



AMERICAN ACADEMY *of* ACTUARIES

May 5, 2005

Ms. Suzanne Goodwin
Secretary's Advisory Committee on Genetics, Health, and Society
NIH Office of Biotechnology Activities
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

Dear Ms. Goodwin:

This letter presents comments of the American Academy of Actuaries'¹ Committee on Federal Health Issues regarding "Coverage and Reimbursement of Genetic Tests and Services," an April 2005 report of the Secretary's Advisory Committee on Genetics, Health, and Society. We raise issues pertaining to four areas—genetic testing in general, health insurance markets, cost-effectiveness data, and the Medicare and Medicaid programs. We commend your initiative to address the complex and important issues surrounding genetic testing.

Genetic testing has been an area of great interest to the Academy and we have published a series of documents to provide education on the actuarial aspects of the issues related to genetic testing.² A clear understanding of genetic testing issues and the use of genetic information is needed so that rules governing their use can find the best balance between the need to better manage an already complex health care system, and the need to use genetic testing and the resulting genetic information for proven beneficial health care treatment. A full understanding of the issues would be useful in making coverage and reimbursement determinations as well.

Genetic Discrimination

In the preface of the report, the issue of potential genetic discrimination is raised in a sidebar. While genetic discrimination is not the focus of this particular report, the appropriate use of genetic information remains perhaps the single most debated public policy question related to genetic testing. The question is complex, and the issues involved differ among the various health insurance markets. We would draw your attention to the Academy issue briefs and monographs on risk classification and the use of genetic information which, when taken together, provide a thorough overview of the actuarial issues involved.

¹ The Academy is the public policy organization for actuaries of all specialties within the United States. In addition to setting qualification and practice standards, a major purpose of the Academy is to act as the public information organization for the profession. The Academy is nonpartisan and assists the public policy process through the presentation of objective analysis. The Academy regularly prepares comments on proposed federal regulations, and works closely with state officials on issues related to insurance. The Academy also develops and upholds actuarial standards of conduct, qualification and practice, and the Code of Professional Conduct for all actuaries practicing in the United States.

² See attachment "Academy Public Statements Related to Genetic Information" for a list of our public statements along with web links.

Health Insurance Markets

The use of genetic testing and information will pose unique challenges in each health insurance market – group, non-group, public, private, etc. This is also an area that the Academy has examined in previous publications and it should be considered in discussions related to coverage and reimbursement of genetic tests. The report seems to focus more on the effect of genetic testing on Medicare and Medicaid, rather than its effect on the private employer and other insurance markets. The introduction of such technology could cause pricing problems and require different changes within each market. As you note in the report, historically if Medicare makes coverage changes, private employers may feel obligated to make similar coverage changes as well. Therefore, coverage and reimbursement changes in the private employer market, as well as the public health insurance market, could have broad implications and should be considered carefully.

Cost-Effectiveness Data

Another topic addressed in the report pertains to cost-effectiveness data. Cost-benefit data is very important and any clinical cost-effectiveness or cost-benefit data should be expanded to the program level basis. Additionally, any such data used to make coverage decisions in the Medicare or Medicaid programs should involve the Office of the Actuary at the Centers for Medicare and Medicaid Services (CMS).

Medicare and Medicaid

The report includes some potential recommendations related to coverage and reimbursement of genetic tests and services under Medicare and Medicaid. Any such recommendations should be considered within the context of the long-term financing of these programs.

In particular, Medicare faces serious long-range financial problems. Medicare's financial condition is a key health care issue for the Academy and we have developed many publications over the past several years related to the long-term financing of this program.³ The *Medicare Prescription Drug, Improvement, and Modernization Act*, which is one of the largest benefit expansions made to the Medicare program, has not yet been fully implemented. The likely cost of the new prescription drug benefit has been the subject of much debate, and the full impact that the new program will have on Medicare's finances will not be realized for several years. Any further expansion of Medicare benefits should be approached cautiously and should be considered in the context of the long-term financing of the Medicare program. In particular, adding coverage for genetic tests or treatment to the Medicare program without fully offsetting the associated cost would exacerbate the program's long-term financial difficulties.

With states cutting back on Medicaid benefits, the addition of benefits under the Medicaid program could also be problematic. While Medicaid doesn't have the same long-term trust fund financing as does Medicare, it is ultimately funded through general revenues at the federal and state levels and recently has been experiencing budget constraints that could make it difficult to offer coverage for genetic testing and services.

³ The Academy's many Medicare publications are available on the web at <http://www.actuary.org/medicare/index.htm>.

Therefore, before any coverage changes are made to Medicare or Medicaid, we recommend that in addition to clinical cost-effectiveness studies, the impact on the long-term financing of these public programs be considered. Specifically, we suggest that the cost-benefit evaluation process be extended to include a CMS Office of the Actuary projection of the long-term impact on Medicare and Medicaid benefit payments and revenues.

The Academy seeks to provide objective actuarial analysis of issues pertaining to genetic testing. We appreciate your efforts to address these complex and important issues and hope you find our comments helpful as this debate continues.

Members of the Academy are available to work with you on issues related to genetic testing. If you would like to discuss these issues further, please contact Academy senior health policy analyst (federal) Holly Kwiatkowski at 202-223-8196 or Kwiatkowski@actuary.org.

Sincerely,

Alfred A. Bingham, MAAA, FSA
Chairperson, Committee on Federal Health Issues
American Academy of Actuaries

Thomas F. Wildsmith, MAAA, FSA
Vice Chairperson, Committee on Federal Health Issues
American Academy of Actuaries



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Academy Public Statements Related to Genetic Information

The Academy's Health Practice Council has developed a series of documents to provide education on the actuarial aspects of the complex issues related to genetic information. The following documents are available on the Academy's website:

- Statement to the House Education and the Workforce Subcommittee on Employer Employee Relations regarding the use of genetic information in health insurance (July 22, 2004)
http://www.actuary.org/pdf/health/genetic_22july04.pdf
- Letter to Congress regarding the use of genetic information in health insurance (May 22, 2003)
http://www.actuary.org/pdf/health/genetic_22may03.pdf
- Issue brief *The Use of Genetic Information in Disability Income and Long-Term Care Insurance* (Spring 2002)
http://www.actuary.org/pdf/health/genetic_25apr02.pdf
- Issue brief *Risk Classification in Voluntary Individual Disability Income and Long-Term Care Insurance* (Winter 2001)
http://www.actuary.org/pdf/health/issue_genetic_021601.pdf
- Monograph *Genetic Information and Medical Expense Insurance* (June 2000)
<http://www.actuary.org/pdf/health/geneticmono.pdf>
- Issue paper *Risk Classification in Individually Purchased Voluntary Medical Expense Insurance* (February 1999)
<http://www.actuary.org/pdf/health/risk.pdf>
- Issue brief *Genetic Information and Voluntary Life Insurance* (Spring 1998)
<http://www.actuary.org/pdf/life/genet.pdf>
- Issue brief *Risk Classification in Voluntary Life Insurance* (Spring 1997)
<http://www.actuary.org/pdf/life/riskclas.pdf>