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January 5, 2010

Submitted through the Federal eRulemaking Portal

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

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

CC:PA:LPD:PR (REG—123829—09)
Room 5205
Internal Revenue Service
P.O. Box 7604
Ben Franklin Station
Washington, DC 20044

RE: Department of Labor RIN 1210-AB27
Department of Health and Human Services CMS—4137—IFC; RIN 0938-AP37
Department of the Treasury REG—123829—08; RIN 1545—BI03

Comments in response to the Departments' Interim Final Rules Prohibiting Discrimination Based on Genetic Information in Health Insurance Coverage and Group Health Plans

To Whom It May Concern:

The U.S. Chamber of Commerce ("Chamber") is pleased to submit this response to the request for comments on the interim final rules implementing sections 101 through 103 of the Genetic

Information Nondiscrimination Act of 2008 ("GINA"). The request was published by the Departments of Labor, Health and Human Services, and the Treasury (collectively, the "Departments") in the *Federal Register* on October 7, 2009.[1] The interim final rules implement provisions of GINA that prohibit group health plans from discriminating on the basis of genetic information.

The Chamber's Interest in the Interim Final Rules

The U.S. Chamber of Commerce is the world's largest business federation, representing more than three million businesses and organizations of every size, sector, and region. Many Chamber members sponsor group health plans. The Chamber has a strong interest in the proposal for its members to continue to provide high quality health coverage and wellness programs. Chamber members provide health coverage as a benefit to employees and compete for qualified employees, in part, through provision of value for such employees in health coverage.

The Chamber's Concerns with the Interim Final Rules

A. Certain Elements of the Interim Final Rules Undermine Wellness Benefits and Disease Management Programs

The interim final rules raise many issues. However, these comments focus primarily on the provisions of the rules that would undermine wellness benefits and disease management programs. The interim final rules would do great damage to these valuable programs and the Departments have failed to consider alternative approaches which preserve the full utility of these programs for beneficiaries. We also address the misinterpretation of the definition of "manifested."

Employers and group health plans often offer health risk assessment (HRA), in the context of wellness programs, as a mechanism to inform beneficiaries or employees regarding the personal relevance of disease management programs and to help tailor such programs to the needs of its recipients. In such circumstances, plans manage personal health information in compliance with current HIPAA regulations. Such assessments promote awareness, provide for health screening, and can be an initial step in identifying and managing health risk factors. Family medical history is a key component of such health risk assessments. In 2009, 78% of large employers surveyed offered wellness programs to their employees, and 83% of large employers surveyed offered disease management programs to eligible individuals. 67% of all employers surveyed said that they intended to expand or improve their wellness programs in the future.[2] 83% of employer-based wellness programs use health risk assessments; sometimes

[1] 74 Fed. Reg. 51,664 (Oct. 7, 2009).

[2] PricewaterhouseCoopers Health and Well-Being Touchstone Survey at 7, 9, 32(May 2009), *available at* http://pwchealth.com/cgi-local/hregister.cgi?link=reg/PwC_2009_health_and_well-being_Touchstone_survey_results.pdf.

the programs consist exclusively of such assessments.[3] A recent survey of 694 employers found that 64% offered employees an incentive to complete an HRA, and that the rate of participation increased significantly in programs that offered incentives.[4] As noted in the Federal Register by the Departments, a Kaiser Family Foundation survey from 2008 estimates that approximately 30,000 group health plans offer wellness and disease management programs that provide an incentive to complete an HRA.[5]

The interim final rules create needless barriers to the use of health risk assessments. First, the rules go beyond GINA to broadly define "underwriting purposes" to include purposes or rules related to eligibility, "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," and, for purposes of the rules related to premiums or contributions, "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."[6]

The interim final rules further set out examples related to the prohibitions on collection for underwriting purposes in 29 CFR 2590.702-1(d)(3)[7] and examples related to determinations of medical appropriateness under 29 CFR 2590.702-1(e). These explain numerous burdensome restrictions.

The interim final rules, at 29 CFR 2590.702-1(d)(2), also provide that genetic information may not be collected prior to the effective date of coverage. Thus, under the interim final rules, an HRA with family medical history questions that is provided to and completed by a new plan participant during open enrollment appears to violate the rule, even if such HRA is completed after the participant has elected his/her medical options, and even if completion of the HRA does not affect his/her eligibility for coverage.

These provisions create several problems with respect to collection of family medical history in the context of health risk assessments.

1) Family medical history may not be collected if an incentive is offered for the health risk assessment in a wellness program—a rule that either reduces participation in risk assessments or forces less accurate risk assessments.

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[3] Forrester Research, *What Consumers do with Health Risk Assessments*, Oct. 2007.
[4] PricewaterhouseCoopers Survey, *supra,* at 28-30.
[5] 74 *Fed. Reg.* at 51672 n. 19 (October 7, 2009).
[6] 29 CFR §2590.702-1(d)(1)(ii)(A); (B).
[7] Note that because of the unique structure of this rule, at least for purposes related to these comments, parallel amendments are made to three sets of regulations under the jurisdiction of each agency, Title 29 under the jurisdiction of the Labor Department, Title 45 under the jurisdiction of the Department of Health and Human Services, and Title 26 under the jurisdiction of the Department of the Treasury. For ease of readability, these comments only cite specifically to the sections modifying Title 29, but the comments and concerns apply equally to the other parts as both have adopted virtually identical provisions.

2) The interim final rules may restrict the collection of family medical history in a health risk assessment if that serves as a screening or advisory function in the context of subsequent disease management programs.

3) By choosing the effective date of coverage as the definition of "enrollment", the interim final rules reduce opportunities for people to obtain health risk assessments that may include family medical history.

Each of these rules punishes beneficiaries and poses burdens and liabilities on health plans. A full and more accurate health risk assessment is a benefit to beneficiaries. Studies, as well as the experience of employers and plans, show that incentives help promote beneficial activities like health risk assessments. It is helpful to beneficiaries to allow wellness and behavioral and disease management programs to use information from such assessments. Finally, interpretations that reduce the window of time for health risk assessments essentially delay a benefit. These issues are discussed in greater detail below.

B. GINA Does Not Compel the Language and Examples in the Interim Final Rule Regarding Incentives for Health Risk Assessments and Use of Family Medical History in Wellness Programs

Statutory Language

We understand that some have raised the proposition that GINA compels the definition of "underwriting purposes" as set out in the interim final rules. Congress did not include the "clarifying" propositions that the Departments have placed into the interim final rules. This is made evident by comparing the text of the statute to the text of the interim final rules.

The statute defines "underwriting purposes" as follows:

> The term 'underwriting purposes' means, with respect to any group health pan, or health insurance coverage offered in connection with a group health plan—
>
> (A) rules for, or determination of, eligibility (including enrollment and continued eligibility) for benefits under the plan or coverage;
>
> (B) the computation of premium or contribution amounts under the plan or coverage;
>
> (C) the application of any pre-existing condition exclusion under the plan or coverage; and
>
> (D) other activities related to the creation, renewal, or replacement of a contract of

health insurance or health benefits.[8]

The interim final rule adds language not in the statute. Of particular concern are the parenthetical phrases that have been added to the statutory language of paragraphs (A) and (B). The proposed language is:

> (A) … (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);
>
> (B) … (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);[9]

The statutory text can be read to focus on whether the requested information would itself be the basis for whether an incentive or reward is provided. However, it cannot be read to include the parenthetical language proposed by the Departments. For example, note the word "computation" in the statutory definition of underwriting purposes. To our knowledge, wellness programs do not compute premium or contribution amounts under the plan or coverage based on genetic information. Computation is a calculation based on a variable. Incentives for completing a health risk assessment depend only on completing the assessment, not on whether or not a person's parents did or did not have heart disease. If a plan varied the size of the incentives based on the content of genetic information, even in a wellness program, that would be in violation of the statute. However, the Departments' rule goes well beyond such a restriction.

Participating in a health risk assessment itself may be the basis for discounts, rebates, and premium differential mechanisms. The Departments seem to acknowledge this in various examples. That fact is not the same as using genetic information for the purpose of computation of premium or contribution amounts.

<u>Purpose Test</u>

The phrase "purposes" in GINA implies a purpose test. Note that the statute does not prohibit collection of information in the ***context*** of underwriting or wellness programs or incentives. Congress could have stated that proposition but focused on a purpose test. HRAs list family medical history in questionnaires or sections because such information provides a better health risk assessment, not because it helps to compute premium or contribution amounts. The relevant prohibited purpose is the computation of a premium or contribution amount. The purpose of providing for a better health risk assessment to benefit a beneficiary is not a prohibited purpose. Since wellness plans place questions about family medical history for the

[8] GINA §§101(d), 102(a)(4), and 103(d) (codifying the definition at 29 U.S.C. §1191b(d)(9), 42 U.S.C. §300gg-91(d)(19), and IRC §9832(d)(10), respectively).
[9] 29 C.F.R. §2590.702-1(d)(ii)(A), (B). 74 Fed. Reg. at 51,685.

latter beneficial purpose and not the prohibited purpose, there is not a statutory prohibition.

Indeed, the Departments' rules create the perverse effect of harming beneficiaries by not getting the best health risk assessment. Those without family medical histories would get the same health risk assessment regardless of this rule. However, those with a family medical history are penalized by not having relevant information considered in a medical evaluation. Instead, as indicated in example 5 for underwriting purposes[10] such parties are further burdened by being forced to take a second health risk assessment in order to get the incentive and have family medical history considered to get a more accurate assessment. The point needs to be emphasized. This is not an employer or human resources evaluation. This is a medical evaluation designed to provide a health care benefit to beneficiaries. The fact that incentives get more people to take a health risk assessment is a function of human behavior. This is a function of human behavior that exists independent of whether or not a person has or might provide relevant genetic information.

Incorrect Reading of Legislative History

The preamble of the interim final rules notes that earlier versions of the bill in the legislative process included exceptions for wellness programs in both the Title I health coverage provisions and the Title II employment provisions, whereas the legislation as enacted included an exception for wellness programs only in Title II.[11] The preamble implies that dropping the exemption from Title I compels the Department's broad reading of the statute. However, this notation misreads the legislative history, the structure of GINA, and the Departments' interim final rules. First of all, this former "exception" applied to a different provision that refers to genetic testing. For example, the specific language for genetic testing in the bill reported out of the Committee on Energy and Commerce was:[12]

> `(c) Genetic Testing-
>
> > `(1) LIMITATION ON REQUESTING OR REQUIRING GENETIC TESTING- A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request or require an individual or a family member of such individual to undergo a genetic test.
> > `(2) CERTAIN RULES OF CONSTRUCTION- Nothing in this part shall be construed to--….
> >
> > > `(B) limit the authority of a health care professional who is employed by or affiliated with a group health plan or a health insurance issuer and who is providing health care services to an individual as part of a bona fide wellness program to notify such individual of the availability of a

[10] 74 *Fed. Reg.* at 51,686, col. 3.
[11] 74 *Fed. Reg.* at 51,669 n. 12.
[12] House Report 110-028, Pt. 3, at 3.

genetic test or to provide information to such individual regarding such genetic test; ….

The Departments appear to take legal cognizance that rule of construction (2)(B) is not in the final law. That prohibition on genetic testing was and is not limited to underwriting purposes. Moreover, requesting that a party take a genetic test and having a questionnaire on family medical history are legally distinct under GINA. The provision restricting collection of genetic information for underwriting purposes is a completely different provision. Referring to this legislative history as set out in the preamble is highly misleading. An exception to the broader prohibition cannot illuminate the smaller universe of underwriting purposes. The narrower universe does not require an exception because the prohibition is not broad enough to cover wellness programs the way the Departments propose. The Departments simply misapply cannons of reviewing legislative history and fail to acknowledge their decision needs both authority and a basis for any choice under that authority.

Accordingly, it is the Departments' arbitrary and capricious choice to embellish the regulation with an unhelpful prohibition, not a dictate of the statute.

C. <u>Use of Genetic Information for Counseling or Determining the Medical Appropriateness of Additional Benefits Provided on a Voluntary Basis Does Not Violate the Statutory Prohibition Related to Underwriting Purposes</u>

Example 4 under the rules related to underwriting purposes indicates that enrolling an individual who has completed an HRA with family medical history questions in a disease management program can violate the rules concerning eligibility.[13] Apparently, this is the case unless the individual is affirmatively seeking benefits. The Department's rules and rationale are at best confusing. To be fair, here the statute is also somewhat confusing. By statute, a plan may not have rules for, or determination of, eligibility for benefits based on collection of genetic information. However, actual coverage is a function of payment and plans; insurers may make determinations of whether a benefit is medically appropriate.

For example, indicia of a chronic disease may be relevant for a chronic disease management program. It would be a more than unfortunate if family medical history or other evidence that could medically justify a benefit or create a more accurate health risk assessment were prohibited. The prohibition harms the future health of many beneficiaries – denying the use of relevant medical information for the simple purpose of assisting them with access to benefits. This makes people with relevant medical history second-class citizens.

The statute itself prohibits rules for, or determination of, eligibility for benefits using genetic information. The approach of the Departments in the interim final rule stretches the term "rule" or "determination of eligibility" beyond logical meaning and overall purposes of GINA. A

[13] 29 CFR 2590.702-1(d)(3), Example 4. 74 Fed. Reg. at 51,686.

health risk assessment can help with the function of counseling beneficiaries and can be used to determine medical appropriateness. The key here is that a plan does not try to weed out people – make them ineligible when they would otherwise be eligible -- based on genetic information. Providing an incentive to an individual who fills out a voluntary HRA and participates in coaching or disease management programs does not limit eligibility or benefits for such individuals. To the contrary, such an approach assists those individuals who may be at risk for an adverse health condition to access benefits under the group health plan. Interpreting the statute in a manner that would allow individuals protected by GINA to participate in such programs and to have full and accurate health risk assessments guide the efforts of plans and beneficiaries would be consistent with GINA and the HIPAA nondiscrimination rules, which specifically permit more favorable treatment of individuals with adverse health factors.[14]

Again, the Departments should look to a purpose test as flowing from the text of "underwriting purposes." Enhancing access by providing a complete health risk assessment is not a rule or determination. One way of addressing any potential concerns under GINA is to make sure that a disease management or other program also allows for eligibility when a beneficiary separately obtains a health risk assessment from his doctor indicating the appropriateness of such program. Moreover, access to such disease management programs should not turn on whether a participant has provided family medical history, but rather whether that program is medically appropriate based on the totality of the health risk assessment. A doctor or health risk assessment should allow for family medical history to help make that case of higher risk factors. That is a benefit to the participant. That is also critical to doctors. The purpose here is more accurate and useful assessment, not limitations on eligibility for benefits.

In example 4, the Departments conclude that use of a health risk assessment containing information about an individual's family medical history to determine eligibility for benefits is an underwriting purpose.[15] The Department further concludes that the exception for determinations of medical appropriateness does not apply because the individual is not seeking the benefit. This is a needless distinction and trip wire. Access to disease management program is a voluntary effort in either case. The individual seeks the benefit when he is armed with information from a full risk assessment and, possibly, a better tailored program.

Beneficiaries are, as a class, eligible for certain follow-up benefits that may flow from a health risk assessment. Such beneficiaries would not be denied eligibility because of genetic information. If a plan simply stated that all employees are eligible but programs are only available where medically appropriate, why wouldn't this fit the statutory provisions? If a plan used a health risk assessment to counsel participants as to benefits that may be available, why does this have to be an underwriting purpose? The Departments indicate that the medically appropriate "exception" would not apply. However, a "purpose" test still applies. If the purpose is to determine whether a benefit is medically appropriate or to helpfully counsel beneficiaries, that is not the same as a prohibited underwriting purpose.

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[14] *See* 29 CFR § 2590.702(g)

[15] 74 *Fed. Reg.* at 51686, col. 2.

In the examples concerning medical appropriateness, the Departments seem to draw a distinction between requesting genetic information only when necessary to make a determination regarding whether a disease management program is medically appropriate after an individual contacts the disease management program.[16] Here too the plan may only request the minimum amount of information to make a determination. Compare this to the example where a plan provides a questionnaire in the notice of available disease management programs and the questionnaire has questions regarding family medical history.[17] Why is this distinction relevant? A health risk assessment is assessing that an individual has diabetes or may have enhanced risk for diabetes. That is the purpose. This is not prohibited unless it requests genetic information for an "underwriting purpose." These kinds of questionnaires the Departments are concerned about are found in magazines and Federal literature. Such questionnaires are standard devices to help people become alert to higher risk factors.

The Departments interim final rule greatly elevates process issues over substance. Is the voluntary nature of the exercise different when a beneficiary voluntary fills a questionnaire to assist in a process to determine whether a disease management program is appropriate for him? What is the policy that supports having fewer people made alert to higher risk status and to guide beneficiaries to programs they are eligible for? These exquisite and complicated distinctions seem to have no stated basis, only an explanation that the distinctions exist. Moreover, the Departments assume that plans and enforcers must know what constitutes the "minimum amount of information necessary to make that determination" Would that mean a plan makes a mistake by asking for family medical history where blood sugar tests already show diabetes? Health risk assessments today routinely ask for family medical information. The Departments have no basis to suggest such practice is not ground in ordinary medical process. Family medical history is on most doctor's or hospital admittance form in this country. If a plan is employing or contracting with a health care professional or has literature consistent with what a medical professional would use, it is counterproductive and intrusive to burden such professionals or forms with legal distinctions that serve to harm beneficiaries.

These rules and distinctions in the interim final rules should be revised to remove the additional language beyond the statutory language and to revise the examples consistent with the flexibility described in these comments.

D. <u>Setting the Date of Enrollment as the Effective Date of Coverage is Not Required by GINA</u>

GINA prohibits group health plans from requesting, requiring, or purchasing genetic information "with respect to any individual *prior to such individual's enrollment under the plan or coverage* in connection with such enrollment."[18] However, the Departments have interpreted this phrase to prohibit collection of genetic information "with respect to any

[16] *Id*. at 51,687, col. 2.(see example 4)
[17] *Id.* at 51,687, col. 3. (see example 5)
[18] GINA §101(b) (adding 29 U.S.C. §1182(d)(2)).

individual *prior to that individual's effective date of coverage under that plan or coverage* [as well as] in connection with the rules for eligibility … that apply to that individual."[19]

The statute does not compel the Department's interpretation. As mentioned by others, an alternative interpretation would: (i) interpret the statutory phrase "prior to such individual's enrollment under the plan or coverage in connection with such enrollment" to mean "prior to a participant's selection of plan option", with the caveat and notice that the participant may not be required to complete an HRA in order to be enrolled in the plan. This would allow that an HRA with family medical history questions that is completed by any participant during the open enrollment period does not violate a prohibition against requesting genetic information prior to enrollment. This allows for administrative efficiency by providing an opportunity for a full and accurate HRA during the time that participants are focused on and receiving other information about benefits. It also simply allows them to potentially obtain guidance and benefits faster.

We understand the fear is that plans would use genetic information to deny enrollment. However, this prohibition can and should be enforced in other ways.

E. <u>These Concerns Raised by the Interim Final Rules do not Further the Purposes of GINA</u>

At its core, the purpose of GINA is to make it easier for patients and beneficiaries to allow genetic information to help them (such as by availing themselves of genetic services) and not have such information used against them. Denials of insurance coverage or increases in premiums based on genetic information are problems addressed by GINA. However, certain elements of the interim final rule follow a counterproductive path by essentially harming those who have genetic information. The rule would make health risk assessments less accurate for those with relevant family medical history. Since these risk assessments may be performed by physicians, one also must consider the liability issues associated by denying and restricting relevant medical information that may be important to diagnosis and assessment. Is that really the purpose of GINA?

The same issue applies to restricting the ability to consider genetic information for counseling or enabling a benefit such as a disease management program. No one is suggesting denying a beneficiary a benefit based on genetic information--quite the opposite. Again, it is hard to see how the interpretation of the Departments is helping anyone. Those with family medical histories that might justify greater assistance are put at a disadvantage.

F. <u>The Burdens and Potential Liabilities Placed on Health Plans are Needless and Counterproductive</u>

It is clear that GINA would place additional burdens and potential liabilities on health plans. However, there is no reason for the Departments to add to the core burdens and liabilities unless there is a clear justification or legal mandate. When the Chamber looks at the interim

[19] 29 C.F.R. §2590.702-1(d)(2). 74 Fed. Reg. at 51,686.

final rule, we see needless trip wires, complexity, and administrative burden. All in all, it appears that interim final rules needlessly compromise wellness programs and disease management programs. It appears, from reading the examples, that employers could provide an incentive for an HRA as long as there is no family medical history. If there is an open ended question that might draw in family medical history there is a separate set of rules. Under example 5, a plan HRA can obtain family medical history as long as an incentive is not attached to completing it. Presumably, this could then be married to the HRA that does not provide for family medical history. That less complete HRA can have an incentive for completing it. Perhaps this is just clever manipulation of confusing rules, but this appears to be a way to accomplish the desired benefit for the beneficiary – a more accurate and complete health risk assessment – albeit in two steps with extra burden, confusion, and potential for error. However, if you could use example 5 and two HRAs to accomplish this result, one wonders why we couldn't just take the approach the Chamber has suggested.

It is a little unclear then how beneficiaries might be allowed to volunteer that their family medical history adds to the story and makes them candidates for a given program. Is this just a matter of routing of information for the Departments? Surely, the disease management program would be allowed to consider family medical history in implementing the program and identifying risks.

What about the role of doctors in this? Plans may be paying doctors to review the health risk assessment. Do doctors really want to provide assessments based on less than complete information? Why would we generate two separate types of medical assessments? This might lead to confusion. Would the doctor be shielded in this case from liability? In fact, why would a medical assessment – which is actually a benefit—be the basis for restrictions designed to prevent discrimination in insurance benefits? Indeed, the discrimination seems to be the additional burdens placed on those with relevant medical histories and the difficulty of getting a full health risk assessment.

Is it really better for plans or employers to provide a less than complete health risk assessment? Apparently, it would be legal for beneficiaries to take the incomplete assessment and find a doctor who will complete it with the full information. Or would that also fall under the Department's proscription on requesting genetic information?

The Departments published the interim final regulations on October 7, more than four months after the statutory deadline and at a time when employer health plans had started their annual enrollment for 2010. The publication of the interim final regulations showed for the first time the depth of restrictions on workplace wellness programs, subsequent disease management programs, and use of health risk assessments. It is not reasonable to force employers to redesign their benefit programs, eliminate incentives previously promised to their employees, recall and reissue printed communications, coordinate with outside vendors, and take the other steps that would be necessary to comply with the new restrictions by January 1, 2010.

We would ask the Departments to step back and consider all of this. The statutes do not compel these results. The Departments have offered no basis sufficient to force this high degree of burden and liability. There is no pressing issue or case. These provisions and problematic examples of the Departments' rules should be rescinded immediately. Further consideration and potential refinements can occur in a more rational and measured process.

G. In Several Cases the Departments Fail to Offer a Basis for Choosing Against Permissible Interpretations of GINA that Do Not Undermine Wellness Benefits and Disease Management Programs

We have read the October 7th notice with great care. That notice acknowledges concerns over prohibiting questions regarding family medical history in the context of health risk assessments where there are incentives for such assessments. Various parties have provided substantial facts regarding these problems. These concerns have been amply stated during the request for information and through this comment period as well. The notice also states there are those who see things the other way. The notice chooses the prohibition as the basis for the interim final rule. It appears that no rationale is provided for this choice – merely that the agencies have made the choice.

A reader might assume that the Departments collectively believe the statute compels this reading. Or that the Departments understand that the statute does not compel these interpretations but believes they have no further obligation to state a rational basis for these choices.

Both of these beliefs would be incorrect. As discussed above, there are permissible readings of GINA that allow questions about family medical history in the context of health risk assessments even where there are financial incentives for participating in such risk assessments and even where the information might provide a basis for participation in a subsequent disease management program. Similarly, the statute does not require the date of enrollment and effective date of coverage to be synonymous for purposes of applying prohibitions under Title I of GINA.

Clearly the Departments are aware of at least the first two issues. Failure to state a rational basis for the regulatory choices the Departments make in the final rule adds to the argument that such decisions are arbitrary and capricious. This is particularly so since these decisions simply appear to harm beneficiaries who might benefit from consideration of family medical history in these contexts. The interim rules disrupt beneficial programs and create perverse and confusing outcomes. There needs to be a compelling, articulated basis to overcome these problems.

H. The Departments' Added Qualification for When a Disease is Manifested Is Inconsistent with GINA and Will Force Needless Confusion

The interim final rule provides that:

> *Manifestation* or *manifested* means, with respect to a disease, disorder, or pathological condition, that an individual has been or could reasonably be diagnosed with the disease, disorder, or pathological condition by a health care professional with appropriate training and expertise in the field of medicine involved. For purposes of this section, a disease, disorder, or pathological condition is not manifested if a diagnosis is based principally on genetic information.[20]

The first sentence is consistent with the statute but the second is not. The obvious point is that there is a statutory definition and the concept that the Departments wish to add is not present. Again, the Departments seem to want to have plans and enforcers dissect how a doctor arrives at his conclusion. One doctor may feel a given piece of information was a principal focus while another may believe a different piece of information is a principal focus. Doctors will provide a diagnosis that a disease is manifested. They are not concerned with irrelevant and false legal questions. There is no way to referee and second guess that process. Is the issue whether a given piece of evidence has dominant weight or is the issue that a diagnosis would not occur but for the genetic information buttressed by additional information. How does a plan or enforcer figure this out and so what if one could? Plans need to have clarity of status. The more factors and playing doctor the rules give to bureaucrats and courts, the more uncertainty.

We also note that the second sentence constitutes a misuse of common logic and the ordinary meaning of the term manifested. Manifested relates to the status of a disease, disorder or pathological condition. The key is whether evidence shows or demonstrates plainly the presence of the disease, disorder or pathological condition. Nothing in that concept removes a type of evidence. Once a person has the status of an actual disease, disorder or pathological condition, the extra sentence in the interim final rule suggests that status can be undone by whether the diagnosis was based on genetic information. This really turns the common definition of status on its head. It divides people who have a disease, disorder or pathological condition into two camps; those diagnosed principally through genetic information and those diagnosed a different way. Nothing in the statute allows for this and the ordinary use of the English language would not provide for this either.

The Chamber is further worried about the use of this concept in Title II of GINA since addressing manifested diseases is in some cases a statutory responsibility (such as under the Americans with Disabilities Act). We have submitted prior comments in this regard to the Equal Employment Opportunities Commission. The potential adverse impact both under Title I and Title II is real as there appears to be a host of manifested diseases and disorders that rely on genetic tests for diagnosis and the list is likely to grow.[21] Whether the diagnosis for these

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[20] 29 C.F.R. §2590.702-1(a)(6); 74 Fed. Reg. at 51,684.

[21] For example, see http://www.genedx.com/tests.php; cystic fibrosis at http://www.cff.org/AboutCF/Testing/GeneticCarrierTest/and http://www.nhlbi.nih.gov/health/dci/Diseases/cf/cf_diagnosis.html; and hereditary hemochromatosis, http://mostgene.org/gd/gdvol14c.htm

diseases and disorders are “principally based on genetics information” is a question that is sure to invite litigation and chill employers and plans from engaging in otherwise-lawful activity.

Again, there seems to be no articulated basis for this qualification. The Departments simply declare the rule but provide little consideration to impacts, complexity or even what policy, if any, is being advanced.

Closing

Thank you for giving us the opportunity to comment on the interim final rules. We ask that the Departments rescind the problematic elements we have cited as soon as possible. We are prepared to work with the Departments to refine these rules to protect genetic information for beneficiaries and to let common sense benefits for beneficiaries proceed without the needless disruptions of elements of the interim final rules.

Sincerely,

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