America's Health
Insurance Plans

601 Pennsylvania Avenue, NW
South Building
Suite Five Hundred
Washington, DC 20004

202.778.3200
www.ahip.org

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Submitted Via the Federal E-Rulemaking Portal: http://www.regulations.gov.

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

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

U.S. Department of the Treasury
Internal Revenue Service
Attention: CC:PA:LPD:PR (REG–123829–08)
Room 5205
P.O. Box 7604
Ben Franklin Station
Washington, DC 20044

Re: Interagency Request for Information Regarding the Genetic Information Nondiscrimination Act of 2008
CMS-4137-NC; RIN 1210-AB27; REG–123829–08

Dear Sir or Madame:

America's Health Insurance Plans (AHIP) is writing to offer comments in response to the Request for Information (RFI) regarding sections 101 through 104 of the Genetic Information Nondiscrimination Act of 2008 (GINA). The RFI was issued in the *Federal Register* on October 10, 2008.

AHIP is the national association representing nearly 1,300 health insurance plans providing coverage to more than 200 million Americans. Our members offer a broad range of products in

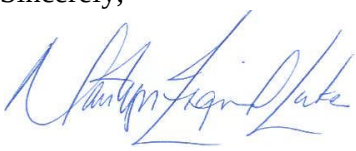
the commercial marketplace including health, long-term care, dental, vision, disability, and supplemental coverage. Our members also have a strong track record of participation in Medicare, Medicaid, and other public programs. Our members maintain protections for genetic information that prevent unauthorized disclosure and their programs and practices reflect this belief.

AHIP supported the GINA legislation and worked with Congressional staff and key stakeholders in the legislative process. We trust that GINA will promote informed health care decision-making by patients and practitioners and allow health insurance plans to maintain their state-of-the art programs to support early prevention and coordination of care programs.

AHIP is pleased to offer information in response to the Interagency RFI. Our comments and recommendations are listed in Attachment A and are intended to highlight those areas that we believe should be clarified when regulations are promulgated. Our comments correlate with the specific questions listed in the RFI.

Thank you for the opportunity to provide comments on this important topic. Please contact me at MZLuke@ahip.org or (202) 861-1473 if you have any questions.

Sincerely,



Marilyn Zigmund Luke
Senior Regulatory Counsel

America's Health Insurance Plans
Response to the Interagency Request for Information
Regarding the Genetic Information Nondiscrimination Act of 2008

Attachment A

The following are answers to specific questions asked in the Request for Information published in the *Federal Register* on October 10, 2008 by the U.S. Departments of Health and Human Services (HHS), Labor, and the Treasury. This response is based on our interpretations of the Genetic Information Nondiscrimination Act of 2008 (GINA) provisions as developed through our conversations with Congressional staff throughout the legislative process and as documented in the legislative history. We support issuance of regulations by the appropriate federal regulatory agencies that are consistent with and further clarify these interpretations. As indicated below, our subject areas correspond with the questions and topics noted in the Interagency request.

Health Insurance Plans' Use of Genetic Information

Question 1: To what extent do group health plans and health insurance issuers currently use genetic information (such as family medical history) and for what purposes?

Answer 1: Group health plans and health insurance issuers have played a vital role in providing access to appropriate preventive screening and other health initiatives for individuals. For example, early detection initiatives, disease management programs, and other quality improvement initiatives can help identify and assist individuals who would benefit from early detection and intervention. Such programs help promote patient-centered care while supporting the best evidence-based treatment for specific illnesses and diseases.[1] In other contexts, health insurance plans can use genetic information for critical health care operations (listed below). Some key practical examples are highlighted in the following eleven scenarios:

- A colorectal cancer disease management program identifies individuals for participation if they are under age 50 and have a family history that indicates they should receive colorectal cancer screenings.[2]

[1] Rep. Camp (R-MI): "But genetic information can also be used to help patients. Health plans have an ability to interact with both patients and providers to highlight recommended tests and courses of action. For example, a person that has a gene for a certain type of cancer would be recommended to receive more frequent cancer screenings. Knowing this, the health insurer would know to approve coverage for these additional screenings because they would be at a higher risk of developing that type of cancer." 154 Cong. Rec. H2961-03 (May 1, 2008), pH2974. Rep. Stark (D-CA): "Enactment of this law is critical to protect patients and is needed to encourage people to use robust genetic research and to encourage more research. Additional research will help us determine when we men will get colon cancer or prostate cancer, and not be afraid to go and receive those tests for fear of being discriminated against." 154 Cong. Rec. H2961-03 (May 1, 2008), pH2973. H.R. Rept. No. 110-28 (Part 1, p. 32), 110th Cong. 1st Session (2008). *See also*, S. Rept. No. 110-48, p. 19, 20, and 26, 110th Cong. 1st Session (2008).

[2] Rep. Camp (R-MI): "But genetic information can also be used to help patients. Health plans have an ability to interact with both patients and providers to highlight recommended tests and courses of action.

- A breast cancer disease management program sends reminders to individuals at risk of developing the disease to have annual mammograms or to perform monthly breast self-examinations to help facilitate early detection.
- A quality improvement initiative evaluates whether contracted hospital facilities consistently perform screenings of newborn babies for genetic and other diseases based on current clinical evidence and accepted standards of clinical practice.
- After enrolling with a health insurance plan, an individual receives a Personal Health Record.[3] The individual voluntarily enters health information (including genetic information and family history) into the PHR and the health insurance plan subsequently uses that information to identify the individual as a potential participant in a disease management program.
- A health insurance plan initiative identifies individuals with a specific genetic disease to provide information about a facility that has been recognized as a "Center for Excellence" because it has demonstrated results for that specific disease or may be a better treatment alternative for the individual.
- As part of a re-credentialing process, a health insurance plan reviews a contracted health care provider's performance to assess whether the provider is performing genetic tests based on currently available standards of clinical practice and evidence-based medicine.
- A health insurance plan requests and reviews the results of an individual's genetic tests to determine whether a prophylactic mastectomy[4] is a medically necessary service.
- As part of its fraud and abuse program, a health insurance plan reviews a provider's billing practices, individuals' medical records containing genetic information, and other information to assess whether fraud or abuse has occurred.
- A health insurance plan responds to an individual's inquiry or appeal related to a question or dispute about whether a service is a covered benefit. As part of the process, the individual offers genetic information, which is used by the health insurance plan to answer or respond to the individual's inquiry or appeal.

For example, a person that has a gene for a certain type of cancer would be recommended to receive more frequent cancer screenings. Knowing this, the health insurer would know to approve coverage for these additional screenings because they would be at a higher risk of developing that type of cancer." 154 Cong. Rec. H2961-03 (May 1, 2008), pH2974.

[3] For purposes of AHIP's response, a "personal health record" or "PHR" means an electronic record of health-related information on an individual that can be drawn from multiple sources while being managed, shared, and controlled by the individual. This is different from an "electronic health record" or "EHR," which is an electronic record of an individual's health-related information that conforms to nationally recognized interoperability standards and that can be created, managed, and consulted by authorized clinicians and staff across more than one health care organization. When a health insurance plans offers an individual a PHR, the individual receives notice of the uses and disclosures of protected health information through a notice of privacy practices as required by the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, 45 C.F.R. §164.520.

[4] Generally, a prophylactic mastectomy is surgery to reduce the risk of developing breast cancer by removing one or both breasts before disease develops. Such a procedure may also be called a preventive mastectomy.

- As part of a wellness program, a health insurance plan coaches an individual about the potential to develop diabetes based on a genetic predisposition for the disease coupled with negative environmental factors, the health risks associated with the onset of such a condition, and ways to avoid development of the disease.
- KRAS testing identifies a mutant oncogene that renders epidermal growth factor receptor treatments ineffective for colorectal cancer. Such testing can be a condition of health plan coverage decisions for certain therapies (e.g., Erbitux and Vectobix) to avoid administering toxic agents to an individual that will not improve cancer survival.

While the above examples are not exclusive, they help illustrate the positive and beneficial ways that genetic information can be used by a health insurance plan.

GINA was not intended to prohibit group health plans, group or individual health insurance issuers, or issuers of Medicare supplemental policies from using genetic information (such as family medical history) for these essential treatment, payment, and heath care operations that are unrelated to underwriting or enrollment or eligibility determinations.[5] In fact, these permissible uses of genetic information help promote and improve the health and care of individual health plan members. Thus, federal regulations should recognize and support such legitimate activities.

In addition, federal regulations should state that GINA prohibits using genetic information in the following circumstances:[6]

- Group health plans and health insurance issuers offering coverage in connection with a group health plan are prohibited from adjusting premium or contribution amounts for the group on the basis of genetic information. Plans and issuers can set an employer's premiums based on the manifestation of a disease in an individual who is enrolled in the group (e.g., a mother with breast cancer), but if related individuals are covered by the same plan or policy (e.g., a mother and daughter covered by the same plan or policy), the plan or issuer cannot use the genetic information of one individual (e.g., the family history of breast cancer for the daughter who has not manifested any symptoms of the disease) to further increase the premium for the employer.

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[5] Sen. Snowe (R-ME): "We have clarified that entities could communicate genetic information consistent with the HIPAA privacy regulations, the Health Insurance Portability [sic] Accountability Act. We worked to ensure that health plans may continue to utilize the presence of actual manifested diseases and issue rating coverages. That is the case today. We don't change that." 154 Cong. Rec. S3363-01 (April 24, 2008), pS3367. Rep. Upton (R-MI): "We also made numerous clarifications to make sure that the new regulatory scheme did not disrupt reasonable and needed activities by health plans to improve health care, coordinate benefits, process benefits, or educate beneficiaries. It is important for the Congress to be mindful that we are not writing on a blank slate each and every time that we launch one of these new regulatory and liability schemes." 154 Cong. Rec. H2961-03 (May 1, 1008), pH2974. H.R. Rept. No. 110-28 (Part 1, p. 32, 34, 66 and 67), 110th Cong. 1st Session (2008). *See also,* S. Rept. No. 110-48, p. 17, 110th Cong. 1st Session (2008).

[6] 26 U.S.C. §9802, 29 U.S.C. §1182, 42 U.S.C. §§300gg-1, 42 U.S.C. §300gg-53, and 42 U.S.C. §1395ss.

- GINA also prohibits plans and issuers from "requesting or requiring" an individual to undergo a genetic test. Plans or issuers are not precluded from obtaining and using the results of a genetic test for payment purposes such as determining coverage for benefits, claims payment, determining medical necessity, prior authorizations, and utilization review activities.
- In the individual market, genetic information cannot be used as a condition of eligibility for coverage.
- In addition, issuers of Medicare supplemental policies are prohibited from denying or conditioning the issuance of a policy, or discriminating in the price of the policy, based on genetic information.

Recommendation 1: Federal rulemaking should recognize and support the legitimate uses of genetic information (including family medical history) by group health plans, group and individual health insurance issuers, and issuers of Medicare supplemental policies, and protect uses of genetic information that help promote and improve the health and care of individual health plan members.

Question 2a: Is genetic information currently used for group rating purposes?

Discussion 2a: Generally, health insurance plans do not use an individual's genetic information as part of the group rating process to determine an individual's eligibility for coverage, to set an employer's or employee organization's premiums based on the belief that an individual at some point in the future may develop a condition or disease, or to charge an individual a higher premium or cost-sharing amount than other similarly-situated members of the same group. However, there are two uses of health information in the group rating process that should be clarified as permissible processes under GINA.

First, GINA does not prohibit health insurance plans from using actual claims experience to set initial and renewal premiums for groups. The costs of medical items and services used by an individual (e.g., the costs of genetic tests or genetic services) do not meet the definition of "genetic information" and, as a result, health insurance plans can set or renew premium rates or contribution amounts for the group as a whole using this information.[7]

Second, when claims data are used to set initial or renewal premium rates or contribution amounts for a group, information about family members will likely be part of the information used whenever one or more members of a family are covered by the same plan or policy. GINA was never intended to restrict the use of information about family history in this context because a health insurance plan is allowed to consider the health information of each person enrolled in the group.[8]

[7] *See*, S. Rept. No. 110-48, p. 18 and 19, 110th Cong. 1st Session (2008).
[8] *Id. at 19*.

As such, any future rulemaking should make clear that group health plans, group and individual health insurance issuers, and issuers of Medicare supplemental policies can: (1) use actual claims experience (including the costs of genetic tests, genetic services, or treatments of manifested diseases) to set initial and renewal premiums or contribution amounts for groups; and (2) use information about family members to set premium or renewal rates for a group whenever one or more members of a family are covered by the same plan or policy, as long as the manifestation of a disease or disorder in one individual is not used as genetic information about other group members to further increase a group's premiums.

Recommendation 2a: Federal rulemaking should explain that GINA does not prohibit health insurance plans, when setting or adjusting premiums for a group, from using: (1) actual claims experience to set initial and renewal premiums for groups, including the costs of services involving genetic information, genetic tests, or genetic services; or (2) individuals' health information, including information about the manifestation of a disease or disorder in the individual; or (3) a family member's health information when an individual and his or her family member are covered under the same group plan or policy.

Question 2b: Is genetic information currently used for purposes of a wellness program?

Discussion 2b: The legislative history of GINA is clear that wellness programs can use genetic information[9] and future Interagency regulations should clarify this key point.

Voluntary wellness programs have been shown to effect positive outcomes for individuals. For example, if an individual participates in a wellness program to reduce high cholesterol levels, he or she may disclose or receive information about his or her family history or genetic tests such as familial hypercholesterolemia (i.e., a genetic propensity to exhibit high levels of "bad" cholesterol). Such a use of genetic information in this context is allowed by GINA and should be recognized as a legitimate use of information as part of the wellness program.

Another possible use of genetic information in the context of a wellness program can involve using an individual's genetic information to evidence eligibility for a "reasonable alternative standard."[10] Federal regulations require that if a wellness program requires an individual to satisfy a standard related to a health factor (e.g., meeting a certain cholesterol count to receive a cash incentive), the program must be available to similarly-situated individuals. As a result, the program must provide a reasonable alternative standard for individuals who cannot satisfy the standard because of a medical condition (e.g., if an individual has familial hypercholesterolemia, a wellness program can legitimately use genetic information to evidence the basis for designing another method

[9] H.R. Rept. No. 110-28 (Part 1, p. 32), 110th Cong. 1st Session (2008). *See,* S. Rept. No. 110-48, p. 19 and 20, 110th Cong. 1st Session (2008).

[10] Final regulations governing nondiscrimination requirements and wellness programs can be found at 26 C.F.R. Part 54, 29 C.F.R. Part 2590, and 45 C.F.R. Part 146.

for an individual to satisfy the program's parameters and receive the cash incentive). It would also be helpful for future rulemaking to explain that GINA does not apply to a wellness program when the program does not require an individual to meet a standard in order to receive a program benefit (e.g., a program that reimburses all or part of the cost of memberships in fitness centers).

Recommendation 2b: Federal rulemaking should clarify that wellness programs are permitted to use or obtain genetic information. Future Interagency regulations should explain and provide examples of legitimate and permissible ways that wellness programs can use genetic information to effect positive outcomes for individuals.

Obtaining Genetic Information

Question 3: How do plans and issuers currently obtain genetic information (e.g., through health risk assessments, the Medical Information Bureau, or other entities under common control)?

Discussion 3: Company-specific policies and procedures and insurance products offered by individual companies in their respective markets will determine if genetic information is currently collected and, if so, for what purposes. Generally speaking, health insurance plans can obtain genetic information in two situations: (1) from individuals who voluntarily complete health risk assessments; and (2) through health care provider claims submissions after an individual receives health care services.

We recognize that once GINA becomes effective, group health plans, group and individual health insurance issuers, and Medicare supplemental issuers will be prohibited from requesting, requiring, or purchasing genetic information about an individual prior to his or her enrollment under a plan or policy, unless the information is obtained incidentally. However, we can reasonably anticipate at least six scenarios that could arise and that would benefit from regulatory clarification:

- A health insurance plan or issuer is purchased by or merges with a succeeding health insurance company. Genetic information is acquired when corporate records are transferred or subsumed.
- An individual applies for insurance coverage in the individual market. After receiving an individual's signed authorization,[11] the health insurance issuer requests the individual's medical records in written or electronic form from his or her health care providers as part of the underwriting process. Genetic information is not requested but is included incidentally in the individual's medical records.
- An individual is covered by a health insurance plan or policy offered by Company A but subsequently cancels and obtains new health coverage through a

[11] Generally, this authorization would comply with the HIPAA Privacy Rule requirements contained in 45 C.F.R. §164.508.

competitor. The individual then cancels the policy and re-enrolls with Company A. In this situation, Company A would have historic health information relating to the individual prior to the re-enrollment that could include genetic information.

- An individual's family member enrolls in a plan or under a policy but was already covered by the health insurance company's product (e.g., two spouses covered by separate employer group policies and each employer contracts with Insurer A to provide health benefits on a fully-insured basis). In this situation, the health insurance issuer may have collected genetic information about the family member prior to his or her enrollment.
- While not requested by a health insurance plan, an individual voluntarily divulges genetic information orally or in writing (e.g., on an application or in a conversation) prior to or at the time of enrollment under a plan or policy.
- An individual utilizes a PHR and voluntarily enters genetic information into the record.

We believe that the above scenarios represent prime examples of situations where genetic information would be "incidentally collected" by a health insurance plan and as such are permitted collections of genetic information under GINA.

In addition, future rulemaking should make clear that group health plans, group or individual health insurance issuers, and issuers of Medicare supplemental policies: (1) cannot request, require, or purchase genetic information for underwriting purposes; and (2) cannot request, require, or purchase genetic information prior to an individual's enrollment.

Recommendation 3: Federal regulations should clarify how genetic information may be "incidentally collected" or obtained for purposes unrelated to underwriting purposes without violating GINA's prohibitions.

Requesting or Requiring a Genetic Test

Question 4: Under what circumstances do plans or issuers currently request or require an individual to take a genetic test?

Discussion 4: The following ten examples illustrate how health insurance plans encourage appropriate genetic testing:

- According to guidelines issued by the National Institutes of Health (NIH), treatment for hepatitis C patients should be extended (from 24 weeks to 48 weeks of therapy) only in cases where a viral genotype guide has been identified in an individual.[12] In this situation, a health insurance plan can request that an individual undergo a genetic test to determine whether an additional 24 weeks of

[12] Consult www.nih.gov and http://digestive.niddk.nih.gov/ddiseases/pubs/chronichepc/#g for more information (accessed December 9, 2008).

therapy would be medically necessary and thus covered under a health plan or policy.

- Last year, the Food and Drug Administration (FDA) approved the MammaPrint test to assess whether a woman is likely to have a breast cancer relapse.[13] This genetic test (as well as other gene expression profile tests) enables tailoring therapy for individual patients and helps a clinician administer chemotherapy to only those patients who would benefit, while also identifying those patients for whom the chemotherapy would be contraindicated. A health insurance plan may request that an individual undergo a genetic test to determine if he or she would be a good candidate for chemotherapy in this situation.
- Health care providers who are employees of or under contract with a health maintenance organization (HMO) or other health plan or issuer can recommend genetic tests to individual patients as part of their treatments.
- HER-2 genetic tests indicate whether breast cancer tumors would be responsive to herceptin therapy. This test helps identify patients who would face adverse side effects, including increased risk of heart disease, if the herceptin therapy is not appropriate based on an individual's genetic makeup. In this scenario, health insurance plans may require contracted health care providers to perform and provide the results of this test when the provider requests payment or reimbursement for administering the herceptin therapy.
- The identification of the presence or absence of the Cytochrome P450 enzyme, a genomic marker, enables a physician to evaluate an individual's ability to process many different medications, adjust dosages intelligently, and avoid potential adverse drug reactions in patients who either metabolize a drug quickly, who metabolize a drug slower than other individuals, or who do not metabolize a drug at all. Specifically, this test can be used to determine how children with certain forms of leukemia will respond to various doses of chemotherapy. A health insurance plan may request an individual undergo a genetic test to ensure appropriate application of clinical guidelines.
- Genomic signatures can be used to derive gene profiles from cell-lines that predict drug sensitivity for difficult-to-treat malignancies such as lung cancer. Health insurance plans will need information about whether the genetic test was performed and the results of the test in order to evaluate, authorize, or pay for the extended course of therapy for the individual.
- As part of a disease management program, a health insurance plan may suggest that an individual undergo a genetic test as part of a prevention or treatment screening covered under a health plan or policy.
- Health insurance plans often provide educational materials to covered members to encourage appropriate genetic testing, such as literature advising men about the benefits of a genetic test that screens for prostate cancer.
- As part of a fraud and abuse investigation, a health insurance plan may solicit information from an individual to evidence whether a genetic test was, in fact, performed by a health care provider or facility.

[13] The press release can be found at http://www.fda.gov/bbs/topics/NEWS/2007/NEW01555.html (accessed December 9, 2008).

- An individual files an appeal of a health insurance plan decision to not cover a prophylactic mastectomy. During the appeals process, the health insurance plan requests that the individual undergo a genetic test before deciding whether the service should be covered under the individual's health benefits plan as a medically necessary service.

As these examples illustrate, health insurance plans often will need to know whether a genetic test was performed, and in some cases will need the test results, in order to make a payment decision or to use the information for prevention and disease management programs. As scientists acquire a greater understanding of the role genes play in disease and develop more genetic therapies and possibly even cures, preventive screening and disease management programs can be tailored to improve outcomes for individuals and can become even more important in the future. The statute and the legislative history are clear that GINA was never intended by Congress to prohibit these beneficial uses of information by health insurance plans.[14]

Recommendation 4: Interagency regulations should explain how group health plans, group and individual health insurance issuers, and Medicare supplemental issuers can request or require genetic tests for payment purposes and for prevention and disease management programs. In addition, any federal regulations should promote consumer access to and education about genetic tests and related services as appropriate based on an individual's health benefits as well as coverage and treatment protocols.

Question 5: Under what circumstances do plans or issuers currently ask for the results of a genetic test in order to make a determination regarding payment of benefits?

Discussion 5: As the examples highlighted in Question 4 indicate, the need to request the results of a genetic test is fact-specific and will vary based on an individual's disease or condition, the therapy being requested, the covered benefits and services, the health insurance plan or issuer's payment policies, and an individual's willingness to undergo such testing. Congress clearly anticipated such business needs and provided for adequate statutory authority for payment functions in the GINA statute.[15]

Recommendation 5: Interagency regulations should not establish federal requirements or restrictions for when and how health insurance plans can ask for the results of genetic tests to make payment determinations.

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[14] 26 U.S.C. §9802(c)(3), 29 U.S.C. §1182(c)(3), 42 U.S.C. §300gg-1(c)(3), 42 U.S.C. §300gg-53(d)(3), and 42 U.S.C. §1395ss(x)(1)(C). H.R. Rept. No. 110-28 (Part 1, p. 32-35), 110th Cong. 1st Session (2008). *See*, S. Rept. No. 110-48, p. 20-22, 110th Cong. 1st Session (2008).

[15] 26 U.S.C. §9802(c)(3), 29 U.S.C. §1182(c)(3), 42 U.S.C. §300gg-1(c)(3), 42 U.S.C. §300gg-53(d)(3), and 42 U.S.C. §1395ss(x)(1)(C).

"Minimum Necessary" Information

Question 6: What is the minimum amount of information necessary for a plan or issuer to make a payment determination using a genetic test?

Discussion 6: As discussed above, the minimum amount of information necessary for a plan or issuer to make a payment determination using a genetic test is highly fact specific and can vary depending upon factors such as an individual health insurance plan's payment policies and procedures, medical necessity guidelines, covered benefits and exclusions, an individual's request for services, a provider's contract, a provider's scope of practice, evidence-based medicine, and many other factors.

Health insurance plans, as well as health care providers who are covered entities under the Health Insurance Portability and Accountability Act (HIPAA), would utilize the HIPAA Privacy Rule's minimum necessary standards[16] when making requests for or sending information related to payment purposes.

Recommendation 6: Future GINA regulations should reinforce the HIPAA Privacy Rule's minimum necessary standards and explain that the minimum necessary requirements apply to requests for information related to genetic tests and payment functions.

Research

Question 7: What types of research do plans or issuers currently conduct or support using genetic tests?

Discussion 7: Some health insurance plans have developed innovative research programs to examine the genetic and environmental factors that influence common diseases such as heart disease, cancer, diabetes, high blood pressure, Alzheimer's disease, and asthma. Through these initiatives, researchers hope to learn more about what combinations of genes and environmental factors influence the risk of complex diseases. Such research projects meet the highest scientific standards and comply with the legal requirements for privacy and confidentiality, including the requirements applicable to federally-funded research projects under HIPAA[17] and other applicable legal provisions.

A prime example is a project being conducted by an AHIP member, Kaiser Permanente of Northern California's Division of Research. In that program, individual participation in the research is completely voluntary and individual genetic information is not used in genetic studies without an individual's written authorization. Last year, 1.9 million Kaiser Permanente Northern California members were invited to participate in the research effort. This is a long-term program with the goals of identifying genetic and environmental factors that affect people's health, and of using that information to

[16] 45 C.F.R. §164.502(b).
[17] 45 C.F.R. §§164.508, 164.512(i).

improve individuals' health and health care. Ultimately, this research program is expected to yield findings that may enable the medical community to be more precise in pinpointing the causes of disease and tailoring treatment for patients.

A second example from another AHIP member, Aetna, involves the evaluation of clinical utility of genetic tests (i.e., those that are currently available as well as those in developmental stages). Aetna's research efforts are underway with academic collaborators that seek to understand how genetic tests used in breast cancer care apply in practical, clinical practice. (It is hypothesized that these tests are underutilized due to lack of physician education about the effective use of these technologies.) The goal of this research is to: (1) collaborate with researchers to build an evidence base to support effective decision making related to testing technologies as they are used in clinical practice; (2) use the results of this research to improve access to genetic technologies; and (3) use the results of this research to design and deliver decision support tools to help members and physicians use these technologies effectively to optimize the care of individuals. We note that federal agencies (e.g., the Centers for Disease Control, the National Institutes of Health) have advocated for similar research collaborations in genetic medicine between health plans, academic, industry, and other non-traditional research partners.[18]

Recommendation 7: Federal GINA regulations should ensure that health plans and issuers have the ability to sponsor, continue, and support valuable research projects, programs, and protocols using genetic tests.[19]

Question 8: Would a model notice be helpful to facilitate disclosure to plan participants and beneficiaries regarding a plan's or issuer's use of the research exception in GINA? If so, what information would be most helpful to participants and beneficiaries?

Discussion 8: In the research context, GINA requires that a group health plan, a group or individual health insurance issuer, or an issuer of a Medicare supplemental policy may request, but cannot require, that a participant or beneficiary undergo a genetic test if: (1) a written request is made that complies with federal regulations and any applicable state or local laws or regulations for the protection of human subjects in research; (2) the plan or issuer clearly indicates to each participant, beneficiary, or legal guardian of a minor to whom a request is made that compliance with the request is voluntary and non-compliance will have no effect on enrollment status or premium or contribution amounts;

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[18] National Institutes of Health Roadmap for Medical Research as available at: http://nihroadmap.nih.gov/ (accessed December 9, 2008). Kathryn A. Phillips, *Closing the Evidence Gap in the Use of Emerging Testing Technologies in Clinical Practice*, JAMA, 300: 2542-2544 (December 3, 2008). In addition, the Secretary's Advisory Committee on Genetics, Health, and Society has released a number of reports that discuss issues related to genetics and public and private collaborations. Consult: http://oba.od.nih.gov/SACGHS/sacghs_home.html and http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS_PGx_report.pdf (accessed December 9, 2008) for more information.

[19] It would also be helpful for the federal agencies to reinforce that "research" in this context is based on the HIPAA definition contained in 45 C.F.R. §164.501.

(3) no genetic information collected or acquired will be used for underwriting purposes; (4) the plan or issuer notifies the Secretary in writing that the plan or issuer is conducting research activities as allowed under GINA, including a description of the activities conducted; and (5) the plan or issuer complies with such other conditions as the Secretary may require by regulation.

AHIP supports a model notice to help facilitate disclosures to plan participants and beneficiaries regarding a plan's or issuer's use of the research exception in GINA. We believe a model notice can help ensure better understanding of federal requirements for participants, beneficiaries, and legal guardians of minors who participate in a research project or program that may require a genetic test. We believe, however, that such a model notice should not be based solely on GINA's research requirements. We recommend that HHS work with other federal agencies and state and local agencies and officials, as appropriate, to develop a model notice that would provide information about all disclosures required by each of the applicable laws and regulations.

Recommendation 8: Federal agencies should work together and with applicable state and local officials to develop a model notice for individuals who participate in research projects or programs to ensure consistent understanding about what GINA is and how it applies to research. Any model notice should also provide information about any other legal requirements that may be applicable to research projects or programs.

Question 9: Would a model form be helpful to report to the Departments if a plan or issuer claims the research exception? If so, what information should plans and issuers report?

Discussion 9: Under GINA, a plan or issuer that requests a participant or beneficiary to undergo a genetic test as part of its research protocol is required to notify the Secretary in writing that the plan or issuer is conducting research activities as allowed under GINA, including a description of the activities conducted. For plans or issuers claiming the GINA research exception, a model notice would help ensure that consistent information will be provided to the required agency official about diverse program types. A model would also help ensure that plans and issuers understand the expectations for the required reporting.

In addition, since several agencies are responsible for enforcing GINA's provisions, it would be helpful to clarify to which agency official or officials should receive the required notice (e.g., group health plans would send the form to the Secretary of Labor) or whether the Secretary of HHS will have authority to receive the required notices for all research projects and programs.

Recommendation 9: We recommend that a model form be developed to report information when a plan or issuer claims the research exception and that the agency or agencies designated to receive the notice be clearly identified.

Collecting Genetic Information

Question 10: When might genetic information be collected incidentally?

Discussion 10: Refer to Question 3 above.

Recommendation 10: Refer to Question 3 above.

The Definitions of "Genetic Information" and "Genetic Test"

Question 11: What terms or provisions (such as genetic information, genetic test, genetic services, or underwriting) would require additional clarification to facilitate compliance?

Discussion 11: A critical component of GINA is understanding the definitions used, particularly "genetic information" and "genetic test." Under GINA, genetic information is defined as "with respect to any individual, information about (i) such individual's genetic tests, (ii) the genetic tests of family members of such individual, and (iii) the manifestation of a disease or disorder in family members of such individual."[20] Genetic test means "an analysis of human DNA, RNA, chromosomes, proteins, or metabolites, that detects genotypes, mutations, or chromosomal changes" but does not include "(i) an analysis of proteins or metabolites that does not detect genotypes, mutations, or chromosomal changes; or (ii) an analysis of proteins or metabolites that is directly related to a manifested disease, disorder, or pathological condition that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved."[21]

Clarification of how these definitions can apply in a real-life setting can help ensure consistent implementation of the GINA requirements, particularly since both medical and non-medical professionals will be interpreting GINA's provisions. Practically speaking, genetic information is predictive information because it can include health indicators or a predisposition of the potential to develop a disease or condition, but does not include information relating to a manifested disease or condition. The statute and the legislative history recognize these important distinctions relating to, and interpretations of, these key terms.[22]

In addition, future rulemaking should clarify a few additional key points. First, genetic tests are not "genetic information" under GINA simply because the testing involves

[20] 26 U.S.C. §9832(d), 29 U.S.C. §1191b(d), 42 U.S.C. §300gg-91(d), and 42 U.S.C. §1395ss(x).
[21] *Id.*
[22] *Id.* H.R. Rept. No. 110-28 (Parts 1, p. 27), 110th Cong. 1st Session (2008).

genetic material or precedes an individual's application for health insurance or actual insurance coverage. If a genetic test is directly related to a manifested disease or condition, future regulations should make clear that it does not meet the definition of "genetic information" under GINA.

It would also be helpful to explain how the agencies will view situations where an individual receives a genetic test, but the treating health care professional misdiagnoses the individual or makes a mistake in analyzing the results of the genetic test (e.g., the genetic test showed that an individual had or has manifested a disease or condition "that could reasonably be detected by a health care professional with appropriate training and expertise in the field of medicine involved," but the disease or condition was not detected because of human error in failing to render an appropriate diagnosis).

Recommendation 11: We encourage the federal agencies to provide as much clarification as possible about the meanings of "genetic information" and "genetic test." At the outset, any Interagency regulations should clarify these keys terms and specifically explain how information about an individual's manifested diseases or conditions is not subject to the GINA protections and prohibitions.

Other Issues

We recommend several additional issues be addressed by the applicable federal agencies. We have also included our recommendations for addressing them.

Issue 12: Federal rulemaking should make clear that the HIPAA "excepted benefits"[23] provisions apply when interpreting GINA's provisions.

Discussion 12: Legislative history indicates that excepted benefits are outside GINA's scope.[24] While Medicare supplemental products typically are excepted benefits, they are covered by GINA section 104. Medicare supplemental products, however, are the only category of "excepted benefits" subject to GINA's provisions. Other excepted benefits (e.g., disability insurance; independent, non-coordinated coverage for a specified disease or illness; independent, non-coordinated hospital indemnity or other fixed indemnity insurance coverage; separate, supplemental coverage provided under a group health plan) are outside GINA's scope.

Recommendation 12: Federal rulemaking should make clear that GINA does not apply to HIPAA's "excepted benefits."

Issue 13: Long-term care insurance was never intended to be covered under GINA.

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[23] 26 U.S.C. §9832(c), 29 U.S.C. §1191b(c), and 42 U.S.C. §300gg-91(c).

[24] H.R. Rept. No. 110-28 (Part 1, p. 35 and 69), 110th Cong. 1st Session (2008). *See also*, S. Rept. No. 110-48, p. 27, 110th Cong. 1st Session (2008).

Discussion 13: GINA's legislative history is clear that the long-term care insurance market is outside the scope of this law.[25]

Recommendation 13: Future rulemaking should specifically recognize long-term care insurance is outside the scope of the GINA law and regulations.

Issue 14: The federal agencies should clarify the application of GINA to government sponsored health benefits programs.

Discussion 14: It would be helpful for the federal agencies to clearly explain in regulations which governmental health benefits programs are affected by the law and regulations. Although GINA does not modify the statutory authority through which the federal government offers the Federal Employees Health Benefits Program (FEHBP) to government officials and employees, we expect that the GINA provisions will apply to the FEHBP when group health issuers contract with the Office of Personnel Management to provide health benefits to federal government employees. Likewise, we expect state and local government health plans to adhere to GINA's requirements pursuant to the Public Health Service Act provisions.[26]

Because GINA does not modify or change the statutory authority for establishing or conducting certain federal health benefits programs such as Medicare, Medicaid, or the State Children's Health Insurance Program, GINA does not apply to these federal health benefits programs. However, if an employer or employee organization sponsors a group health benefits plan for retirees (e.g., a private health benefits plan for retirees [self-funded or fully-insured] or an employer-sponsored Medicare Advantage retiree plan), we expect that the GINA requirements will apply. Given the various applications of GINA, future regulations should clearly explain how the GINA statute and corresponding regulations will affect all federally-sponsored and state-sponsored health benefits programs.

Recommendation 14: GINA regulations should clarify the application of GINA to federal, state, and local health benefits programs.

Issue 15: Federal regulations should make clear that GINA regulates all Medicare supplemental products, whether the product is offered on an individual or group basis and whether the plan or policy covers one or more persons.

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[25] Rep. Green (D-TX): "One segment of the health care marketplace was excluded from the bill's protections--the long-term care insurance market. This bill was never intended to regulate the long-term care insurance market, and I understand that current statute treats long-term care insurance differently." 154 Cong. Rec. H2961-03 (May 1, 2008), pH2978. H.R. Rept. No. 110-28 (Parts 1, p. 35), 110th Cong. 1st Session (2008). S. Rept. No. 110-48, p. 27, 110th Cong. 1st Session (2008).

[26] Refer to http://www.cms.hhs.gov/SelfFundedNonFedGovPlans/ for more information (accessed December 9, 2008).

Discussion 15: GINA applies to Medicare supplemental products.[27] Federal regulations should explain that the statutory requirements will apply to all Medicare supplemental products, issued on a one-person basis, that cover one or more persons, or that are available to members on an association group basis. It would be helpful for federal regulations to explain that policies issued by employers or employee organizations for retirees are not Medigap policies,[28] but these plans and policies may be covered by corresponding GINA requirements.

Recommendation 15: Future regulations should explain that GINA applies to all Medicare supplemental products, whether offered on an individual or on a group basis and whether a plan or policy covers one person or more than one person.

Issue 16: The HIPAA Privacy Rule changes should be limited to: (1) treating genetic information as health information; and (2) restricting the use or disclosure of protected health information that is genetic information about an individual for underwriting purposes by a covered entity that is a group health plan, health insurance issuer that issues group or individual health insurance coverage, or issuer of a Medicare supplemental policy.

Discussion 16: We recognize that HHS is required to change the HIPAA Privacy Rule to conform to the GINA requirements. We urge HHS to craft such changes carefully so that the entities and products offered by them (as discussed in Issues 12 -15 listed above) that are not covered by GINA are not inadvertently "swept in" when the Privacy Rule changes are proposed.

Recommendation 16: We propose the following language to accomplish the required Privacy Rule changes. (Note that bold text is new text.)

Revise 45 C.F.R. §160.103 as follows:

> The term "health information" means any information, whether oral or recorded in any form or medium, that: (1) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual. **(3) While health information can include "genetic information" (as such term is defined in §160.103), only a health plan that meets: (i) subsections (i),(ii), (vi), or (xiii) of 45 C.F.R. §160.103); and (ii) is either: (a) any policy, plan, or program to the extent that it does not provide, or pay for the cost of, excepted benefits that are listed in section 2791(c) of the PHS Act, 42 U.S.C. 300gg-91(c); or (b) an issuer**

[27] *Id.*
[28] 42 U.S.C. §1395ss(g).

of a Medicare supplemental health insurance plan or policy, shall adhere to the restrictions on the uses and disclosures of "genetic information" listed in §164.501.

Add the following as a new section to 45 C.F.R. §160.103:

"Genetic information" means, with respect to any individual:
(a) information about (i) such individual's genetic tests, (ii) the genetic tests of family members of such individual, and (iii) the manifestation of a disease or disorder in family members of such individual.
(b) any request for, or receipt of, genetic services, or participation in clinical research which includes genetic services, by such individual or any family member of such individual.
(c) The term "genetic information" shall not include information about the sex or age of any individual.

Revise 45 C.F.R. §164.501(3) as follows:

Health care operations means any of the following activities of the covered entity to the extent that the activities are related to covered functions: . . .
(3) Underwriting, premium rating, and other activities relating to the creation, renewal or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care (including stop-loss insurance and excess of loss insurance), provided that the requirements of § 164.514(g) are met, if applicable.
(A) If a health plan is required to treat "genetic information" as "health information" (as defined in §160.103), then the use or disclosure by such health plan of an individual's protected health information that is genetic information for underwriting purposes shall not be a permitted use or disclosure.

Issue 17: Federal regulations should make clear that there are no provisions in GINA that restrict or interfere with the delivery of health care services, or that change the uses and disclosures of health information for treatment or payment purposes.[29]

Discussion 17: GINA prohibits discrimination based on genetic information in insurance and underwriting. The legislative history is clear that GINA was never intended to restrict or interfere with the delivery of health care services. In addition, there are no provisions in GINA that would require a change to the HIPAA Privacy Rule's definitions for treatment or payment functions.

[29] "Treatment and payment" in this context are based on the definitions and permitted uses and disclosures contained in the HIPAA Privacy Rule, 45 C.F.R Part 164, Subpart E.

Recommendation 17: Future rulemaking should make clear that GINA does not restrict or interfere with the delivery of health care services, or change the uses and disclosures of health information for treatment or payment purposes.[30]

Issue 18: Future regulations should clarify GINA's preemption provisions and the interaction with state laws and regulations.

Discussion 18: As the legislative history indicates, states have been highly active in enacting laws and regulations to prevent genetic discrimination.[31] It would be helpful if federal regulations discussed how the federal GINA law and regulations will intersect with these existing as well as future state requirements.

In addition, the National Association of Insurance Commissioners (NAIC) has developed a model regulation for states to consistently implement the GINA requirements for Medicare supplemental products. It would be helpful for federal regulations to explain that the NAIC's activities for Medicare supplemental products are required by GINA, and that state laws or regulations consistent with the NAIC Medigap Model Regulation are not preempted by federal law. Federal regulations should also explain how federal legal requirements will intersect with state laws and regulations that implement GINA's requirements for Medicare supplemental products in a manner that differs from the NAIC model regulation.

Recommendation 18: Federal regulations should explain how the GINA law and regulations will intersect with existing and future state requirements.

Issue 19: Federal regulations should make clear that GINA does not mandate health insurance plans to cover or reimburse coverage for genetic tests and services.

Discussion 19: There are no provisions in GINA that require a group health plan, a group or individual health insurance issuer, or an issuer of a Medicare supplemental policy to cover genetic testing or all treatments related to genetic-related conditions.[32] In

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[30] *Id.* Sen. Snowe (R-ME): "We have clarified that entities could communicate genetic information consistent with the HIPAA privacy regulations, the Health Insurance Portability [sic] Accountability Act. We worked to ensure that health plans may continue to utilize the presence of actual manifested diseases and issue rating coverages. That is the case today. We don't change that." 154 Cong. Rec. S3363-01 (April 24, 2008), pS3367. Rep. Upton (R-MI): "We also made numerous clarifications to make sure that the new regulatory scheme did not disrupt reasonable and needed activities by health plans to improve health care, coordinate benefits, process benefits, or educate beneficiaries. It is important for the Congress to be mindful that we are not writing on a blank slate each and every time that we launch one of these new regulatory and liability schemes." 154 Cong. Rec. H2961-03 (May 1, 1008), pH2974.

[31] H.R. Rept. No. 110-28 (Part 1, p. 30), 110th Cong. 1st Session (2008).

[32] Rep. McKeon (R-CA): "Foremost, I am pleased that the bill we will send today to the White House for President Bush to sign embodies the same logic as a past executive order issued by President Clinton to ensure that this legislation would not inadvertently serve as a broad new Federal mandate requiring all insurance plans and employers to cover all treatments related to genetic-related conditions. That is exactly

fact, section 209(a)(7) specifically recognizes that nothing in the law requires any specific benefit for an employee or member or a family member of an employee or member under any group health plan or group health issuer. Thus, health plans and issuers can structure plan provisions and policies that exclude coverage for services related to genetic testing, genetic diseases, or genetic services.

The ability for health insurance plans to cover or exclude services related to genetic testing, genetic diseases, or genetic services is important because many genetic tests are not supported by clinical evidence. Health insurance plans need the ability to make benefits and coverage decisions based on factors such as evidence-based medicine, currently accepted clinical guidelines and decision-making, whether genetic counseling is required as a prerequisite to receiving coverage for a genetic test, and other legitimate factors.

Recommendation 19: Federal regulations should make clear that GINA does not mandate specific benefits for health care services related to genetic tests, genetic diseases or conditions, or genetic services.

Issue 20: Federal regulations should explain that GINA's Title I and Title II provisions contain separate enforcement processes and remedies.

Discussion 20: Section 209(a)(2)(B) states that nothing in the law provides for enforcement of, or penalties for violation of, any requirement or prohibition applicable to any employer, employment agency, labor organization, or joint labor-management committee that should be brought under Title I or subsection (a) of section 701 of the Employee Retirement Income Security Act. The legislative history is clear that Congress intended a "firewall" between Titles I and II.[33] Since this was a significant and highly contentious issue during the legislative process, federal regulations should explain this important aspect of GINA.

Recommendation 20: Federal regulations should explain that GINA's Title I and Title II provisions contain separate enforcement processes and remedies.

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the type of unintended consequences we were seeking to avoid, and I am pleased we were able to work this out." 154 Cong. Rec. H2961-03 (May 1, 1008), pH2973.

[33] Rep. Miller (D-CA): "This final bill makes it clear that, even though employers may not be held accountable for violations committed by health plans under title I, employers remain fully liable for any violations of title II, including violations involving health benefits." 154 Cong. Rec. H2961-03 (May 1, 1008), pH2977.