or the affordability of their health coverage at risk.

GINA's comment period is open through January 5, 2010 and we would be happy to include your letter, and any additional information you wish to submit, in the public record. Thank you for your feedback, which is valuable, as the Departments continue to focus our efforts on assisting the regulated community in complying with the provisions of this historic new law.

Sincerely,

Kathleen Sebelius

Kathleen G. Sebelius