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## Personalized Medicine & Health Care Reform: Realizing the Promise

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## Our Road Map

- Brief Overview of the Personalized Medicine Industry – Where it is Now, and Where it is Headed.
- How will health care reform impact this industry and technology development?
- Genomics and Personalized Medicine Act of 2010
- Priority and Funding Support
- Medicare Issues.
- Comparative Effectiveness.
- Patient Outcomes Research Institute.
- Genetic Information Act (GINA) Issues.
  - How GINA impacts the industry in general.
  - New implications from health care reform.

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## Personalized Medicine

- Personalized Medicine.
  - Traditional medicine utilizes standards of care based on epidemiological studies of large cohorts that do not take into account genetic variability of individuals within a population.
  - Personalized medicine uses genetic, proteomic and familial history to provide the best treatment for the individual patient at the right time.

***“The right treatment for the right patient at the right time.”***

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## The Future is Now

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- *The Language of Life: DNA and the Revolution in Personalized Medicine*
  - Dr. Francis S. Collins, Director of the National Institute of Health, former director of the Human Genome Project.
  - Long QT Syndrome – a genetic disorder that predisposes sufferers from sudden death from cardiac arrest.
    - Syndrome is linked to a mutation in the HERG gene. Risk of sudden death can be greatly reduced by lifelong treatment with beta-blockers.

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## The Future is Now (cont.)

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- Cystic Fibrosis – a genetic disorder that results in severe lung and intestinal malfunction.
  - Disease is linked to a single mutation in the gene located on chromosome 7. Disease can be managed with diet and physical therapy and for the most serious cases, lung transplantation.
- Sickle Cell Anemia, Huntington's Disease, Neurofibromatosis, Marfan Syndrome.

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## The Time is Right

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- Advances in genomics, proteomics and high-throughput screening advanced the underlying science from the implausible to the doctor's office.
- In late 2009, PricewaterhouseCoopers estimated the U.S. market for personalized medicine at about \$232 billion and projected an annual 11 % growth rate, nearly doubling in size by 2015 to over \$450 billion...

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### The Time is Right (cont.)

- ...The group also reported that the core diagnostic and therapeutic segment of the market presently was around \$24 billion with an estimated 10 % annual growth, reaching \$42 billion by 2015.
  - The new science of personalized medicine, PriceWaterhouseCoopers, available at [www.pwc.com](http://www.pwc.com).

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### Genomics and Personalized Medicine Act of 2010

- Introduced on May 28th, 2010, by Congressman Patrick J. Kennedy (D-RI) and Congresswoman Anna Eshoo (D-CA).
- Kennedy previously introduced this legislation in the 110th Congress; the bill was also introduced in the Senate during the 109th and 110th Congresses by then-Senator Barack Obama (D-IL).
- The Act will coordinate research and promote collaboration throughout the government and private sector to stimulate innovation and investment in this medical field.

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### Genomics and Personalized Medicine Act of 2010 (cont.)

- A human biological specimen repository will be established within the National Institutes of Health (NIH) to increase the understanding of diseases and the influence of the environment.
- The Act would establish the Office of Personalized Healthcare (OPH) to facilitate the coordinated movement of genomics and personalized medicine throughout the Federal government and private sector.

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## Genomics and Personalized Medicine Act of 2010 (cont.)

- The Act also increases oversight of genetic tests (including direct to consumer tests) and reimbursement of personalized medicine products.
- The Act would also direct the FDA, FTC and CDC to evaluate these products that circumvent the both the normal regulatory environment and patient-health care provider relationship.

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## 2010 Affordable Care Act (ACA)

- Patient Protection and Affordability Act and Health Care and Education Reconciliation Act (Pub.L. 111-148, a/k/a H.R. 3590, and Pub. L. 111-152, a/k/a H.R. 4872) – finalized by President Obama's signatures on March 23 and 30, 2010
- Consolidated language compiled by the House Legislative Counsel now available at <http://www.premierinc.com/about/advocacy/issues/10/healthcarereform/PPACA-CONSOLIDATED.pdf>
- [Foley.com/HCRreform](http://Foley.com/HCRreform) (resource site)

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## Section 3011 of the Act

- Prioritizes the establishment of a national strategy to improve the delivery of health care services, patient health care outcomes, and population health.
  - The national strategy must, in part, enhance the use of health care data to improve quality and efficiency and address gaps in quality, efficiency, comparative effectiveness information, and health outcome measures and the collection of data.

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## Section 3013 of the Act

- Authorizes the Secretary of Health and Human Services to give funding priority to the development of quality measures that allow the assessment of the efficiency of care as well as the safety, effectiveness, patient-centeredness, and appropriateness of patient care as part of the national strategy to improve health care quality.
- Authorizes \$75 million for each of fiscal years 2010 through 2014 to develop the measures.
  - "Quality measure" means a standard for measuring the performance and improvement of population health or of health plans, providers of services, and other clinicians in the delivery of health care.

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## Medicare Issues

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## Medicare Issues - Introduction

- **Medicare** is a federal program which covers the aged and disabled based on quarters of coverage from employment or length of disability. Expenditures of \$468.1 billion in 2008.
  - Part A – Institutional care (e.g. hospital) – 45 million beneficiaries in 2008.
  - Part B – Certain medical services (e.g. physician) and supplies (e.g. DME) – 42 million beneficiaries in 2008.
  - Part C – Managed Care.
  - Part D – Prescription Drugs – 32 million beneficiaries in 2008.

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## Medicare Issues – Introduction (cont.)

- **Medicaid** (Medi-Cal in California) is a needs and categorically-based program unique to each state which is partially funded by the federal government.

Source: *Brief Summaries of Medicare and Medicaid (as of November 1, 2009)*, available at:  
<http://www.cms.gov/MedicareProgramRatesStats/Downloads/MedicareMedicaidSummaries2009.pdf>

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## Medicare – Introduction (cont.)

- ***Problem Statement: Problems with coverage and reimbursement of genetic tests and services are limiting their accessibility and integration into the health care system.***

Source: Secretary's Advisory Committee on Genetics, Health and Society (2006)

- Medicare generally covers only services and supplies which are reasonable and necessary for the diagnosis or treatment of illness or injury.

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## Medicare Issues - Introduction

- Statutory exceptions required for very limited preventive care currently provided:
  - Abdominal Aortic Aneurysm Screening
  - Adult Immunizations
  - Bone Mass Measurements
  - Cancer Screenings
  - Cardiovascular Screening
  - Diabetes Screening
  - Diabetes Supplies
  - Diabetes Self-Management Training
  - Glaucoma Screening
  - Medical Nutrition Therapy (for Medicare beneficiaries with diabetes or renal disease)
  - Initial Preventive Physical Exam ("Welcome to Medicare" Physical Exam)
  - Smoking and Tobacco-Use Cessation Counseling

Quick Reference Information: Medicare Preventive Services, available at  
[http://www.cms.gov/MLNProducts/downloads/MPS\\_QuickReferenceChart\\_1.pdf](http://www.cms.gov/MLNProducts/downloads/MPS_QuickReferenceChart_1.pdf)

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### Medicare as an Unlikely Forum for Personalized Medicine?

- Generally no reproductive care or services are covered under Medicare.
- Given the aged nature of the population, with multiple co-morbidities, and multiple drug usage, genetic testing and counseling may be considered of limited value (although no consensus).

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### Medicare as an Unlikely Forum for Personalized Medicine? (cont.)

- CMS historical focus on PERSONAL, rather than FAMILY, history, rules out some tests as “screening.”
- BUT – many private payers follow Medicare’s lead for coverage decisions; Medicare beneficiaries may benefit from some such tests and/or counseling (and there are a LOT of beneficiaries).

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### Medicare Coverage for Genetic Tests

- Considerations in seeking coverage:
  - ✓ Provide adequate evidence that
  - ✓ the incremental information obtained by new diagnostic technology compared to alternatives
  - ✓ changes physician recommendations
  - ✓ resulting in changes in therapy
  - ✓ that improve clinically meaningful health outcomes
  - ✓ in Medicare beneficiaries,

Source: CMS (James Rollins and Jeffrey Roche) Presentation to Personalized Medicine Coalition, entitled “Evidence, Medicare Coverage and Diagnostic Genetic Testing,” discussing MEDCAC’s Recommendations to CMS (March 2010)

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### ACA Provisions – Covered Complex Diagnostic Tests (Section 3113)

- Authorizes the Secretary to conduct a demonstration project to allow separate payment under Medicare Part B.
- Limited to covered complex diagnostic tests (as defined by the Act) that link a patient's genetic makeup to a cancer chemotherapy where no alternative test is available having equivalent performance characteristics, under certain limited circumstances.

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### ACA Provisions – Covered Complex Diagnostic Tests (Section 3113) (cont.)

- Payment dates to be determined by the Secretary.
- Limited to tests on patient samples collected during hospitalization but performed after hospitalization.
- Will ultimately result in a report to Congress with an assessment of the project's impact on access to care, quality of care, health outcomes, and Medicare expenditures (including savings).

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### ACA Provisions - Medicare Annual Wellness Visit (Section 4103)

- Medicare will provide coverage for an annual "wellness visit" (previously just a "Welcome to Medicare" visit).
- The annual wellness visit should include a personalized prevention plan for an individual that takes into account the results of a health risk assessment.

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### ACA Provisions - Medicare Annual Wellness Visit (Section 4103) (cont.)

- The prevention plan should provide personalized health advice aimed at reducing identified risk factors and improving self-management of an individual's health care and treatment.
- Health risk assessments will be based on guidelines developed by the Secretary. The assessments will identify chronic diseases, modifiable risk factors, and emergency or urgent health needs.

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### ACA Provisions - Medicare Annual Wellness Visit (Section 4103) (cont.)

- The assessment could be provided through an interactive telephone- or Web-based program during an encounter with a health professional. The Secretary will set standards for the electronic tools that can be used to deliver the assessment. In carrying out the assessment, the Secretary will encourage the use of, integration with, and coordination of HIT, and may experiment with personalized technology to aid in the development of self-management skills and adherence to provider recommendations.

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### Comparative Effectiveness

ACA Section 6301 and 10602

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**ACA Provisions – Patient-Centered Outcomes Research Institute (Section 6301)** 28

- Establishes a nonprofit corporation to be known as the Patient-Centered Outcomes Research Institute to assist in the analysis of the health outcomes and the clinical effectiveness, risks, and benefits of more medical treatments such as therapies, diagnostic tools, and pharmaceuticals (including drugs and biologicals).

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**Patient-Centered Outcomes Research Inst. (cont.)** 29

- The research funded must take into account, as appropriate, the potential for differences in the effectiveness of health care treatments in various subpopulations; for example, individuals with different genetic and molecular sub-types.
- Results of the studies are to be published in a format that is comprehensible to patients and providers, with safeguards to protect patient privacy and confidentiality of study subjects.

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**Patient-Centered Outcomes Research Inst. (cont.)** 30

- The purpose of the Institute is “to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations, and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of medical treatments, services, and items.”

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**Patient-Centered Outcomes Research Inst. (cont.)**

- “Comparative clinical effectiveness research” = “research evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of 2 or more medical treatments, services, and items.”
- “Medical treatments, services, and items” includes health care interventions, protocols for treatment, care management, delivery, procedures, medical devices, diagnostic tools, pharmaceuticals, integrative health practices, and any other strategies or items being used in the treatment, management, and diagnosis of, or prevention of illness or injury in individuals.

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**Patient-Centered Outcomes Research Inst. (cont.)**

- 21 Member Board of Governors (including AHRQ and NIH).
- Identify research priorities.
- Research findings will be made publicly available.
- Peer review to avoid bias and conflicts of interest.
- Funded in part by Medicare Parts A and B Trust Funds.

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**Patient-Centered Outcomes Research Inst. (cont.)**

- HHS will make available data collected by CMS under Medicare, Medicaid, or Children’s Health Insurance Program, as well as provide access to data networks developed under Section 937(f) of the Public Health Service Act.
- Annual Report to Congress.
- HHS may use data for coverage determinations, but Institute may not mandate coverage or reimbursement.

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## GINA & Personalized Medicine

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### Genetic Information Nondiscrimination Act

- Congress recognized the importance of genetic research and personalized medicine:
  - “Deciphering the sequence of the human genome and other advances in genetics open major new opportunities for medical progress. New knowledge about the genetic basis of illness will allow for earlier detection of illnesses, often before symptoms have begun. Genetic testing can allow individuals to take steps to reduce the likelihood that they will contract a particular disorder. New knowledge about genetics may allow for the development of better therapies that are more effective against disease or have fewer side effects than current treatments.”

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### Genetic Information Nondiscrimination Act (cont.)

- Congress was concerned that new advances in genetic research would give rise to misuse of genetic information to discriminate in health insurance and employment. It based this concern on:
  - State sterilization laws.
  - The possibility of racially based genetic issues, such as mandatory sickle cell anemia screenings of African Americans in the 1970s.
  - Discrimination in the workplace as reflected in *Norman-Bloodsaw v Lawrence Berkeley Laboratory*, 135 F.3d 1260 (9<sup>th</sup> Cir. 1998).

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### Genetic Information Nondiscrimination Act (cont.)

- Definition of Genetic Information:
  - “The term ‘genetic information’ means, with respect to any individual, information about:
    - Such individual’s genetic tests;
    - The genetic tests of family members of such individual; and
    - The manifestation of a disease or disorder in family members of such individual.”
  - It includes information about a participant’s fetus or embryo.

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### Genetic Information Nondiscrimination Act (cont.)

- The GINA Act Prohibits Insurance companies from adjusting premium or contribution amounts for group or individual insureds based on genetic information.
  - This rule does not prohibit the insurer from raising the premium based on **the manifestation of a disease** of an individual who is enrolled in the plan, provided that such information is not used as genetic information about other group members.

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### Genetic Information Nondiscrimination Act (cont.)

- The GINA Act Prohibits an insurer from requesting or requiring an insured individual or a family member of such individual to undergo a genetic test.
  - **This provision does not prevent a health care provider from requesting an individual under his or her care from undergoing a genetic test.**
  - The provision does not prohibit an insurer from obtaining and using genetic information in connection with a payment decision, provided that it obtains the minimum amount of information that it needs to make the payment decision.

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### Genetic Information Nondiscrimination Act (cont.)

- Research Exception:
  - An insurer may request **but not require**, a participant to undergo a genetic test if the following conditions are met:
    - The request is in writing pursuant to research that complies with statutory requirements;
    - The insurer indicates that:
      - Compliance with the request is voluntary; and
      - Non-compliance will have no effect on enrolment or premium or contribution amounts;
    - No collected genetic information will be used for underwriting purposes;
    - The insurer notifies the Secretary in writing that it is conducting activities under this exception and describes the activities; and
    - The insurer complies with the Secretary's regulations.

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### Genetic Information Nondiscrimination Act (cont.)

- Prohibition on the collection of Genetic information.
  - Insurer may not request, require or purchase genetic information for underwriting purposes.
  - Insurer may not request require or purchase an individual's genetic information prior to the individual's enrolment or coverage.
  - If insurer obtains genetic information incidental to the obtaining of other information, it shall not be considered a violation if such request, requirement of purchase is not for underwriting purposes.

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### Genetic Information Nondiscrimination Act (cont.)

- Monetary Penalties for Insurer's Violation:
  - \$100/day/participant.
  - Minimum of \$2,500/participant where Secretary notifies insurer of violation before violation is corrected.
  - Minimum of \$15,000/participant if the violations are not deminimus.
  - No penalty if insurer had no knowledge of violation and could not have known of at after reasonable diligence.

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### Genetic Information Nondiscrimination Act (cont.)

- No penalty if violation was due to reasonable cause and was corrected within 30 days after insurer knew or should have known of violation.
- Cap of \$500,000 or 10% of premium for unintentional violations.
- Failures due to reasonable cause are subject to having the penalties waived by the Secretary.
- Adverse tax consequences for group health plans.

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### Genetic Information Nondiscrimination Act (cont.)

- Prohibited Employment Discrimination:
  - Employer may not refuse to hire, discharge, or otherwise discriminate against any employee based on genetic information.
  - To limit segregate or classify employees in a way that would deprive them of employment opportunities based on genetic information.

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### Genetic Information Nondiscrimination Act (cont.)

- Prohibited collection of genetic information:
- It shall be an unlawful employment practice for an employer to request, require, or purchase genetic information with respect to an employee or a family member of the employee except —
  - 1) Where an employer inadvertently requests or requires family medical history of the employee or family member of the employee;

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### Genetic Information Nondiscrimination Act (cont.)

2) Where –

- a) Health or genetic services are offered by the employer, including such services offered as part of a wellness program;
- b) The employee provides prior, knowing, **voluntary**, and written authorization;
- c) Only the employee (or family member if the family member is receiving genetic services) and the licensed health care professional or board certified genetic counselor involved in providing such services receive individually identifiable information concerning the results of such services; and
- d) Any individually identifiable genetic information provided under subparagraph c) in connection with the services provided under subparagraph a) is only available for purposes of such services and shall not be disclosed to the employer except in aggregate terms that do not disclose the identity of specific employees;

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### Genetic Information Nondiscrimination Act (cont.)

3) Where an employer requests or requires family medical history from the employee to comply with the certification H. R. 493-28 provisions of section 103 of the Family and Medical Leave Act of 1993 (29 U.S.C. 2613) or such requirements under State family and medical leave laws;

4) Where an employer purchases documents that are commercially and publicly available (including newspapers, magazines, periodicals, and books, but not including medical databases or court records) that include family medical history;

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### Genetic Information Nondiscrimination Act (cont.)

5) Where the information involved is to be used for genetic monitoring of the biological effects of toxic substances in the workplace, but only if:

- a) The employer provides written notice of the genetic monitoring to the employee;
- b) (i) The employee provides prior, knowing, voluntary, and written authorization; or (ii) the genetic monitoring is required by Federal or State law;
- c) The employee is informed of individual monitoring results;

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### Genetic Information Nondiscrimination Act (cont.)

- d) The monitoring is in compliance with – (i) any Federal genetic monitoring regulations, including any such regulations that may be promulgated by the Secretary of Labor pursuant to the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 et seq.), the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 801 et seq.), or the Atomic Energy Act of 1954 (42 U.S.C. 2011 et seq.); or (ii) State genetic monitoring regulations, in the case of a State that is implementing genetic monitoring regulations under the authority of the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 et seq.); and
- e) The employer, excluding any licensed health care professional or board certified genetic counselor that is involved in the genetic monitoring program, receives the results of the monitoring only in aggregate terms that do not disclose the identity of specific employees; or

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### Genetic Information Nondiscrimination Act (cont.)

- 6) Where the employer conducts DNA analysis for law enforcement purposes as a forensic laboratory or for purposes of human remains identification, and requests or requires genetic information of such employer's employees, but only to the extent that such genetic information is used for analysis of DNA identification markers for quality control to detect sample contamination.

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### Genetic Information Nondiscrimination Act (cont.)

- Final Interim Regulations
  - The Regs make clear that if genetic information is necessary to determine if a treatment is medically appropriate, an insurer may require that it be provided in order to make a payment determination.

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### Genetic Information Nondiscrimination Act (cont.)

- Final Interim Regulations.
  - Health Risks Assessments (“HRA”).
    - If a health risk assessment seeks genetic information (**including family medical history**) there can be no premium reduction or other financial reward for participating, even if the request for participation is made after enrollment. The HRA would violate the prohibition on collecting genetic information for underwriting activity.

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### Genetic Information Nondiscrimination Act (cont.)

- Final Interim Regulations.
  - Health Risks Assessments (“HRA”).
    - It is permissible to seek genetic information in an HRA only if the information is requested **post enrollment** and **no reward is offered**.
    - If an HRA requests genetic information it violates the Act to make the participant eligible for additional services based on the genetic information. To do so would violate the prohibition on using genetic information for underwriting purposes. **This is true even if the medical necessity of the additional services are based on the genetic information.**

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### Genetic Information Nondiscrimination Act (cont.)

- Final Interim Regulations.
  - Health Risks Assessments (“HRA”).
    - An insurer can use two HRAs, one of which seeks no genetic information one of which seeks genetic information. The act will not be violated if a reward is offered for completing the non-genetic HRA so long as no reward is offered for completing the genetic HRA.

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**Genetic Information Nondiscrimination Act (cont.)**

- Final Interim Regulations.
  - Health Risks Assessments (“HRA”).
    - An insurer may have disease management programs and may make those programs available to participants who present genetic information indicating that they have a predisposition to the disease. The insurer may require or accept genetic information in order to establish eligibility from individuals who seek to enroll in the disease management program. The insurer may not ask all enrollees for the genetic information for the purpose of recommending that they participate in the disease management program.

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**Genetic Information Nondiscrimination Act (cont.)**

- GINA prohibitions apply only to insurers and employers. They do not prevent health care practitioners from requesting genetic information or recommending genetic tests during the course of patient treatment (even if the health care practitioner is employed by an HMO).

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**Genetic Information Nondiscrimination Act (cont.)**

- General Conclusions:
  - GINA will help to promote personalized medicine because it removes many of the risks associated with genetic testing by prohibiting health insurers, health plans, and employers from discriminating based on genetic information.
  - GINA severely restricts health plans and insurers from ensuring that their insureds receive the full benefits of personalized medicine by prohibiting them from requiring genetic tests and providing rewards for individuals who utilize preventative genetic testing.

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### Genetic Information Nondiscrimination Act (cont.)

- General Conclusions:
  - Health care reform will help promote personalized medicine. The eventual prohibition of preexisting condition exclusions and providing for guaranteed renewability of coverage will hopefully erode the concern over insurance companies obtaining genetic information and will be eventually amended to allow health insurance providers to more aggressively promote the use of genetic information in preventative health care.

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### Genetic Information Nondiscrimination Act (cont.)

- General Conclusions (cont.):
  - The health care reform provisions discussed today demonstrate that the Congress is aware of the benefits of personalized medicine and will hopefully act in the future to remove some of the restriction imposed by GINA on the ability of insurance companies to promote the use of genetic information to improve the health care of their insureds.

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### Thank You & Questions

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