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January 4, 2010

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4137-IFC
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-4137-IFC, Interim Final Rules Prohibiting Discrimination Based on Genetic Information in Health Insurance Coverage and Group Health Plans, 74 *Fed. Reg.* 51664 (October 7, 2009)

Ladies and Gentlemen:

Laboratory Corporation of America Holdings ("LabCorp") is pleased to submit the following comments in response to the Interim Final Rules Prohibiting Discrimination Based on Genetic Information in Health Insurance Coverage and Group Health Plans ("Interim Final Rule") published at 74 *Fed. Reg.* 51664 on October 7, 2009. LabCorp is an industry-leading independent clinical laboratory providing a broad range of medical testing services, including genetic testing and counseling. As a responsible employer of over 28,000 employees, LabCorp offers self-funded group health plans to its workforce. As such, LabCorp is directly affected by the Interim Final Rule.

LabCorp strongly supported enactment of the Genetic Information Nondiscrimination Act of 2008 (GINA), Public Law 110-233. GINA was necessary because the law prior to its enactment consisted of a patchwork of Federal and State genetic nondiscrimination laws that collectively had failed to alleviate the fear of genetic discrimination, which significantly hampered the utilization of beneficial genetic testing. By establishing a uniform and comprehensive Federal framework prohibiting genetic discrimination in health insurance and employment, GINA promises to unlock the potential of genetic testing to improve the health and lives of all Americans.

While the Interim Final Rule generally implements Sections 101 through 103 of GINA in a manner that fairly reflects the scope and intent of those Sections, there is one glaring exception, which is the focus of our comments. The definition of "underwriting purposes" in the Interim Final Rule not only exceeds the scope of the statute, but results in outcomes that do not advance the purposes of GINA and will in fact negatively impact efforts to improve the public health.

Proposed 45 C.F.R. § 146.122(d)(1)(i) states the general rule that a group health plan, and a health insurance issuer offering health insurance coverage in connection with a group health plan, must not collect genetic information for underwriting purposes. 74 *Fed. Reg.* 51690.

Proposed 45 C.F.R. § 146.122(a)(1) defines "collect" as meaning, with respect to information, to request, require, or purchase such information. 74 *Fed. Reg.* 51688. Proposed 45 C.F.R. § 146.122(a)(3)(i)(C) defines "genetic information" to mean, with respect to an individual, information about the manifestation of a disease or disorder in family members of the individual, among other things. 74 *Fed. Reg.* 51688. Each of the foregoing proposed rules closely tracks the statutory provisions on which they are based. Therefore, the Interim Final Rule would prohibit group health plans, and health insurance issuers offering health insurance coverage in connection with a group health plan, from requesting family history for "underwriting purposes".

Section 101(d) of GINA amended Section 733(d) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. § 1191b(d)) by adding, among other things, the following definition of "underwriting purposes":

> (9) UNDERWRITING PURPOSES- The term `underwriting purposes' means, with respect to any group health plan, 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.

29 U.S.C. § 1191b(d)(9).

Applying subsections (A) and (B) of the statutory definition of "underwriting purposes" in GINA, group health plans and health insurance issuers offering health insurance coverage in connection with a group health plan are prohibited from using family history to determine eligibility for benefits or to compute premiums or contribution amounts. We fully support this outcome, which directly advances the public policy objectives of GINA – to encourage utilization of genetic testing services by prohibiting the use of genetic information in a discriminatory manner.

Unfortunately, the Interim Final Rule defines "underwriting purposes" very differently than GINA does. Proposed 45 C.F.R. § 146.122(d)(2) defines the term as follows:

(ii) *Underwriting purposes defined.* Subject to paragraph (d)(1)(iii) of this section, *underwriting purposes* means, with respect to any group health plan, 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 as described in § 146.121(b)(1)(ii) of this part **(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) The 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)**;

(C) The application of any preexisting 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.

74 *Fed. Reg.* 51690-51691 (Emphasis added).

The Interim Final Rule's changes to the definition of "underwriting purposes" are so significant that they would prohibit activities that a plain reading of the statutory definition in GINA would clearly permit. Under GINA's definition, so long as family history is not used to determine eligibility for benefits or to compute premiums or contribution amounts, a group health plan or a health insurance issuer offering health insurance coverage in connection with a group health plan can request family history through a health risk assessment or wellness program and offer financial incentives, such as changes in deductibles or other cost sharing mechanisms, or discounts, rebates, payments in kind, or other premium differential mechanisms, for the completion of such health risk assessments or participation in a wellness program. The Interim Final Rule's definition of "underwriting purposes" would prohibit such activities regardless of whether they affected eligibility for benefits or the computation of premiums or contribution amounts.

There is no legitimate basis for the Interim Final Rule's revisions to GINA's statutory definition of "underwriting purposes". The provision of financial incentives for the completion of health risk assessments and participation in wellness programs in which family history is requested does not involve discrimination on the basis of genetic information (family history). The financial incentive is triggered by the activity of completing the assessment or participation in the program, not by the content of the family history provided. A participant whose family

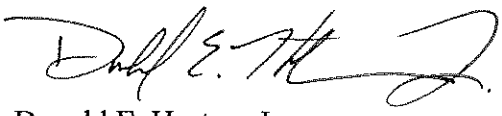
history includes every genetic abnormality known to mankind would be entitled to the same financial incentive available to a participant whose family history completely lacked genetic abnormality. Likewise, a non-participant with a family history devoid of genetic abnormality would be just as ineligible for the financial incentive as an individual whose family history reflected severe genetic abnormality. The activity GINA seeks to prohibit, and which its definition of "underwriting activities" does prohibit, is the use of family history to discriminate in eligibility determinations and premium settings. The provision of financial incentives to encourage participation in health risk assessments and wellness programs is not the activity GINA seeks to prohibit, and there is no need to revise or elaborate on GINA's statutory definition of "underwriting purposes" to achieve its intended purpose.

The risk that family history collected in association with health risk assessments and wellness programs could potentially be used by a group health plan or insurer for other purposes, including eligibility determinations and premium settings, can be, and typically is, effectively managed through arrangements in which a business associate of the group health plan or insurer collects the data and is contractually obligated to maintain its confidentiality and use the data solely for the purpose for which it was collected. GINA's existing definition of "underwriting purposes" is sufficient to render the use of such information for eligibility determinations and premium setting illegal in the event of a breach.

The practical effect of the Interim Final Rule's definition of "underwriting purposes" would be to discourage participation in effective health risk assessments and wellness programs, which have been shown to improve health outcomes and reduce health care costs. Without financial incentives, fewer individuals will participate in such programs. Without family history, health risk assessments will be incomplete, and wellness programs based on such assessments will be ill-informed. This result is completely contrary to what Congress intended when it enacted GINA. GINA was enacted to enable genetic information to inform health and wellness activities, not to stifle its use for such activities.

For the foregoing reasons, we respectfully request that the Interim Final Rule be amended to conform the definition of "underwriting purposes" to the statutory definition in GINA, including elimination of references to financial incentives for completion of health risk assessments and participation in wellness programs. We appreciate the opportunity to comment on the Interim Final Rule, and look forward to seeing the promise of GINA come to full fruition.

Very truly yours,



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