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Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
P.O. Box 8017  
Baltimore, MD 21244-8010

ATTENTION: CMS-4137-IFC

Re: WellPoint, Inc. comments on the Interim Final Rules Prohibiting Discrimination Based on Genetic Information in Health Insurance Coverage and Group Health Plans

Dear Sir or Madam:

On behalf of WellPoint, Inc. thank you for the opportunity to comment on the interim final rules, with request for comments, which are intended to implement sections 101 through 103 of the Genetic Information Nondiscrimination Act of 2008 (GINA), that were issued in the *Federal Register* on October 7, 2009 (74 Fed. Reg. 51664). These provisions are intended to prohibit discrimination based on genetic information in health insurance coverage and group health plans

WellPoint, Inc. (WellPoint) is the largest health benefits company in terms of medical membership in the United States, with medical enrollment of nearly 35 million members. Through its nationwide networks, the company delivers a number of leading health benefit plan solutions, along with a wide range of specialty insurance products and services including life and disability, pharmacy benefit management, dental, vision, behavioral health, long term care and flexible spending accounts. Headquartered in Indianapolis, Indiana, WellPoint is an independent licensee of the Blue Cross and Blue Shield Association and serves its members as the Blue Cross licensee in California; the Blue Cross and Blue Shield licensee for Colorado, Connecticut, Georgia, Indiana, Kentucky, Maine, Missouri (excluding 30 counties in the Kansas City area), Nevada, New Hampshire, New York (as Blue Cross Blue Shield in 10 New York City metropolitan and surrounding counties and as Blue Cross or Blue Cross Blue Shield in selected upstate counties only), Ohio, Virginia (excluding the Northern Virginia suburbs of Washington, D.C.), and Wisconsin; and also serves members across the country through UniCare.

WellPoint understands the intent of the GINA to prohibit discrimination based on an individual's genetic information with respect to both health coverage and employment. In particular, with respect to health coverage, Title I of GINA generally intends to prohibit discrimination in group premiums based on genetic information, proscribes the use of genetic information as a basis for determining eligibility or setting premiums in the individual and Medicare supplemental policy (Medigap) insurance markets, and limits the ability of group health plans, health insurance issuers, and Medigap issuers to collect genetic information or to request or require that individuals undergo genetic testing. We have been commenting through our trade associations, Blue Cross Blue Shield Association (BCBSA) and the America's Health Insurance Plans (AHIP) on the The Equal Employment Opportunity Commission (EEOC) proposed rule, entitled Regulations Under the Genetic Information Nondiscrimination Act of 2008, that would implement Title II of the GINA which was intended to protect job applicants, current and former employees, labor union members, and apprentices and trainees from discrimination based on their genetic information.

We continue to value the opportunity to be involved in the regulatory process through the formal notice and comment rulemaking process. We are however concerned with possible unintended consequences related to GINA implementation and the two proposed rules and one interim final rule that are currently being discussed. These rules are:

- The EEOC proposed rule entitled Regulations Under the Genetic Information Nondiscrimination Act of 2008 (Title II rule);
- The HHS/OCR proposed rule entitled HIPAA Administrative Simplification: Standards for Privacy of Individually Identifiable Health Information (HIPAA GINA rule); and,
- Department of the Treasury (Treasury), Department of Labor (DoL), and HHS notice of interim final rule with request for comments entitled Interim Final Rules Prohibiting Discrimination Based on Genetic Information in Health Insurance Coverage and Group Health Plans (Title I rule).

We are concerned that the implementation of these GINA rules may result in unintended consequences for employers, employees, health plans, and others. Because of this concern we would like to submit some overarching comments on all of the regulations.

- Effective Date Issues: Confusion has been generated by the issuance of separate regulations by multiple agencies and ambiguity as to how effective dates apply -- for example, where genetic information appropriately collected prior to an effective date is linked to a previously-promised incentive in the form of enhanced benefits in a plan year beginning after the effective date. The proposed restrictions on uses and disclosure of PHI would seem to prohibit all use or disclosure of genetic information for underwriting purposes, even if the use or disclosure relates to a function that would be permitted by GINA and the other related regulations (e.g. an appeal of a pre-GINA claim).
- Incentives: Clarity is needed as to the true parameters of any prohibitions associated with the payment of incentives (or the imposition of penalties) associated with collections of genetic information.
- Definition of "Voluntary": Clarity is needed as to the definition of "voluntary" and what constitutes a "voluntary wellness program" is needed. The definition and concept should be consistent across all federal laws and regulations affecting wellness programs -- notably HIPAA, GINA, and ADA and regulations issued by HHS, DOL, IRS, and EEOC.
- Definition of "Underwriting purposes": The regulations take a very expansive view, which significantly expands liability with respect to activities that have not in the past been regarded as "underwriting" and which restrict the ability of plans and insurers to implement meaningful health care management, wellness, and prevention programs.
- Disease Management and other Healthcare Management Programs: The regulations restrict the flow of meaningful family medical history information that would permit more accurate and efficient identification of high-risk individuals who could benefit from disease management, maternity management, and other healthcare management, wellness, and preventive care programs.
- Wellness Incentive Programs: We would also like to encourage the agencies to preserve flexibility for employers who wish to design and maintain wellness incentive programs intended to motivate employees to change unhealthful personal habits such as alcohol consumption, illicit drug use, smoking sedentary lifestyle choices, and poor eating habits. Overly restrictive rules as to the collection and use of family medical history (GINA) and as to disability-related inquiries and medical examinations (ADA) would be counterproductive to the development of such programs, which have been promoted by the Obama administration as effective methods of reducing the nation's health care costs.

We request that these comments be considered when implementing the HIPAA GINA rule, the Title II rule, and any subsequent regulation, including the Title I rule, when applying the provisions of the GINA.

Specific to the interim final rules, with request for comments, which are intended to implement sections 101 through 103 of the Genetic Information Nondiscrimination Act of 2008 (GINA), that were issued in the *Federal Register* on October 7, 2009 (74 Fed. Reg. 51664), we would like to offer the following comments:

- **Section 148.180 Prohibition of discrimination based on genetic information (2) (iii) Example 2 I**
  - **Medical Records**
    - Example (2)(i) and (ii) conclude that the incidental collection exception will not apply in the circumstance in which medical records are obtained and the materials did not state that genetic information should not be provided
    - Most medical records will contain genetic information (in the form of family member health history)
    - Redaction of genetic information will require a page by page review of every medical record requested for the purposes of underwriting
      - This will slow down turn around time and create a barrier to coverage for individuals
      - This will increase administrative fees as providers will be required to spend a significant amount of time reviewing every record for genetic information
      - This could also stop physicians from documenting family medical history in medical records so they won't have to redact it when the records are requested, and it may even stop physicians from obtaining it at all. This harms the patient.
    - Insurers are already prohibited from using genetic information therefore this additional step is unnecessary
  - With the move towards electronic medical records, omitting or redacting genetic information from medical records will become even more burdensome
- **Section 148.180 Prohibition of discrimination based on genetic information (2) (ii) (A) & (B)**
  - **Incidental Collection Exception**
    - If an issuer offering health insurance coverage in the individual market obtains genetic information incidental to the collection of other information concerning any individual, the collection is not a violation of this paragraph (f)(2), as long as the collection is not for underwriting purposes in violation of paragraph (f)(1) of this section.
    - *Limitation:* The incidental collection exception of this paragraph (f)(2)(ii) does not apply in connection with any collection where it is reasonable to anticipate that health information will be received, unless the collection explicitly provides that genetic information should not be provided.
      - The limitation on the incidental collection provision is administratively burdensome
- **“Underwriting purposes.”**
  - **§2590.702-1(d)(ii)(A) needs clarification.** Section (d) prohibits plans and issuers from collecting genetic information for underwriting purposes. In subsection (ii)(A), it then defines “underwriting purposes” in part as “rules for, or determination of eligibility. . .for benefits under the plan (including changes in deductibles or other cost-sharing mechanisms *in return for activities such as completing a health risk assessment or participating in a wellness program.*” [Bold italics added.] It’s difficult to interpret what this really means. For example, in the case of a plan’s deductible change, the prohibition can be reduced to:
    - “A group health plan. . .must not collect. . .genetic information for. . . determination of eligibility. . .for changes in deductible. . .in return for completing a health risk assessment.”
      - If the deductible change is “in return for completing a health risk assessment” then it is the act of completing the HRA (and not the genetic information) that “determines eligibility” for the deductible change.
      - Similarly, if the deductible change is “in return for participating in a wellness program,” then it is the act of participating (and not the genetic information) that determines eligibility for the deductible change.
    - It is not clear how genetic information can be used to determine eligibility for a change that one becomes eligible for by completing an HRA and/or by participating in a wellness program. If the intent is to regulate the *content* of health risk assessments, this is a very confusing method of doing so and arguably doesn’t succeed.
- **“Underwriting purposes.”**
  - **§2590.702-1(d)(ii)(B) also needs clarification.** Here, “underwriting purposes” is defined, in part, as “computation of premium or contribution amounts under the plan or coverage (including 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).” Again, this is difficult to interpret. For example, in the case of a discount for completing a health risk assessment, the prohibition reduces to:

- “A group health plan. . . must not collect. . . genetic information for. . . computation of . . . discounts. . . in return for . . . completing a health risk assessment.”
  - If the discounts are given “for completing a health risk assessment,” then it is the act of completing the assessment (and not the genetic information) which results in the discount.
  - It is unclear how genetic information could be used to compute an amount.
  - Again, if the intent is to regulate the *content* of health risk assessments, this does not achieve that goal.

- **Disease Management Programs.**

- **§2590.702-1(d)(3), Example 4 needs clarification as to both the meaning of the term “benefits” and the applicability of the medical appropriateness exception.** Subsection (i), Facts, indicates that “certain people completing the health risk assessment may become eligible for additional *benefits* under the plan by being enrolled in a disease management program based on their answers to questions about family medical history.” [Bold italics added.] Subsection (ii), Conclusion further indicates that the request for family medical history “could result in the individual being eligible for *benefits*.” [Bold italics added.] However, the Conclusion then goes on to rule out the applicability of the medical appropriateness exception “because the individual is not seeking *benefits*.” [Bold italics added.]
  - Ambiguity is created by apparently inconsistent use of the undefined term “benefits.” The term seems to mean, in the first two instances, the right to receive disease management services. It seems to mean something entirely different in the third instance, such as reimbursement of charges for medical treatment.
  - Is participation in the Disease Management (DM) program a “benefit” in and of itself? I.e., is the intent of this example (disregarding the part about the medical appropriateness exception) to prohibit using genetic information gathered on a health risk assessment to determine eligibility for participation in a DM program? Or, alternatively, is this example intended to mean that (1) it is permissible to use genetic information gathered on an HRA to determine eligibility for participation in the DM program, but (2) impermissible for such participation to then result in coverage by the plan of medical services that would not otherwise be covered?
  - If participation in a DM program, in and of itself, is a “benefit” as to which genetic information cannot be used to determine eligibility for participation, this rule seems to run counter to the public policy goals of the Obama administration’s pro-wellness stance. As expressed in the administration’s positive communications about wellness programs such as the one offered by Safeway to its employees, the administration seems to favor encouraging employers to help individual improve their health. Additionally, health care reform measures now before Congress would increase wellness-related incentives allowed under HIPAA. To be consistent with the administration’s stance, the use of genetic information to identify individuals who could benefit from disease management programs should be a permissible benign use of the genetic information. Forcing such programs to offer disease management to all plan enrollees, and then identify for participation only those who demonstrate that they are at risk for the managed condition impairs the effectiveness of these programs and the engagement of individuals whose health could be improved by them.
- As to the medical appropriateness exception, consider the following hypothetical situation:
  - A group health plan offers its participants who are expectant mothers a maternity management program. Participation in the program results in, among other things, waived co-payments to encourage appropriate pre-natal care. An assessment questionnaire administered to those who have enrolled in the maternity management program is used to target enrollees in the program who may have high-risk pregnancies. In addition to questions about the expectant mother’s health conditions, nutrition, etc., the assessment asks about her family medical history – such as “Has anyone in your family (e.g., your mother or sister) had pregnancy-related medical problems or complications?” All of the responses (both family medical history and other responses not constituting genetic information) are clinically relevant and consequently used as factors in identifying those program participants who are “high risk.”

- Is this example analogous to Example 4? If so, is the practice described above prohibited, or is it permissible (*unlike* the request in Example 4) under the medical appropriateness exception?

- **Applicability.**

- **The Supplementary Information, Background section of the Preamble to the final interim regulations addresses their applicability.** Footnote 3 specifically addresses applicability with respect to Medigap issuers. However, it is difficult to determine whether (and if so how) the regulations apply to governmental plans (FEHBP, Medicare, Medicaid) and to issuers of Medicare Advantage policies. The proposed regulations issued by the HHS Office for Civil Rights under HIPAA are clearly intended to apply more broadly than the final interim GINA Title I regulations, as explained in the preamble to the OCR proposed regulations. However, the applicability of either set of regulations to the FEHBP is unclear, as is the potential applicability of the final interim GINA Title I regulations to Medicare, Medicaid, and issuers of Medicare Advantage coverage.

- **Effective/applicability date issues.**

- **According to §2590.702-1(f), the regulations apply in the group market for plan years beginning on or after 60 days following their date of publication in the Federal Register.** However, as the regulations address both the collection and the use of genetic information, it is unclear how they are intended to apply. For example:
  - Consider the hypothetical case in which an individual completed an HRA including family medical history questions during her plan’s annual open enrollment period on September 1, 2009, having been promised (prior to the publication of the regulations) that doing so would entitle her to an incentive (such as the waiver of certain co-payments) during the 2010 plan year beginning on January 1, 2010. What action(s) must the group health plan take in order to be fully compliant with the regulations? If required to retroactively rescind entitlement to the incentive, might the employer be placed in the position of violating ERISA in order to comply with GINA?
  - Also consider the hypothetical case in which genetic information was provided via a health risk assessment during 2008, well before the issuance of the regulations, and still resides in the data base of the health risk assessment vendor. The vendor is capable of using the stored data as a factor in calculating the individual’s risk of developing certain chronic conditions that are affected by family medical history. That risk could then be used to identify the individual for participation in a disease management program. Since the data was collected prior to the effective date of the statute and the effective date of the regulations, can it be used in this manner?

- **Rewards.**

- **The preamble to the regulations [at paragraph 9 of §II(A)(5)] seems to state the prohibition regarding incentives associated with genetic information requests much more broadly than either the statute or the regulations themselves.** That section of the preamble states that “wellness programs that provide rewards for completing HRAs that request genetic information, including family medical history, violate the prohibition against requesting genetic information for underwriting purposes.” However, this rule as stated in §2590.702-1(d)(ii)(B) of the regulations seems narrower, in that it is expressed as a prohibition against the collection of genetic information for “[t]he computation of premium or contribution amounts under the plan or coverage (including discounts, rebates, payments in kind, *or other premium differential mechanisms....*”). [Bold italics added.] Clarification is needed as to the definition of “premium differential mechanism,” and as to the true parameters of this prohibition. For example, are the following types of incentives for completing a health risk assessment with family medical history questions prohibited?
  - A notional deposit to the employee’s health reimbursement account
  - A deposit of funds to the individual’s health savings account provided through the employer’s cafeteria plan
  - A reward card that can be used to pay the employee’s portion of charges for covered medical supplies
  - Eligibility to purchase discounted health-related products, such as over-the-counter vitamins, medical supplies, etc.
- In addition, Example 5 in §2590.702-1(d)(3) uses the undefined term “wholly voluntary” to illustrate how a health risk assessment *could* permissibly include family medical history questions. Moreover, while the “Facts” portion of this example states that “the plan offers *no reward for completing the second HRA*” and does not address the use to which the genetic information collected via that method

will be used, the “Conclusion” portion states that the “Facts” indicate that “no *benefits* or other rewards” are conditioned on the request. [Bold italics added.]

- A definition of “wholly voluntary” is needed. Does offering a reward render a request not “wholly voluntary” regardless of the kind or amount of the reward?
  - If the genetic information gained cannot be used to determine “benefits,” it is difficult to understand how the permissible collection of it via the method set forth in this example would be at all useful. It would be helpful to have examples of permissible uses that could be made of genetic information collected in the manner set forth in this example.
- **“In connection with” enrollment; and “in connection with” the rules for eligibility.”**
    - **§2590.702-1(d)(2)(i) needs clarification.** The heading of the section uses as different term (“in connection with enrollment”) than the rule itself (“in connection with the rules for eligibility”) and neither term is adequately defined. There is a reference to §2590.702(b)(1)(ii); however that section merely lists a number of examples of eligibility rules. Are “enrollment” and “the rules for eligibility” meant to be interpreted as synonyms? What does “in connection with” mean? Examples 1 and 6 in subsection d(3) hint that these terms may mean “having an effect on an individual’s enrollment status or on the enrollment status of members of the individual’s family,” but this concept too is vague in that it is not clear whether “enrollment” refers to *enrollment* in the group health plan generally, or to *eligibility* for particular benefits or programs within the group health plan.

We appreciate the opportunity to comment on these important issues. We hope that our comments will assist the Department of Health and Human Services with implementing the Genetic Information Nondiscrimination Act, especially those regarding the privacy and confidentiality of genetic information, as well as the objective to make certain other changes to the HIPAA Privacy Rule. Please contact me by phone at (202) 628-7844 or by email at [Elizabeth.Hall@WellPoint.com](mailto:Elizabeth.Hall@WellPoint.com) with any questions.

Sincerely,



Elizabeth P. Hall  
Vice President for Public Policy