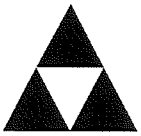
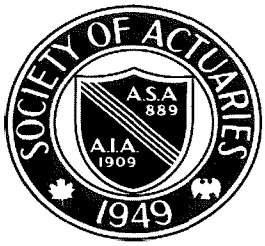


AMERICAN ACADEMY *of* ACTUARIES




Oct. 13, 2011

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
Hubert Humphrey Building
200 Independence Avenue S.W.
Washington, D.C. 20201

Dear Secretary Sebelius:

On behalf of an ad hoc work group comprised of members of the Society of Actuaries'[1] (SOA) Long-Term Section Council and the American Academy of Actuaries'[2] (Academy) Federal Long-Term Care Task Force, we offer the following analysis of the key actuarial considerations associated with respect to the potential application of the Genetic Information Nondiscrimination Act of 2008 (GINA) to long-term care (LTC) insurance. As you know, the Department of Health and Human Services (HHS) has proposed extending GINA's prohibition against using genetic information for underwriting purposes to LTC insurance.[3] We ask that you consider this analysis of the effect of GINA on the cost and availability of LTC insurance as you finalize the regulations.

Barring LTC insurers from obtaining test results already known to such applicants could result in a significant imbalance of information between LTC insurers and applicants. Such asymmetric information could result in adverse selection that would have a direct and significant impact on LTC insurance-premium and insurance coverage rates.

GINA did not affect life insurance and LTC insurance when it was signed into law. That exclusion was not arbitrary; these insurance products are fundamentally different from medical coverage. Both life insurance and LTC insurance have substantially longer terms than medical insurance, with premium rates intended to remain stable or fixed for long periods of time. Neither product is seen by consumers as a practical necessity to ensure access to health care. Both life insurance and LTC insurance depend on insurers having access to similar information as the applicant so that insurers can charge appropriate premiums and protect their risk pools from adverse selection. If applicants were to adversely select against the insurer, premium rates

[1] The Society of Actuaries (SOA) is the largest professional organization dedicated to serving 20,000 actuarial members and the public in the United States and Canada. The SOA's vision is for actuaries to be the leading professionals in the measurement and management of financial risk. To learn more, visit www.soa.org.
[2] The American Academy of Actuaries is a 17,000-member professional association whose mission is to serve the public and the U.S. actuarial profession. The Academy assists public policymakers on all levels by providing leadership, objective expertise, and actuarial advice on risk and financial security issues. The Academy also sets qualification, practice, and professionalism standards for actuaries in the United States.
[3] Federal Register 74(193):51698–51710 (Oct. 7, 2009).

would be significantly higher (and less stable in the case of LTC insurance), fewer carriers would offer such coverage, and significantly fewer individuals would elect to purchase it.

In the 2009 proposed regulations for implementing GINA, HHS indicated its intent to apply the law to LTC insurance. Because the final regulations have not been released yet, we want to take this opportunity to point out that LTC insurance is more akin to life insurance than to medical insurance—both with respect to both the use of genetic information in underwriting and the voluntary nature of the purchasing decision. As such, the adverse effect on consumers if GINA were applied to LTC would be greater than the relatively modest effect on medical insurance. We believe, therefore, that GINA should not apply to LTC insurance.

Like whole life insurance, LTC insurance premium rates are designed to remain level for the life of the policy, and the pricing period is measured in multiple years, rather than in months as is true for medical insurance. Also like whole life insurance, the decision to purchase LTC insurance is entirely voluntary and premiums rarely are subsidized; only about 10 percent of eligible Americans have LTC insurance coverage.[4] In contrast, with approximately 85 percent of Americans currently having medical insurance coverage,[5] the purchase of medical insurance will become mandatory in 2014 and the premiums for such coverage will continue to be subsidized for large proportions of the population.

The economic impact of applying GINA to LTC insurance would be significant (using the $100 million "significance" threshold in Executive Order 12866 as cited by HHS in its 2009 notice in the *Federal Register*).[6] Indeed, the potential effect for the LTC insurance industry of having no genetic information available to them, when the LTC insurance applicants have such information, eventually could be significantly in excess of $100 million per year based on the following considerations:

- New sales of individual LTC insurance in 2010 generated $525 million in new annual premium.[7]
- If, for example, apolipoprotein E (APOE) genetic information—one gene associated with a higher risk of developing Alzheimer's Disease—were to become readily available to potential applicants, but not to the insurers, the adverse selection eventually could result in an increase in premiums by an amount in excess of 30 percent.[8] This would be based solely on currently available genetic testing for the disease.
- The final amount likely would be much greater due to continuing advances in genetic testing.

An ad hoc work group was convened to quantify the potential impact of the proposed regulations on the LTC insurance marketplace. To quantify the effect on consumers, the work group conducted a morbidity analysis using Alzheimer's Disease, which provided the basis for estimating the substantial negative economic impact this extension of the GINA regulations would have on the LTC insurance marketplace. Based on this analysis, we believe that GINA should not apply to LTC insurance. The remainder of this letter presents the work group's findings and our conclusions.

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[4] A.M. Best Company. U.S.—Long-Term Care. March 29, 2010

[5] U.S. Census Bureau. Statistical Abstract of the United States: 2011, Table 151, 2011.

[6] Federal Register 74(193):51698–51710 (Oct. 7, 2009).

[7] Fisherkeller, Karen, *U.S. Individual LTC Insurance—Annual Review 2010* (powerpoint). LIMRA. http://marketing.cpsinsurance.com/visionscape/2011/April/pdf/LIMRA-%20US%20Individual%20LTC%20Insurance-%20Annual%20Review%202010.pdf.

[8] The body of this report shows how this amount was derived.

## Executive Summary

Voluntary insurance mechanisms function properly if rates charged to individuals reflect actuarial risks that are based on known characteristics of the insured. Each insured is assigned to a homogenous risk pool, a pool of multiple insureds with similar risks. If an applicant for LTC insurance has material knowledge that he or she is likely to require LTC services but the insurance company is not allowed to obtain and factor in that information, the homogenous risk pool mechanism will break down. Applicants who understand that their risk is substantially higher than the risk of other applicants likely would use that information to buy insurance coverage that effectively pools their higher risk and cost with lower-risk insureds. For a voluntary product, like LTC insurance, with fairly low sales penetration, higher-risk applicants have a significantly greater effect on the overall risk pool than for mandatory or other insurance products with significantly high participation rates, such as the current medical insurance marketplace.

Higher-risk insureds initially are not charged a premium commensurate with the risk they bring to their pool. As time progresses and the higher-risk insureds produce more claims, it then becomes apparent that the risk pool needs a premium rate increase. In other words, the initial premium rate is too low to cover the unexpected claims presented by the higher representation of higher-risk individuals in the pool. When premium rates are increased, lower-risk individuals paying a higher premium rate than the risk they represent are more likely to terminate their coverage. This behavior could be exaggerated by insureds who find through genetic tests that they are not at as great a risk as other insureds. As these insureds opt out of the insurance pool, the average cost for the remaining insureds increases again. This creates a rate spiral in which the increased cost causes lower-risk individuals to forgo insurance, further driving up the cost for those remaining in the pool. The cycle continues its spiral until only the higher-risk individuals remain in the pool.

If LTC insurers do not have access to the health information that individual applicants possess, this rate spiral is inevitable. Underwriting known morbidity risk and assigning to homogenous risk pools is vital to pricing LTC insurance properly. The result will be a shrinking private LTC insurance market and an increase in the number of individuals who will have to rely on programs such as Medicaid. This appears to us to contradict other public and private efforts that have been designed to encourage individuals to plan for their long-term care needs and help alleviate the growing costs of Medicaid programs.

It should be emphasized here that it is not enough to permit LTC insurers to use genetic information for underwriting if the individual provides written permission. Insurers need to be able to decline applicants who have had genetic testing but do not provide permission to use the results. Genetic tests that indicate an elevated risk level likely would not provide such permission unless it was a requirement to get the coverage.

As an example of a potential effect should GINA regulations be extended to LTC coverage, the work group evaluated a single genetic test. Since Alzheimer's Disease is a leading and costly LTC insurance claim, the work group decided to focus on a gene that has been shown to be associated with a higher risk of developing the disease. This gene is the apolipoprotein E (APOE) gene, and the specific subtype that carries increased risk for developing Alzheimer's Disease is the APOE ε4 allele.

The total LTC claim costs (including Alzheimer's Disease and all other causes) for an individual with two APOE ε4 alleles is 5 times as great as for an individual with no APOE ε4. The total claim costs for an individual with one APOE ε4 allele is 1.55 times as great as for an individual with no APOE ε4 alleles (from the data contained in Table 5). Although APOE testing is not commonly performed, if it were to become prevalent, the cost of LTC insurance would increase by as much as 32 percent (see Tables 6 and 7).

As new genetic research finds even better predictors for Alzheimer's Disease (or other debilitating conditions), the risk of adverse selection would be greater. If GINA were to be applied to LTC insurance, this risk could result in fewer carriers being willing or able to write this business, leading to further strain on public programs.

If insurers were to price for the anti-selection due to the applicants' enhanced knowledge that the insurer cannot obtain, individuals who are average risks could be priced out of the LTC insurance market. They likely would recognize that they are paying more than their expected future costs without insurance. This would increase the volatility of LTC insurance rates and add another risk factor (more effective testing or more widespread use of testing) that could increase the likelihood of future in-force rate increases.

**Details of Analysis**

Aggregate claim costs were developed using an SOA intercompany experience study for long-term care insureds.[9] We divided those claim costs between Alzheimer's and other conditions. Then we determined the total claim costs for insureds with 0, 1, or 2 APOE ε4 alleles along with their relative risk compared to the aggregate insured population. We applied Appendix D2-A and Appendix E3 to represent incidence by attained age and average length of stay (ALOS) in days by age at claim.[10] We geometrically interpolated figures for missing ages. We multiplied the incidence rates and ALOS values to arrive at claim costs per dollar of daily benefit. Sample age results are provided in Table 1.

[9] Society of Actuaries (SOA). *Long-Term Care Experience Committee Intercompany Study: 1984—2004.* (November 2007)

[10] Society of Actuaries (SOA). *Long-Term Care Experience Committee Intercompany Study: 1984—2004.* (November 2007). Appendix D2-A is a pivot table that provides incidence by issue age, duration and other characteristics. Appendix E shows continuance by elimination period, region, diagnosis, and other demographic characteristics.

| Table 1: Derivation of Aggregate Claim Costs Unisex | | | |
|---|---|---|---|
| Attained Age | Incidence | ALOS | Aggregate Claim Costs* |
| 42 | 0.0002278 | 820.90 | 0.187 |
| 45 | 0.0002787 | 820.90 | 0.229 |
| 47 | 0.0003183 | 820.90 | 0.261 |
| 52 | 0.0004435 | 820.90 | 0.364 |
| 55 | 0.0005411 | 820.90 | 0.444 |
| 57 | 0.0006502 | 820.90 | 0.534 |
| 60 | 0.0008564 | 820.90 | 0.703 |
| 62 | 0.0010290 | 808.83 | 0.832 |
| 67 | 0.0020280 | 779.43 | 1.581 |
| 70 | 0.0035078 | 762.30 | 2.674 |
| 72 | 0.0050545 | 758.82 | 3.835 |
| 77 | 0.0124027 | 750.20 | 9.304 |
| 80 | 0.0199636 | 745.07 | 14.874 |
| 82 | 0.0274192 | 722.70 | 19.816 |
| 87 | 0.0516468 | 669.68 | 34.587 |
| 92 | 0.0783281 | 539.75 | 42.277 |

*Aggregate claim costs are equal to incidence times ALOS (e.g., 0.187 = 0.0002278 x 820.90); ALOS assumed constant under age 60.

Using Appendix G5 of the SOA intercompany study, the aggregate incidence and length of stay were then adjusted to derive Alzheimer's and non-Alzheimer's claim costs.[11]

| Table 2: Incidence Distribution and Severity Relativities by Alzheimer's and Non-Alzheimer's Claims | | | | | | |
|---|---|---|---|---|---|---|
| Attained Age | Incidence Distribution | | | Severity Relativities | | |
| | Alzheimer's | Non-Alz | Total | Alzheimer's | Non-Alz | Total |
| 0-64 | 7% | 93% | 100% | 2.83 | 0.86 | 1.00 |
| 65-69 | 14% | 86% | 100% | 2.43 | 0.76 | 1.00 |
| 70-74 | 18% | 82% | 100% | 2.02 | 0.77 | 1.00 |
| 75-79 | 21% | 79% | 100% | 1.74 | 0.81 | 1.00 |
| 80-84 | 21% | 79% | 100% | 1.61 | 0.83 | 1.00 |
| 85-89 | 21% | 79% | 100% | 1.43 | 0.89 | 1.00 |
| 90+ | 18% | 82% | 100% | 1.39 | 0.91 | 1.00 |
| Total | 20% | 80% | 100% | 1.71 | 0.83 | 1.00 |

[11] Society of Actuaries (SOA). *Long-Term Care Experience Committee Intercompany Study: 1984—2004.* (November 2007). Appendix G describes how claims were mapped into diagnosis categories.

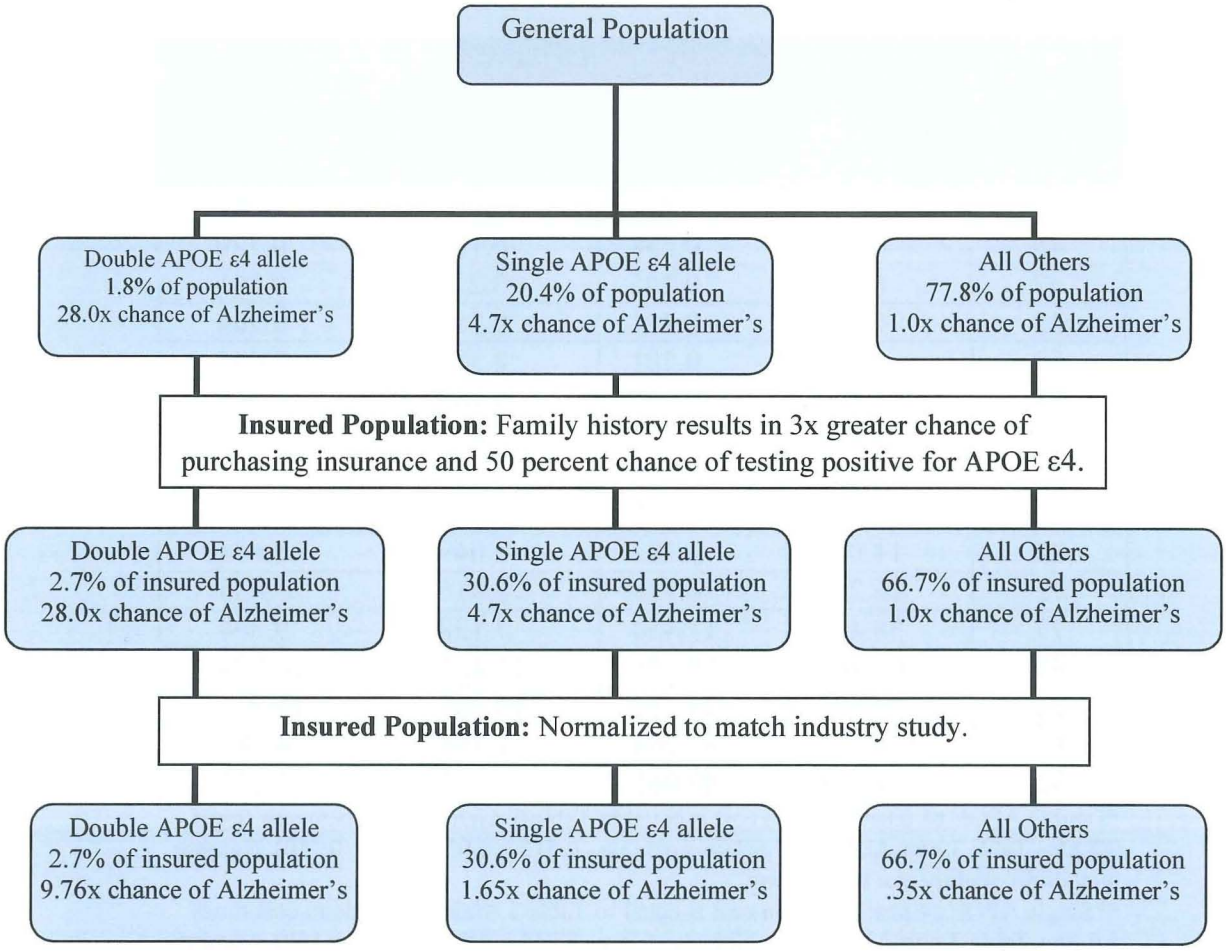
| Table 3: Claim Costs by Alzheimer's and Non-Alzheimer's Unisex | | | |
|---|---|---|---|
| **Attained Age** | **Alzheimer's*** | **Non-Alzheimer's**** | **Aggregate Claim Costs***** |
| 42 | 0.037 | 0.150 | 0.187 |
| 45 | 0.045 | 0.183 | 0.229 |
| 47 | 0.052 | 0.209 | 0.261 |
| 52 | 0.072 | 0.292 | 0.364 |
| 55 | 0.088 | 0.356 | 0.444 |
| 57 | 0.106 | 0.428 | 0.534 |
| 60 | 0.140 | 0.563 | 0.703 |
| 62 | 0.165 | 0.667 | 0.832 |
| 67 | 0.542 | 1.038 | 1.581 |
| 70 | 0.958 | 1.715 | 2.674 |
| 72 | 1.414 | 2.421 | 3.835 |
| 77 | 3.328 | 5.977 | 9.304 |
| 80 | 5.205 | 9.668 | 14.874 |
| 82 | 6.833 | 12.983 | 19.816 |
| 87 | 10.335 | 24.252 | 34.587 |
| 92 | 10.499 | 31.778 | 42.277 |

*Alzheimer's claim costs are equal to Table 1 aggregate claim cost times Table 2 Alzheimer's incidence distribution times Table 2 Alzheimer's severity relativity factor (e.g., 0.037 = 0.187 x 7% x 2.83).
**Non-Alzheimer's claim costs are equal to Table 1 aggregate claim cost times Table 2 non-Alzheimer's incidence distribution times Table 2 non-Alzheimer's severity relativity factor (e.g., 0.150 = 0.187 x 93% x 0.86).
***Aggregate claim costs are equal to Table 1. They may not equal the Alzheimer's plus non-Alzheimer's claim costs due to rounding.

We know the underlying insured population consisted of a mix of APOE ε4 positive and negative insureds. Based on a study published in the Journal of Clinical Psychiatry,[12] 20.4 percent of the control population tested positive for the presence of one APOE ε4 allele, indicating they have a 4.7 times greater likelihood of developing Alzheimer's Disease than those without APOE ε4. Of the control population, 1.8 percent tested positive for the presence of two APOE ε4 alleles, which corresponds to a 28.0 times greater likelihood of developing the disease. In addition, the *Risk Evaluation and Education for Alzheimer's Disease* (REVEAL) study, conducted between 2000 and 2003, indicated that individuals with a family history of the disease were 3 times as likely to purchase LTC insurance.[13] In addition, the presence of a family history of Alzheimer's was associated with a 50 percent chance of testing positive for APOE ε4.[13] Data from elderly controls in the Swedish Kungsholmen Project indicated that the probability of a family history of dementia-related symptoms was approximately 18.6 percent (46/247).[14]

[12] Coon, Keith D., et al. "A High Density Whole-Genome Association Study Reveals That *APOE* is the Major Susceptibility Gene for Sporadic Late-Onset Alzheimer's Disease." *Journal of Clinical Psychiatry* (April 2007; 68:4, pp. 613-618).
[13] Zick, Cathleen D., et al. "Genetic Testing for Alzheimer's Disease and its Impact on Insurance Purchasing Behavior." *Health Affairs* (March/April 2005; 24:2, pp. 483-490)
[14] Fratiglioni, Laura. "Risk Factors for Late-Onset Alzheimer's Disease: A Population-Based, Case-Control Study." *Annals of Neurology* (March 1993; 33:3, pp. 258-266).

Using the above research results, we estimated that 2.7 percent of the LTC insured population would test positive for two APOE ε4 alleles and that 30.6 percent of the LTC insured population would test positive for one APOE ε 4 allele.[15]




Combining these distributions resulted in the following claims projections:

- Those insureds who are positive for two APOE ε4 alleles will have a claim cost 9.76 times that of the aggregate Alzheimer's claim cost (9.76 is equal to 28.0 / (2.7% x 28 + 30.6% x 4.7 + 66.7% x 1)—values are rounded).
- Those insureds who are positive for a single APOE ε4 allele will have a claim cost 1.65 times that of the aggregate Alzheimer's claim cost (1.65 is equal to 4.7 / (2.7% x 28 + 30.6% x 4.7 + 66.7% x 1)—values are rounded).
- In contrast, those insureds who are negative for the APOE ε4 allele will have a claim cost 0.35 times that of the aggregate Alzheimer's claim cost (0.35 is equal to 1 / (2.7% x 28 + 30.6% x 4.7 + 66.7% x 1)—values are rounded).

[15] The 2.7 percent estimate represents the conditional probability of having two APOE ε4 alleles, given that the person actually purchased LTC insurance; the 30.6 percent estimate represents the conditional probability of having one APOE ε4 allele, given that the person actually purchased LTC insurance. In making these estimates, we reduced the 18.6 percent family-history estimate from Sweden to 16.6 percent for the U.S. to reflect, in part, reports that APOE ε4 allele frequencies are lower at mid-latitudes than at high latitudes (such as in Sweden); *see* Eisenberg et al. "Worldwide Allele Frequencies of the Human Apolipoprotein E Gene: Climate, Local Adaptations, and Evolutionary History." *American Journal of Physical Anthropology* (2010; 143, pp. 100-111).

The following table applies the above assumptions and calculates Alzheimer's claim costs as well as the non-Alzheimer's claim costs and shows the total based on the presence or absence of APOE ε4.

| Table 4: APOE ε4 Specific Claim Costs Unisex | | | | |
|---|---|---|---|---|
| Attained Age | Double APOE ε4 Positive* | Single APOE ε4 Positive** | APOE ε4 Negative*** | Aggregate Claim Costs**** |
| 42 | 0.512 | 0.211 | 0.163 | 0.187 |
| 45 | 0.627 | 0.258 | 0.199 | 0.229 |
| 47 | 0.716 | 0.295 | 0.228 | 0.261 |
| 52 | 0.997 | 0.411 | 0.317 | 0.364 |
| 55 | 1.217 | 0.501 | 0.387 | 0.444 |
| 57 | 1.462 | 0.602 | 0.465 | 0.534 |
| 60 | 1.925 | 0.793 | 0.612 | 0.703 |
| 62 | 2.279 | 0.939 | 0.725 | 0.832 |
| 67 | 6.333 | 1.931 | 1.228 | 1.581 |
| 70 | 11.066 | 3.292 | 2.049 | 2.674 |
| 72 | 16.226 | 4.749 | 2.915 | 3.835 |
| 77 | 38.455 | 11.454 | 7.138 | 9.304 |
| 80 | 60.464 | 18.236 | 11.485 | 14.874 |
| 82 | 79.674 | 24.231 | 15.367 | 19.816 |
| 87 | 125.122 | 41.264 | 27.858 | 34.587 |
| 92 | 134.248 | 49.061 | 35.442 | 42.277 |

*Double APOE ε4 positive claim cost is equal to Table 3 Alzheimer's claim cost times 9.8 plus Table 3 non-Alzheimer's claim cost (e.g., 0.512 = 0.037 x 9.8 + 0.150). Number may differ slightly due to rounding.

**Single APOE ε4 positive claim cost is equal to Table 3 Alzheimer's claim cost times 1.6 plus Table 3 non-Alzheimer's claim cost (e.g., 0.211 = 0.037 x 1.6 + 0.150). Number may differ slightly due to rounding.

***APOE ε4 negative claim cost is equal to Table 3 Alzheimer's claim cost times 0.35 plus Table 3 non-Alzheimer's claim cost (e.g., 0.163 = 0.037 x 0.35 + 0.150). Number may differ slightly due to rounding.

****Aggregate claim cost remains equal to Table 1. It is the sum of the three APOE ε4 statuses with each weighted by the portion of the insured pool that each status represents.

From Table 4, double APOE ε4 positive claim costs are 274 to 423 percent of the aggregate claim costs, and single APOE ε4 positive claim costs are 113 to 124 percent of the aggregate claim costs. As has been noted, this history can be priced for in current premium rates. If LTC insurance is purchased by 10 percent of the population, and if we have a population of 1,000, the required premium (using claim costs as a proxy) could be viewed in the following manner:

| Table 5: Claim Cost Relativities by APOE ε4 Presence | | |
|---|---|---|
| | Number of Policies | Relativity to Aggregate* |
| Double APOE ε4 Positive | 2.7 | 3.904 |
| Single APOE ε4 Positive | 30.6 | 1.214 |
| APOE ε4 Negative | 66.7** | 0.784 |
| Aggregate | 100.0 | 1.000 |

*Relativity to aggregate equals the sum of the relativities by age from the data in Table 4 multiplied by the weight of the number of claims at each age to the total number of claims in the 2004 Intercompany Study.

**Balancing item equals aggregate (10 percent of 1,000 population) minus 2.7 percent of insured population testing double APOE ε4 positive minus 30.6 percent of insured population testing single APOE ε4 positive.

If genetic testing were to become widely available without insurers having access to the same information, the risk pool will worsen by 28 percent from the APOE test alone. This would occur with the likelihood that the remainder of the APOE ε4 positive lives will buy insurance but the penetration rate of APOE ε4 negative lives will remain unchanged.

| Table 6: Claim Cost Relativities by APOE ε4 Presence 100% Purchase by APOE ε4 Positive Population | | |
|---|---|---|
| | Number of Policies | Relativity |
| Double APOE ε4 Positive | 18* | 3.904 |
| Single APOE ε4 Positive | 204** | 1.214 |
| APOE ε4 Negative | 67 | 0.784 |
| Aggregate | 289 | 1.283 |

*18 = 1.8% of 1,000 population

**204 = 20.4% of 1,000 population

According to a Forbes Consulting report, "a 20-25% increase in premiums is associated with a 30% decline in sales."[16] Those who have tested positive for the APOE ε4 allele, however, are not likely to change their purchasing behavior, causing further deterioration in the purchasing pool to be 32 percent worse than today.

| Table 7: Claim Cost Relativities by APOE ε4 Presence 100% Purchase by APOE ε4 Positive Population, 30% Reduction in APOE ε4 Negative | | |
|---|---|---|
| | Number of Policies | Relativity |
| Double APOE ε4 Positive | 18 | 3.904 |
| Single APOE ε4 Positive | 204 | 1.214 |
| APOE ε4 Negative | 47* | 0.784 |
| Aggregate | 269 | 1.320 |

*67 x 70% (30% reduction in APOE ε4 negative purchasers)

As testing improves and becomes more readily available, those who purchase LTC insurance will become more heavily weighted toward the 3.9 cost relativity. As the lower-risk population determines that it no longer is willing to bear this price and leaves the insured pool, the required premium rates will continue to increase. As such, only the very highest-risk individuals would

[16] *Price Elasticity and Optimization.* Forbes Consulting (2004).

purchase LTC insurance, which would shrink the market drastically, causing more individuals to rely on public programs such as Medicaid.

**Conclusions**

The analysis performed by this work group serves to emphasize some of the actuarial implications of extending GINA regulations to the LTC insurance market. GINA would prevent an LTC carrier from being able to underwrite its potential risk appropriately. It would promote anti-selection as more high-risk individuals would apply for coverage at the same time low-risk individuals potentially would leave the market due to increasing premiums. This likely would lead to rate spirals and a significant contraction of the LTC market. It would threaten the financial stability of LTC market, potentially resulting in carriers' inability to pay their customers' claims. One important result would be more pressure on the already strained public programs such as Medicaid.

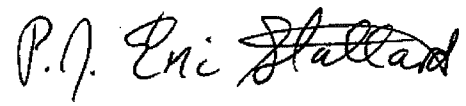
We urge you to carefully consider the actuarial considerations outlined above. Extending GINA to LTC insurance has the potential to disrupt the financial stability of an insurance market of vital importance by preventing proper assignment of risks to homogenous premium rate pools.

*****

We would welcome the opportunity to speak with you in person about our concerns. If you have any questions or would like to discuss these comments further, please contact Heather Jerbi, the Academy's senior health policy analyst (202.785.7869; Jerbi@actuary.org).

Sincerely,

David R. Plumb, MAAA, FSA
Member, Long-Term Section Council
Society of Actuaries



P.J. Eric Stallard, MAAA, ASA, FCA
Chairperson, Federal Long-Term Care Task Force
American Academy of Actuaries

ACLI
Financial Security. For Life.

December 7, 2009

U.S. Department of Health and Human Services
Office of Civil Rights
*Attention:* GINA NPRM (RIN 0991-AB54)
Hubert H. Humphrey Building
Room 59F
200 Independence Avenue, SW
Washington, D.C. 20201

Re: GINA NPRM (RIN 0991-AB54)
HIPAA Administrative Simplification: Standards for Privacy of Individually Identifiable Health Information

Ladies and Gentlemen:

These comments are submitted on behalf of the American Council of Life Insurers (ACLI) in response to the request for public comment on the proposed rule of the Department of Health and Human Services (HHS), to modify certain provisions of the "Standards for Privacy of Individually Identifiable Health Information" ("Privacy Rule"), issued under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), to implement section 105 of Title I of the Genetic Information Nondiscrimination Act of 2008 (GINA). The ACLI is the principal trade association of life insurance companies, whose 340 member life insurance companies account for 93 percent of the industry's assets, 94 percent of life insurance premiums, and 94 percent of annuity considerations. ACLI member companies are also major participants in the long term care insurance market.

ACLI commends HHS for its efforts in crafting this important rule and appreciates the opportunity to submit these comments. However, ACLI member companies are gravely concerned by and respectfully strongly oppose the proposed rule's extension of GINA's prohibition on use and disclosure of genetic information to long term care insurance and issuers of long term care insurance policies. Such expansion of the scope of the rule is in conflict with clear Congressional intent not to subject long term care insurance to GINA's prohibitions applicable to health insurance and is likely to have significant unintended adverse consequences, never contemplated or debated by Congress. For these reasons, and as explained more fully below, ACLI member companies respectfully strongly urge HHS to exclude long term care insurance and issuers of long term care insurance policies from the limits on use and disclosure of genetic information and the related notice requirements to be imposed under the rule.

## Background

The proposed rule seeks to modify the HIPAA Privacy Rule to, among other things: (i) provide that genetic information is health information for purposes of the HIPAA Privacy Rule; and (ii) prohibit certain "health plans," subject to the HIPAA Privacy Rule, from using and disclosing protected health information that is genetic information for "underwriting purposes." As indicated above, of most significance to ACLI member companies, the proposed rule seeks to expand the scope of GINA's prohibition on using and disclosing genetic information, by applying the prohibition to *all* health plans that are subject to the

HIPAA Privacy Rule, including long-term care insurance policies, rather than solely to the plans GINA explicitly requires be subject to the prohibition.

Scope

In the narrative to the proposed rule, HHS indicates that its proposed application of the GINA requirements to all health plans subject to the HIPAA Privacy rule is consistent with the HIPAA administrative simplification provisions of the Social Security Act (SSA), GINA itself, and the uniform privacy construct currently provided under the HIPAA Privacy Rule. By contrast, ACLI respectfully submits that GINA and its legislative history reflect clear Congressional intent to track the HIPAA framework, to exempt "excepted benefits" from any of the substantive prohibitions applicable to health insurance, and specifically not to subject long term care insurance to any of the legislation's prohibitions applicable to health insurance discrimination. Moreover, it is not at all clear that the administrative simplification provisions of the SSA charge the Secretary to uniformly apply all standards adopted under the administrative simplification provisions to *all* health plans. Finally, while uniformity in the protections provided by all health plans subject to the HIPAA Privacy Rule may seem to be a desirable goal, the jeopardy to the relatively young long term care insurance market and to long term care insurers' continued ability to most fairly and prudently serve their customers, that is likely to result from extension of the proposed rule to long term care insurance, far outweighs the goal of uniformity.

*GINA and its Legislative History*

The narrative of the proposed rule states that "nothing in GINA explicitly or implicitly curtails the broad authority of the Secretary to promulgate privacy standards for any and all health plans that are governed by the HIPAA Administrative Simplification provisions."[1] However, GINA Section 105 requires the Secretary to revise the HIPAA Privacy Rule to prohibit use and disclosure of genetic information for underwriting purposes "...by a covered entity that is a group health plan, a health insurance issuer that issues health insurance coverage, or issuer of a medicare supplemental policy" - the same health plans subject to GINA Sections 101-104. Moreover, GINA Sections 101-103 were intentionally crafted to modify particular sections of the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Service Act (PHSA), and the Internal Revenue Code (IRSC), so that "excepted benefits," including benefits for long term care, would be exempt from the substantive provisions of these sections. Given the approach taken in GINA Sections 101-103, coupled with GINA's legislative record, discussed below, it is clear that Congress intended for "excepted benefits," particularly benefits for long term care, not to be subject to the limits on use and disclosure of genetic information, required to be included in the HIPAA Privacy Rule by Section 105.

GINA's legislative history reflects clear Congressional intent to track the HIPAA framework and, specifically not to apply GINA to long term care insurance. In fact, in subjecting long term care insurance to its prohibitions on use and disclosure of genetic information, the proposed rule is in conflict with express Congressional intent not to subject long term care insurance to any of GINA's prohibitions.

The Senate Health, Education and Labor Committee Report, to accompany S. 358, reads in pertinent part as follows:

> Long term care insurance is not intended to be subject to section 104. Since benefits for long term care insurance are "excepted benefits" under section 733(c)(2)(B) of ERISA, section 2791(c)(2)(B) of the PHSA and section 9832(c)(2)(B) of the IRC, it has never been the intent of the bill to subject long-term care insurance to any of the bill's prohibitions with respect to health insurance discrimination on the basis of genetic information or genetic services. "Excepted benefits," including benefits for long-term care, are not subject to the provisions of sections 101

[1] 74 *Fed.Reg.*51700

or 102 which track the HIPAA framework that exempts "excepted benefits" from its substantive provisions. Accordingly, long-term care insurance is not subject to section 104.[2]

It is important to note that the Report language quoted above not only reflects Congressional intent not to subject long term care insurance to *any* of the bill's prohibitions applicable to health insurance, it also indicates intent not to subject long term care insurance to section 104 of the version of the genetic testing legislation passed by the Senate, S. 358. Although it used different language, section 104 of S. 358 was the precursor to GINA section 105. Also, the Report language above indicates that excepted benefits, including benefits for long term care are not subject to sections 101-102 only, because S. 358 did not seek to modify the IRC, as GINA does in Section 103.

Similarly, the Congressional Record from the House of Representatives includes the following statement with respect to GINA: " ...The bill was never intended to regulate the long-term care insurance market, and I understand that current statute treats long-term care insurance differently."[3]

Even HHS preliminary analyses of and guidance on the application of GINA, issued in publications published earlier this year, state that "GINA's health coverage non-discrimination protections do not extend to life insurance, disability insurance and long-term care insurance."[4] In line with the discussion above, this original HHS assessment is the correct interpretation, reflected in GINA itself and its legislative history.

*HIPAA Administrative Simplification Provisions*

ACLI respectfully submits that it is not at all clear, as suggested in the narrative, that the Administrative Simplification subtitle "...instructs that 'any standard' [adopted under the subtitle] will apply to all such health plans [subject to the subtitle]"[5]

42 U.S.C. 1320d-1 provides in pertinent part as follows:

> (A) Applicability
> Any standard adopted under this part shall apply *in whole or in part* to:
> (1) A health plan
> (2) A health care clearinghouse
> (3) A health care provider ...
> *(italics added)*

The statute quoted above does not explicitly direct the Secretary to make *all* standards adopted under the administrative simplification provisions applicable to *all* of the covered entities specified in subsections (1) – (3); and the statute only provides for any standard to apply *in whole or in part*. In fact, HHS is not seeking to subject all of the covered entities referenced in the statute to the proposed rule – only health plans. Moreover, as discussed above, GINA and its legislative history reflect clear Congressional intent not to subject excepted benefits, particularly benefits for long term care insurance, to GINA's prohibitions on use and disclosure of genetic information. In view of the above, ACLI respectfully strongly questions HHS's interpretation " ... that the HIPAA administrative simplification provisions provide the Secretary with broad authority to craft privacy standards that uniformly apply to all

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[2] S. Rept. No. 110-48, p. 27, 110th Cong. 1st Session (2007).
[3] 154 Cong. Rec. H2961-03 (May 1, 2008), pH2978. H.R. Rept. No 110-28 (Parts 1, p. 35), 110th Cong. 1st Session (2008).
[4] See, Guidance on the Genetic Information Nondiscrimination Act: Implications for Investigators and Institutional Review Boards (3/24/09):http://www.hhs.gov/ohrp/humansubjects/guidance/gina.html; also see,
The Genetic Information Nondiscrimination Act of 2008:Information for Researchers and Health Care Professionals (4/6/09):http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf?bcsi_scan_6ECE3CE8A6386863=0&bcsi_scan_filename=GINAInfoDoc.pdf
[5] 74 *Fed.Reg.* 51699

health plans, regardless of whether such health plans are governed by other portions of the HIIPAA statute. [6]

*HIPPA Privacy Rule – Uniform Protection of Individuals' Privacy Interests*

In the narrative, HHS states its belief "... that individuals' interests in uniform protection under the Privacy Rule against the use or disclosure of their genetic information for underwriting outweigh any adverse impact on health plans that are not covered by GINA. This is particularly true since we do not expect that all of the health plans subject to the Privacy Rule use or disclose PHI that is genetic information for underwriting today..."[7]. By contrast, ACLI respectfully submits that while uniformity in privacy protection provided by all health plans subject to the HIPAA Privacy Rule may seem to be a desirable goal, the jeopardy to the relatively young long term care insurance market and to long term care insurers' continued ability to most fairly and prudently serve their current and prospective customers, that is likely to result from application of the proposed rule to long term care insurance, far outweighs the goal of uniformity.

ACLI is concerned that significant unintended adverse consequences, never contemplated, examined, or debated by Congress, are likely to result from extension of the proposed prohibition on use and disclosure of genetic information for "underwriting purposes" to long term care insurance and issuers of long term care insurance polices. Although HHS indicates it does not believe that all of the health plans subject to the Privacy Rule use genetic information in underwriting today, ACLI is gravely concerned that the proposed rule could significantly jeopardize long term care insurers' current, as well as future, underwriting practices.

This concern arises in large part because it is unclear what information and tests may be construed to fall within the scope of the terms "genetic information" and "genetic test," set forth in proposed rule § 160.103.[8] It is not clear that these terms may not be construed to include traditional medical information or medical tests, used in underwriting today, or other information or tests, that may be the most effective and appropriate for long term care insurers to use to best serve their customers in the future. ACLI's concern with the terms "genetic information" and "genetic test" is exacerbated by the breadth of the definition of "manifestation or manifested," also set forth in § 160.103,[9] and used in the definitions of both "genetic information" and "genetic test." The definition of "manifestation or manifested," would require diagnosis of a disease or disorder for it to be manifested and provide that a "disease, disorder, or pathological condition is not manifested if the diagnosis is based principally on *genetic information." (italics added.)* By contrast, in underwriting for long term care insurance, insurers seek to determine the likelihood that an individual may require long term care in the future. Diagnosis of a particular condition is not the only way this may be determined and may only be relevant to the extent it indicates likelihood of the applicant requiring long term care in the future. Also, inclusion of the reference to "genetic information" in the definition of "manifestation or manifested" causes the definitions of "genetic information" and "genetic test" to be circular.

There is significant concern that if long term care insurance is subjected to the underwriting limits of the proposed rule, that long term care insurers' ability to continue to make their products available at affordable prices is likely to be jeopardized. Permitting consumers to withhold information about serious health problems (that may incentivize them to purchase long term care coverage they otherwise would not have purchased and for which there may be significant symptoms, but no clear diagnosis of a particular condition) will jeopardize long term care insurers' ability to fully, fairly, and prudently underwrite. Individuals with serious health conditions would be increasingly motivated to purchase long term care insurance – a retirement planning choice that relatively few people now make. Healthy individuals then would be likely to be forced to subsidize the costs of unhealthy individuals, whose premiums were set inappropriately low. There is concern that this could give rise to a spiral of adverse selection, which could be exacerbated by future increases in the already high costs of long term care.

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[6] 74 *Fed.Reg.* 51699
[7] 74 *Fed.Reg.* 51700
[8] 74 *Fed.Reg.*51708-9
[9] 74 *Fed.Reg.* 51709

*Congressional recognition of the Importance of Long Term Care Insurance*

Congress recognized the importance of long term care insurance to American consumers' long range financial security in the Deficit Reduction Act of 2006 (DRA), and the Pension Protection Act of 2006 (PPA). The DRA authorizes Long Term Care Partnerships, the purposes of which are to encourage the sale of long term care insurance policies and to potentially reduce Medicaid costs. The PPA permits long term care coverage to be attached as riders to annuities and life insurance policies, reflecting further Congressional recognition of the possible consumer and societal benefits that may be derived from long term care insurance.

Subjecting long term care insurance and issuers of long term care insurance policies to GINA's prohibitions on use and disclosure of genetic information, not only would be in conflict with Congressional intent in connection with GINA, but may jeopardize the viability of the relatively new and innovative long term care insurance market and Congress's initiatives under the DRA and the PPA.

*Significant Differences Between Long Term Care Insurance And Health Insurance*

It is appropriate for long term care insurance not to be subjected to GINA or the proposed rule because long term care insurance policies differ from health insurance policies in a number of significant respects. Long term care and health insurance have different purposes. Long term care insurance policies are usually purchased to be used 20-30 years after purchase – to address the insured's *future* needs – to maintain quality of life during one's senior years. By contrast, health insurance is purchased to address *immediate* needs – to improve or correct medical problems as of the effective date of coverage.

Most long-term care insurance is individually underwritten. Therefore, risk classification through medical underwriting is critical to long term insurers' ability to continue to make these products available at affordable prices (which is why extension of the proposed rule to long term care insurance and issuers of long term care policies gives rise to such significant concern and opposition). At the present time, most health insurance is underwritten on a group basis.

Long term care policies are designed to provide financial protection against some future event. These contracts, therefore, are likely to be in force over long periods of time. Consequently, long term care insurers get essentially "one bite at the apple" to use medical information to fully evaluate the risk they are being asked to assume – possibly for decades.

Long term care insurance is a relatively new product – less than 20 years old. The pool of insureds is smaller than that for health insurance. Because claims under a long term care policy may not be submitted until decades after the policy was issued and because the plan is guaranteed renewable and cannot be canceled, if an inadequate amount of premium was charged at the time the policy was issued, there may be inadequate monies to honor a future claim.

By contrast, currently, the accident and health insurance market is mature, well established and has huge penetration. The risk may be spread among a larger pool of insureds. Accident and health insurance claims are "immediate." In the current market, rates can be adjusted periodically to reflect claims and increase in medical service costs; and since accident and health insurance policies are not guaranteed renewable, the company may cancel them at any time.

## ACLI's Proposed Modifications to the Proposed Rule

### PART 164—SECURITY AND PRIVACY

### §164.501 Definitions.

*Health care operations*

In the narrative, HHS requests comment on whether removal of the term "underwriting" from the definition of "health care operations," and substitution of the word "enrollment" in lieu thereof, could give rise to unintended consequences. [10] ACLI believes that use of the term "enrollment" in connection with long term care insurance may give rise to confusion, which would be very worrisome given the critical importance of the term "health care operations." Accordingly, ACLI respectfully urges that the proposed change, to modify the definition of "health care operations," to substitute the word "enrollment "for the word "underwriting," not be made, and that the word "underwriting" be retained in the definition of "health care operations."

*Underwriting purposes*

To address concern regarding confusion that may result from use of the terms "underwriting" and "underwriting purposes" in the HIPAA Privacy Rule, ACLI respectfully urges that the definition of "underwriting purposes" be modified to read as follows *(Language proposed to be added is underlined.):*

*Underwriting purposes* means for purposes of §164.502(a)(3), with respect to a health plan:

(1) Except as provided in paragraph (2) of this definition:

(i) Rules for, or determination of, eligibility (including enrollment and continued eligibility) for, or determination of, benefits under the plan, coverage, or policy (including changes in deductibles or other cost-sharing mechanisms in return for activities such as completing a health risk assessment or participating in a wellness program);

(ii) The computation of premium or contribution amounts under the plan, coverage, or policy (including discounts, rebates, payments in kind, or other premium differential mechanisms in return for activities such as completing a health risk assessment or benefits.

(2) Underwriting purposes does not include determinations of medical appropriateness where an individual seeks a benefit under the plan, coverage, or policy.

(Concern that specific types of activities included in the definition of "underwriting purposes" also fall within the definitions of "payment" and "health care operations" is addressed by HHS's inclusion of the phrase "except as prohibited under §164.502(a)(3)" in the definition of "payment," and the phrase "Notwithstanding any other provision of this subpart" at the beginning of §164.502(a)(3).)

**§164.502 Uses and disclosures of protected health information: General rules.**

To exclude long term care insurance and issuers of long term care insurance policies from the scope of the proposed rule's prohibition on use and disclosure of genetic information for the many reasons described above, ACLI respectfully strongly urges that §164.502(a)(3) be modified to read as follows *(Language proposed to be added is underlined)*:

(3) Prohibited uses and disclosures. Notwithstanding any other provision of this subpart, a health plan, other than an issuer of a long term care policy, shall not use or disclose protected health information that is genetic information for underwriting purposes.

**§164.520 Notice of privacy practices for protected health information.**

Since ACLI strongly urges that issuers of long term care insurance policies be excluded from the proposed rule's prohibitions on use and disclosure of genetic information, ACLI also respectfully strongly

[10] 74 *Fed.Reg.* 51703

urges that issuers of long term care insurance policies be excluded from the proposed rule's related new privacy notice requirements, and that proposed new §164.520(b)(1)(iii)(D) be amended to read as follows *(Language proposed to be added is underlined.):*

> (D) If a covered entity that is a health plan, other than an issuer of a long term care policy, intends to use or disclose protected health information for underwriting purposes, a statement that the covered entity is prohibited from using or disclosing protected health information that is genetic information of an individual for such purposes.

**Conclusion**

For the reasons stated above, ACLI again respectfully strongly urges HHS to exclude long term care insurance and issuers of long term care insurance policies from the proposed rule. We thank you for your consideration of our views and would be glad to answer questions regarding any of the above.

Sincerely,

Roberta B. Meyer
Vice President and Associate General Counsel

Robert H. Neill, Jr.
Counsel

ACLI
Financial Security. For Life.

January 14, 2011

The Honorable Kathleen Sebelius
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
Room 59F
200 Independence Avenue, SW
Washington, D.C. 20201

Re: GINA NPRM (RIN 0991-AB54)
HIPAA Administrative Simplification: Standards for Privacy of Individually Identifiable Health Information

Dear Secretary Sebelius: Kathleen,

As you may know, late last year I joined the American Council of Life Insurers (ACLI) as President and CEO. ACLI is the principal trade association for the life insurance industry. Our more than 300 members account for over 90 percent of the assets and premiums of the U.S. life insurance and annuity industry. ACLI member companies are also major participants in the long term care insurance market.

You may remember that during my tenure as Chairman of the National Governor's Association in 2003, I chose long term care as the focus of the NGA Chair's Initiative. With the aging baby boomer population in the United States approaching 80 million, long term care continues to be an important issue in this country. Accordingly, I am writing to you today in connection with HHS' proposed rule to modify certain provisions of the "Standards for Privacy of Individually Identifiable Health Information" issued under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), to implement the Genetic Information Nondiscrimination Act of 2008 (GINA). ACLI is very concerned by, and respectfully strongly opposes, the proposed HHS rule's extension of GINA's prohibition on use and disclosure of genetic information to long term care insurance and issuers of long term care insurance policies.

GINA imposes underwriting restrictions on the use of genetic information on health insurers and employers only. In addition, GINA's legislative history reflects clear Congressional intent to track the HIPAA framework, and not to subject long term care insurance to any of the substantive prohibitions applicable to health insurance. Senator Kennedy chaired the Senate HELP Committee at the time the legislation was considered by the Congress, and the following language was included in the Committee report relating to its deliberations:

> Long term care insurance is not intended to be subject to section 104. Since benefits for long term care insurance are "excepted benefits" under section 733(c)(2)(B) of ERISA, section 2791(c)(2)(B) of the PHSA and section 9832(c)(2)(B) of the IRC, it has never been the intent of the bill to subject long-term care insurance to any of the bill's prohibitions with respect to health insurance discrimination on the basis of genetic information or genetic services. "Excepted benefits," including benefits for long-term care, are not subject to the provisions of sections 101 or 102 which track the HIPAA framework that exempts "excepted benefits" from its substantive provisions. Accordingly, long term care insurance is not subject to section 104.[1]

[1] S. Rept. No. 110-48, p. 27, 110th Cong. 1st Session (2007).

Similarly, the Congressional Record from the House of Representatives includes the following statement by Congressman Gene Green (D-TX) with respect to GINA: " ...The bill was never intended to regulate the long term care insurance market, and I understand that current statute treats long-term care insurance differently."[2]

Attached for your reference is a copy of the 12/7/09 letter which ACLI submitted to HHS' office of Civil Rights in response to the request for comments on the proposed rule. The letter provides further detail regarding GINA's legislative history and how the proposed rule ignores critical distinctions between health insurance and long term care insurance. Significantly, the letter also explains how application of the underwriting prohibitions in the proposed rule to long term care insurers could jeopardize long term care insurers' current, as well as future, underwriting practices and their ability to most fairly and prudently serve their existing and prospective customers.

To supplement our original analysis, ACLI also submits for your review the attached legal memorandum from the law firm of Patton Boggs LLP that concludes that HHS lacks statutory authority to extend GINA's prohibitions on the use of genetic information for enrollment and underwriting purposes to long term care insurance issuers and other health plans not specified in GINA.

As Americans continue to live longer, millions will face the prospect of needing or providing long term care at some point in their lives. To avoid the adverse impact to this increasingly important product, I respectfully strongly urge you to exclude long term care insurance and issuers of long term care insurance policies from the proposed HHS rule.

ACLI staff and representatives of several member companies met with HHS Office of Civil Rights staff regarding the proposed rule in August of 2010. However, given the great importance of this issue to our member companies and long term care consumers, and given your experience as a former insurance commissioner, I wanted to make sure you were aware of the industry's concerns about this issue and its potential effect on the underwriting process.

I very much appreciate your consideration of our views and am available to answer any questions that you may have.

Sincerely,

Dirk

DIRK KEMPTHORNE
President and Chief Executive Officer

Kathleen, congratulations on your role in this administration. You have always been great to work with. Best wishes!

Cc: Mark Childress, Esq.
General Counsel

Sue McAndrew
Director, Office of Civil Rights

Attachments:
ACLI letter re GINA NPRM (RIN 0991-AB54) dated December 7, 2009
Memorandum from Patton Boggs LLP, dated January , 2011

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[2] 154 Cong. Rec. H2961-03 (May 1, 2008), pH2978. H.R. Rept. No 110-28 (Parts 1, p. 35), 110th Cong. 1st Session (2008).

PATTON BOGGS LLP

2550 M Street, NW
Washington, DC 20037
202-457-6000

Facsimile 202-457-6315

# MEMORANDUM

**From:** John Jonas and Kathy Lester
**Date:** January 10, 2011
**Subject:** Legal Analysis of HHS Proposed Rule Implementing Section 105 of the Genetic Information Nondiscrimination Act of 2008

You have asked us to analyze the Department of Health and Human Services' (HHS') Notice of Proposed Rulemaking dated October 7, 2009 (Proposed Rule) implementing Section 105 of the Genetic Information Nondiscrimination Act of 2008 (GINA). For the reasons set forth below, we believe that HHS lacks statutory authority to extend GINA's prohibitions on the use of genetic information for enrollment and underwriting purposes to long-term care insurance issuers and other health plans not specified in GINA.

Section 105, on its face, applies only to group health plans, health insurance issuer that issues health insurance coverage, HMOs and issuers of Medicare supplemental policies.[1] This interpretation is bolstered by a review of GINA's broader statutory scheme and its legislative history, as well as language in the Proposed Rule itself. Under well-established doctrine, "this is the end of the matter"[2] because HHS has no legal authority to extend GINA's applicability beyond the entities specified in the statute.

Recognizing this limitation, HHS claims it may apply GINA to long-term care insurance based on its "broad authority" to issue privacy regulations under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). However, because GINA is subsequent to and more specific than HIPAA, it controls and limits any interpretation of HIPAA. Indeed, if HHS had the authority it now claims under HIPAA, passage of genetic nondiscrimination legislation would not have been necessary. Congress' enactment of GINA demonstrates that HHS lacked authority to issue regulations prohibiting the use of genetic information for underwriting purposes in the individual market. Thus, the HIPAA statute provides no justification or basis for the Department's effort to extend GINA beyond the four types of health plans listed in the statute.

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[1] This Memorandum does not address provisions of the Genetic Information Nondiscrimination Act of 2008 (GINA) applicable to employers.

[2] *See Chevron U.S.A. v. Natural Resources Defense Council*, 467 U.S. 837, 842 (1984).

## I. STATUTORY BACKGROUND AND SUMMARY OF PROPOSED RULE

GINA prohibits group and individual health insurers from requesting or requiring a person to take a genetic test and from using genetic information to determine eligibility or set premiums. Prior to GINA's passage, HIPAA prohibited group health plans and issuers from using genetic information to establish rules for eligibility, treating such information as a preexisting condition, or using genetic information to set individual premiums. However, HIPAA did not address the use of genetic information by insurers in the individual market.

Sections 101 through 104 of GINA augment HIPAA's protections by prohibiting cost increases for a group based on genetic information of group members. For those seeking to purchase individual health insurance, GINA provides new Federal limits on the use of genetic information for enrollment or underwriting.

Section 105 of GINA requires the Secretary to revise the HIPAA Privacy Rule to "clarify that genetic information is health information" and to prohibit **group health plans, health insurance issuers that issue health insurance coverage** (including health maintenance organizations, or HMOs), **and issuers of Medicare supplemental policies** from "using or disclosing genetic information for underwriting purposes." *See* 74 Fed. Reg. at 51699 (emphasis added). On October 7, 2009, HHS issued the Proposed Rule to implement Section 105 and to make "certain other changes" to the Privacy Rule.[3] Among these "other changes" are provisions applying GINA's nondiscrimination requirements to **all** health plans subject to the Privacy Rule, including long-term care insurance.

## II. HHS LACKS STATUTORY AUTHORITY TO ISSUE THE PROPOSED REGULATIONS WITH RESPECT TO HEALTH PLANS NOT SPECIFIED IN GINA

In the Proposed Rule, HHS acknowledges that Section 105 requires it to apply GINA's nondiscrimination provisions **only** to selected health plans covered by the Privacy Rule. However, the Department reaches beyond its limited statutory authority to apply them to **all** plans falling under the Privacy Rule:

> "The Department proposes to apply the prohibition in GINA on using and disclosing protected health information that is genetic information for underwriting to all health plans that are subject to the Privacy Rule, **rather than solely to the plans GINA explicitly requires** be subject to the prohibition. We believe that **this interpretation is consistent with both GINA and the Secretary's broad authority under HIPAA.**"

74 Fed. Reg. at 51699.

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[3] *Id.* at 51698. HHS, the Department of the Treasury and the Department of Labor also jointly published Interim Final Rules implementing GINA's nondiscrimination provisions (sections 101-103) on October 7, 2009. *See* 74 Fed. Reg. 51633 *et seq.*

HHS argues that, although GINA doesn't explicitly apply to long-term care (and other types of) insurance, such a broad application is justified by HIPAA Sections 262 and 264. However, because GINA's statutory language and legislative history show Congress' clear intent to exclude long-term care insurance from its requirements, HHS lacks statutory authority to issue the proposed regulations. Moreover, the HIPAA statute provides no justification or basis for the Department's effort to extend GINA's reach to include long-term care insurance.

### A. Because GINA is Inapplicable to Long-Term Care Insurance, HHS Has No Authority to Apply the Statute as Proposed

#### 1. *Judicial Standard of Review For Federal Regulations*

HHS, like other Federal agencies, "literally has no power to act . . . unless and until Congress confers power upon it." *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986). It "has no constitutional or common law existence or authority, but only those authorities conferred upon it by Congress." *Michigan v. EPA*, 268 F3d 1075, 1081 (D.C. Cir. 2001). Thus, its authority to promulgate regulations is limited to the scope of authority Congress has delegated to it.

In determining whether an agency regulation exceeds its delegated authority, courts utilize the two-step process set forth by the Supreme Court in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984). First, the court must determine "whether Congress has directly spoken to the precise question at issue." 467 U.S. at 842. "If the intent of Congress is clear, that is the end of the matter," and the court must give effect to that intent. *Id.* at 842-3.

If, however, "Congress has not directly addressed the precise question at issue," the question is whether the regulation "is based on a permissible construction of the statute." *Id.* at 842-3. Thus, where Congress has left a gap for the agency to fill (expressly or by implication), the agency's interpretation is entitled to deference, as long as it is reasonable.

#### 2. *GINA Applies Only to Group Health Plans, Health Insurance Issuer That Issues Health Insurance Coverage, HMOs and Medigap Plans*

Sections 101 through 104 of GINA amend the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Services Act (PHSA), the Internal Revenue Code (IRC), and the Social Security Act (SSA) to apply its protections to participants in group health plans, health insurance issuers that issue individual or group health insurance coverage, and Medigap plans, respectively. GINA Section 105 directs the Secretary to revise the Privacy Rule so it is consistent with the following:

> (1) Genetic information shall be treated as health information described in section 1320d(4)(B) of this title.

> (2) **The use or disclosure by a covered entity that is a group health plan, health insurance issuer that issues health insurance coverage, or issuer of a medicare supplemental policy** of protected health information that is genetic information about an individual for underwriting purposes[4] under the group health plan, health insurance coverage, or medicare supplemental policy shall not be a permitted use or disclosure.

42 U.S.C. § 1320d-9(a) (emphasis added). Section 105 therefore instructs the Secretary to amend the Privacy Rule **only** with regard to group health plans, health insurance issuers that issue health insurance coverage, HMOs and issuers of Medicare supplemental policies.

This limitation is consistent with the GINA statute as a whole. It is a "fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *Davis v. Michigan Dept. of Treasury*, 489 U.S. 803, 809 (1989). Because GINA applies only to group health plans, health insurance issuers that issue health insurance coverage, HMOs and Medigap plans, **Congress instructed the Secretary to modify the Privacy Rule as to these entities only.**

Indeed, in the preamble to the Proposed Rule, HHS differentiates between "plans GINA explicitly requires be subject to the prohibition" and "health plans that are not covered by GINA." *See* 74 Fed. Reg. at 51699-70. In its regulatory analysis of the Rule, the Department refers to health plans "not covered by GINA but subject to the proposed prohibition in the Privacy Rule." *Id.* at 51705-06; *see also id.* at 51706 (referring to "plans that . . . are subject to the Privacy Rule's prohibition but not otherwise subject to GINA") and 51707 (discussing "[h]ealth plans not subject to the regulations implementing sections 101-103 of GINA but subject to this proposed rule"). Thus, **the agency itself admits that GINA only applies to certain subcategories of health plans subject to the Privacy Rule.**

This is consistent with other HHS statements regarding GINA's inapplicability to long-term care insurance. For example, the Department noted in a summary of the statute distributed to health care researchers and professionals that "**GINA's health coverage non-discrimination protections do not extend to life insurance, disability insurance and long-term care insurance.**" *See* U.S. Dep't of Health and Human Services, GINA: Genetic Information Nondiscrimination Act of 2008 Information for Researchers and Health Care Professionals (April 6, 2009) (emphasis added). The Department's Office for

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[4] The definition of "underwriting purposes" in GINA Section 105 also applies only to group health plans, health insurance issuers that issue health insurance coverage, and Medicare supplemental policies and means "(A) Rules for, or determination of, eligibility (including enrollment and continued eligibility) for, or determination of, benefits under the plan, coverage or policy; (B) the computation of premium or contribution amounts under the plan, coverage or policy; (C) the application of any pre-existing condition exclusion under the plan, coverage or policy; and (D) other activities related to the creation, renewal or replacement of a contract of health insurance or health benefits. 42 U.S.C. § 1320d-9(b)(4).

Human Research Protections also issued guidance on GINA stating that the statute did not prohibit discrimination based on genetic information by life, disability or long-term care insurers. *See* HHS Office for Human Research Protections Guidance on GINA – Implications for Investigators and IRBs (March 24, 2009) at 3.

Moreover, GINA's legislative history coupled with HHS statements and the words of the statute clearly evidence Congress' intent to exempt such plans from its requirements. As the Senate HELP Committee noted in its report on GINA,

> **Long-term care insurance is not intended to be subject to section 104** [the precursor to GINA section 105]. Since benefits for long-term care are "excepted benefits" under section 733(c)(2)(B) of ERISA, section 2791(c)(2)(B) of the PHSA, and section 9832(c)(2)(B) of the IRC, **it has never been the intent of the bill to subject long-term care insurance to any of the bill's prohibitions with respect to health insurance discrimination on the basis of genetic information or genetic services.** "Excepted benefits," including benefits for long-term care, are not subject to the provisions of sections 101 or 102 which track the HIPAA framework that exempts "excepted benefits" from its substantive provisions. **Accordingly, long-term care insurance is not subject to section 104.**

S. Rep. No. 110-48 (April 10, 2007) at 27 (emphasis added).

GINA's inapplicability to long-term care insurance was also discussed during floor debate in the House of Representatives. Representative Gene Green noted that GINA's "sponsors and supporters all agreed that **this bill was never intended to regulate the long-term care insurance market**" and urged Members to "**ensure that future legislation extends the patient protections** inherent in this bill to consumers who want to plan for their future and purchase long-term care." 110 Cong. Rec. H4100 (2007) (emphasis added).[5]

In interpreting statutes, courts assume that Congress means what it says. *See, e.g., United States v. LaBonte*, 117 S. Ct. 1673, 1677 (1997); *see also Connecticut Nat'l Bank v. Germain*, 503 U.S. 249, 253-54 (1992) ("We have stated time and time again that courts must presume that a legislature says in a statute what it means and means in a statute what it says there."). In addition, courts often rely on legislative history to determine whether

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[5] This was no unintentional oversight. Congress affirmatively decided to exempt long-term care, disability and life insurance, among others, from GINA's requirements. As Dr. Francis Collins, then-Director of the National Human Genome Research Institute, noted in an editorial discussing GINA's passage in the *New England Journal of Medicine*, "a strategic decision was made early on to recognize the very distinct markets, social purposes, risks of adverse selection, and bodies of relevant law governing these types of insurance." K. Hudson, M. Holohan and F. Collins, *Keeping Pace With the Times: The Genetic Information Nondiscrimination Act of 2008*, N. Eng. J. Med. 358;25, 2663 (2008).

Congress intended to delegate certain authority to administrative agencies. *See, e.g., Chevron,* 467 U.S. at 851; *Aid Assoc. for Lutherans v. U.S. Postal Serv.*, 321 F.3d 1166, 1174-75 (D.C. Cir. 2003).

Thus, applying this and other well-established case law, Congress "has directly spoken to the issue" and limited HHS' authority to modify the Privacy Rule to ensure it is applied consistently with requirements GINA imposes on group health plans, health insurance issuers that issue health insurance coverage, HMOs and Medigap plans. *See Chevron*, 467 U.S. at 842. **Because Congress clearly intended to exempt long-term care insurance from GINA's requirements, "that is the end of the matter," and HHS has no authority to extend GINA's reach to such plans in the Proposed Rule.** *Id.* at 843; *see also Emily's List v. FEC*, 581 F.3d 1, 20 (D.C. Cir. 2009) (holding that the agency's proposed regulation "runs roughshod over the limits on its statutory authority"); *American Library Ass'n v. FCC*, 406 F.3d 689, 704 (D.C. Cir. 2005) ("We can find nothing in the statute, its legislative history, the applicable case law or agency practice indicating that Congress meant to provide the sweeping authority the [agency] now claims.").

### B. The Department Cannot Use its Authority Under HIPAA to Extend GINA's Reach to Long-Term Care Insurance

#### *1. HHS' Claim of Authority Under the HIPAA Administrative Simplification Provisions*

Recognizing that its authority under GINA is speculative at best, HHS seeks to justify the Proposed Rule's expansive reach under its "broad authority" to promulgate uniform privacy standards under HIPAA Sections 262 and 264. *See* 74 Fed. Reg. at 51699. Section 264 of HIPAA required the Secretary to transmit to Congress within 12 months of enactment recommendations for legislation regarding the privacy of individually identifiable health information. The recommendations were to address at least the following subjects:

> "(1) The rights that an individual who is a subject of individually identifiable health information should have.
> (2) The procedures that should be established for the exercise of such rights.
> (3) The uses and disclosures of such information that should be authorized or required."

Health Insurance Portability and Accountability Act of 2006, Pub. L. No. 104-191, 110 Stat. 1939 *et seq.* (1996) (*see* note accompanying 42 U.S.C. § 1320d-2).

Section 264 further provided that, if Congress failed to enact such legislation within 36 months, the Secretary should promulgate final regulations containing standards addressing "at least the subjects" listed above within 42 months of enactment. Although HHS transmitted the recommendations, Congress did not enact privacy legislation within the required timeframe. HHS therefore published a final HIPAA Privacy Rule and

modifications thereto in December 2000 and August 2002, respectively. *See* 65 Fed. Reg. 82461 *et seq.* (2000); 67 Fed. Reg. 53181 *et seq.* (2002).

HIPAA Section 262 states that "any standard" adopted under the administrative simplification portion of the HIPAA statute "shall apply, in whole or in part," to "health plan(s)," the definition of which is broader than the four categories of plans covered by GINA and includes, among others, long-term care insurance. *See* 42 U.S.C. § 1320d-1(5). The Department therefore claims:

> "Based on [HIPAA'S] broad definition of 'heath plan,' the wide latitude Congress provided to the Secretary to promulgate privacy standards, and the charge that 'any standard' should apply to all health plans, **we interpret that the HIPAA administrative simplification provisions provide the Secretary with broad authority to craft privacy standards that uniformly apply to all plans, regardless of whether such health plans are governed by other portions of the HIPAA statute.**"

74 Fed. Reg. at 51699 (emphasis added).

### *2. The Department's Attempt to Bootstrap its GINA Rulemaking Authority Based on HIPAA Cannot Stand*

#### a. GINA Limits the Bounds of HHS' HIPAA Authority

As noted above, Congress clearly did not intend to subject long-term care insurance to GINA's prohibition on the use of genetic information for underwriting purposes. Recognizing the absence of any specific delegation of authority in GINA,[6] HHS instead claims that Section 105 establishes the **minimum** categories of plans to which GINA's protections should apply. The Department notes in the Proposed Rule that "nothing in GINA explicitly or implicitly curtails the broad authority of the Secretary to promulgate privacy standards for any and all health plans that are governed by the HIPAA Administrative Simplification Provisions." *Id.*

However, the fact that Congress did not specifically preclude HHS from modifying the Privacy Rule to prevent long-term care insurers from using genetic information does not mean the agency can do so. As the D.C Circuit has noted, "[w]ere courts to *presume* a delegation of power absent an express *withholding* of power, agencies would enjoy

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[6] Even if HHS sought to argue (which it does not) that Congress' intent was unclear, or that it left some interpretive "gap" for it to fill, absent statutory authority the Department's interpretation is not entitled to deference. *See American Library Assoc. v. FCC*, 406 F.3d 689 (D.C. Cir. 2005) (where agency had no delegated authority, its claim of authority under ancillary jurisdiction was not entitled to deference); *Motion Picture Ass'n of America v. FCC*, 309 F.3d 796, 801 (D.C. Cir. 2002) (holding that an "agency's interpretation of [a] statute is not entitled to deference absent a delegation of authority from Congress to regulate in the areas at issue").

virtually limitless hegemony, a result plainly out of keeping with *Chevron* and quite likely with the Constitution as well." *Ry. Labor Execs. Assoc. v. Nat'l Mediation Bd.;* 29 F.3d 655, 671 (1994) (emphasis in original); *see also Aid Assoc.*, 321 F.3d at 1174-75 ("[T]he [agency's] position seems to be that the disputed regulations are permissible because the statute does not expressly foreclose the construction advanced by the agency. We reject this position as entirely untenable under well-established case law.").

Moreover, because GINA is subsequent to and more specific than HIPAA on the issue of genetic discrimination, the former controls the interpretation of the latter. The Supreme Court has noted on multiple occasions that the meaning of a statute "may be affected by other Acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000), *citing United States v. Estate of Romani*, 523 U.S. 517, 530-31 (1998); *see also U.S. v. Fausto*, 484 U.S. 439, 453 (1988). The only statutory provisions in HIPAA specifically relating to the use of genetic information apply to group health plans; HIPAA did not address the use of genetic information in connection with "excepted benefits" or by individual insurers, such as issuers of long-term care insurance.

By contrast, GINA's **entire focus** is preventing group health plans, health insurance issuers that issue health insurance coverage, HMOs and issuers of Medigap policies from using genetic information for enrollment and underwriting purposes. "A specific policy embedded in a later federal statute should control our construction of the [earlier] statute, even though it has not been expressly amended." *Estate of Romani* at 530-31. As the Supreme Court noted in *Brown & Williamson*, "[t]his is particularly so where the scope of the earlier statute is broad but the subsequent statutes more specifically address the topic at hand." 529 U.S. at 143. Thus, even if HIPAA left an interpretive "gap" for HHS to fill, GINA closed this gap entirely.

b. <u>HHS' Argument Based on HIPAA's Definition of "Health Plan" is Flawed</u>

The Department's attempt to justify including long-term care insurance based on the broad definition of "health plan" in the HIPAA administrative simplification provisions also fails. HHS claims that, under these provisions, the Secretary has " broad authority to craft privacy standards that uniformly apply to all plans, regardless of whether such health plans are governed by other portions of the HIPAA statute." 74 Fed. Reg. at 51699. However, while the definition of "health plan" in HIPAA includes a "long-term care policy," it also includes a "health insurance issuer." *See* 42 U.S.C. § 1320d(5); 42 U.S.C. § 300gg-91. This indicates that, **within the HIPAA Administrative Simplification statute itself, Congress differentiated between "health insurance issuer" and "long-term care polic[ies]"** -- in the same way it did in the GINA statute. If Congress chose not to subject long-term care insurance to these provisions, HHS cannot do so under its authority to issue privacy regulations under HIPAA. *Cf. MCI Telecomms. Corp. v. AT&T,* 512 U.S. 218, 231 (1994) (noting the unlikelihood that Congress would leave the determination of whether an entire industry would be rate regulated to agency discretion).

## III. CONCLUSION

For the reasons discussed above, our review of the Proposed Rule, GINA and its legislative history indicates that HHS has no statutory authority to extend GINA's applicability to long-term care insurance issuers via regulation. Section 105 of GINA applies only to group health plans, health insurance issuers that issue health insurance coverage, HMOs and issuers of Medicare supplemental policies and, under well-established doctrine, this is the end of the matter. HHS has no statutory authority to extend GINA's applicability beyond the entities specified in the statute. Moreover, neither Sections 262 nor 264 of HIPAA provide any legal basis for HHS' proposed expansion of GINA to include long-term care insurance. Because GINA was enacted after, and is more specific than HIPAA, it controls and limits any interpretation of HIPAA regarding the use of genetic information for underwriting purposes. Congress' enactment of GINA demonstrates that the agency lacked such authority.

United States Senate
WASHINGTON, DC 20510

January 18, 2011

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
Hubert Humphrey Building
200 Independence Avenue S.W.
Washington, D.C. 20201

Dear Secretary Sebelius:

We write concerning HHS' proposed rule (74 Fed. Reg. 51698) to implement section 105, Title I, of the Genetic Information Nondiscrimination Act of 2008 (GINA). For reasons discussed below, we believe that the proposed rule's prohibition on the use of genetic information by long-term care insurance carriers for underwriting purposes is overreaching.

Long-term care insurance carriers, and disability and life insurers, have traditionally used family histories and, more recently, genetic information, to underwrite applicants. As a corollary, individuals who wish to apply to purchase such policies provide voluntary, informed, written consent to releasing their protected health information to long-term care insurers, which then use it for underwriting purposes. The legislative history of GINA recognizes this in its discussion of long-term care insurance, which is among the "excepted benefits" under ERISA and the Public Health Service Act.

The Senate Health, Education, Labor and Pensions Committee Report (S. Rep. No. 110-48) published to accompany the markup of GINA (S. 358) states:

> "....[I]t has never been the intent of the bill to subject long-term care insurance to any of the bill's prohibitions with respect to health insurance discrimination on the basis of genetic information or genetic services. "Excepted benefits," including benefits for long-term care, are not subject to the provisions of sections 101 or 102 which track the HIPAA framework that exempts "excepted benefits" from its substantive provisions. Accordingly, long-term care insurance is not subject to section 104 [the precursor to GINA section 105]."

Additionally, the Congressional Record of April 25, 2007, includes the following statement from Rep. Gene Green, a leading proponent of GINA, that "sponsors and supporters all agreed that this bill was never intended to regulate the long-term care insurance market." Rep. Green further urged Members of Congress to work toward

ensuring "that future legislation extends the patient protections inherent in this bill to consumers who want to plan for their future and purchase long-term care." (153 Congressional Record H4100 (daily ed. April 25, 2007).

However, the proposed rule issued by HHS, published on October 7, 2009, (74 Federal Register 51698) to amend the Health Insurance Portability and Accountability Act privacy rule would *remove* the ability of individuals to control the release of their protected health information through written informed consent for use in underwriting for long-term care insurance products. We urge the Department to re-examine and revise the proposed regulation to permit such written authorizations for underwriting purposes for these products. [i]

Subjecting private long-term care insurance carriers to GINA's prohibitions on the use and disclosure of genetic information at this juncture could jeopardize the viability of this still-evolving market. It would also undermine Congress' intent that long-term care insurance should play a helpful role in financing the nation's long-term care costs, and would ensure that those individuals who can afford and wish to purchase such policies can readily do so, if they provide written authorization before releasing their protected health information for purposes of underwriting.

In closing, we would note that Congress, State legislatures or the National Association of Insurance Commissioners may decide to examine whether underwriting practices in the long-term care insurance market need to be revisited at the point that advances in genetic testing technology allow illness and disability to be predicted years before a condition actually manifests. Until such time, the legislative history of GINA makes it clear that Congress did not intend to include long-term care insurance in GINA's prohibitions on use and disclosure of protected health information in the context of underwriting.

Sincerely,

Herb Kohl
U.S. Senator

Olympia Snowe
U.S. Senator

[i] In March 2010, the Patient Protection and Affordable Care Act (PL 111-148 and 111-152) was enacted, which includes a new publicly financed long-term care program known as the Community Living Assistance Services and Supports (CLASS) program. In contrast to GINA, this program expressly prohibits an individual's health and genetic information from being used for purposes of underwriting.

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# Congress of the United States
## House of Representatives
Washington, DC 20515

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SUBCOMMITTEE ON FISHERIES, WILDLIFE, AND OCEANS

March 10, 2011

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
Hubert Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Sebelius:

I write regarding the proposed HHS rule to implement section 105 of Title I of the Genetic Information Nondiscrimination Act of 2008 (GINA). I am concerned that the proposed rule's extension of GINA's prohibition on use and disclosure of genetic information to long-term care insurance is in conflict with clear congressional intent not to subject long-term care insurance to GINA's prohibitions applicable to health insurance. I respectfully urge you to exclude long-term care insurance and issuers from the proposed rule in accordance with congressional intent.

The House Education and Labor Committee Report expressly stated that it was never the intent of GINA to subject long-term care insurance to any of the bill's prohibitions with respect to health insurance discrimination on the basis of genetic information or genetic services. The Education and Labor Committee Report that accompanied GINA makes congressional intent clear when it states:

> "The Committee believes that long term care insurance is not intended to be subject to Section 104 [the precursor to GINA Section 105]. Since benefits for long term care are ''excepted benefits'' under Section 733(c)(2)(B) of ERISA, Section 2791(c)(2)(B) of the PHSA, and Section 9832(c)(2)(B) of the Internal Revenue Code, it has never been the intent of the bill to subject long term care insurance to any of the bill's prohibitions with respect to health insurance discrimination on the basis of genetic information or genetic services."

Even members of Congress who disagreed with the exclusion of long-term care insurance from the scope of GINA still acknowledged that long-term care was treated differently by the legislation. The Congressional Record from the House of Representatives includes the following statement with respect to GINA: " ...[T]he bill was never intended to regulate the long-term care insurance market, and I understand that current statute treats long-term care insurance differently." Congressman Gene Green, a member of the Energy and Commerce Committee, who made clear in his Floor speech that he wanted long-term care insurance included within the scope of GINA made that statement.

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Congressional intent was equally clear in the Senate. The Senate HELP Committee Report language used virtually identical language to the House Education and Labor Committee Report. The Senate Health, Education and Labor Committee Report, to accompany S. 358 states:

> "Long term care insurance is not intended to be subject to section 104 [the precursor to GINA Section 105]. Since benefits for long term care insurance are "excepted benefits" under section 733(c)(2)(B) of ERISA, section 2791(c)(2)(B) of the PHSA and section 9832(c)(2)(B) of the IRC, it has never been the intent of the bill to subject long-term care insurance to any of the bill's prohibitions with respect to health insurance discrimination on the basis of genetic information or genetic services. "Excepted benefits," including benefits for long-term care, are not subject to the provisions of sections 101 or 102 which track the HIPAA framework that exempts "excepted benefits" from its substantive provisions. Accordingly, long-term care insurance is not subject to section 104."

Subjecting long-term care insurance to GINA's prohibitions on use and disclosure of genetic information may jeopardize the viability of the long-term care insurance market. Expanding GINA to cover long-term care could therefore undermine the private long-term care insurance market which has an important role to play in protecting the financial security of many Americans. As genetic testing becomes more advanced, there may be a time when Congress determines that GINA should be extended to cover the long-term care market. However, the clear congressional intent in GINA was to exclude long-term care from the law's prohibitions on using genetic information. I therefore respectfully urge you uphold the clear congressional intent of GINA to exclude long-term care from its scope.

Thank you for your consideration.

Sincerely,

Ron Kind

Ron Kind
Member of Congress

RICHARD E. NEAL
SECOND DISTRICT, MASSACHUSETTS

AT-LARGE WHIP

COMMITTEE ON WAYS AND MEANS
RANKING MEMBER,
SUBCOMMITTEE ON SELECT
REVENUE MEASURES
DEMOCRATIC LEADER,
FRIENDS OF IRELAND CAUCUS

# Congress of the United States
## House of Representatives
## Washington, DC 20515

November 30, 2011

The Honorable Kathleen Sebelius
Secretary
U.S. Department of Health and Human Services
Hubert Humphrey Building
200 Independence Ave, S.W.
Washington, DC 20201

Dear Secretary Sebelius:

I am writing regarding the proposed U.S. Department of Health and Human Services (HHS) rule to extend the Genetic Information Nondiscrimination Act's (GINA) prohibition on the use and disclosure of genetic information to long-term care insurance. This rule is in conflict with clear congressional intent not to subject long-term care insurance to GINA's prohibitions, and is likely to have significant unintended adverse consequences, never contemplated by Congress. I urge HHS to exclude long-term care insurance and issuers in the final rule.

GINA imposes underwriting restrictions on the use of genetic information on health insurers and employers only. GINA's legislative history reflects clear congressional intent to track the HIPAA framework, and accordingly not to subject long-term care insurance to any of the substantive prohibitions applicable to health insurance. The pertinent part of the Senate HELP Committee's report on GINA reads as follows:

> Long term care insurance is not intended to be subject to section 104. Since benefits for long term care insurance are "excepted benefits" under section 733(c)(2)(B) of ERISA, section 2791(c)(2)(B) of the PHSA and section 9832(c)(2)(B) of the IRC, it has never been the intent of the bill to subject long-term care insurance to any of the bill's prohibitions with respect to health insurance discrimination on the basis of genetic information or genetic services. "Excepted benefits," including benefits for long-term care, are not subject to the provisions of sections 101 or 102 which track the HIPAA framework that exempts "excepted benefits" from its substantive provisions. Accordingly, long-term care insurance is not subject to section 104.
>
> (See S. Rept. No. 110-48, p. 27, 110th Cong. 1st Session (2007).

The proposed rule ignores this clear statement of congressional intent. Long-term care insurance policies are significantly different from health insurance policies. Medical underwriting is critically important to ensure both appropriate pricing of the long-term care product and its fiscal viability. Long-term care insurance policies are usually purchased to be used 20 to 30 years after

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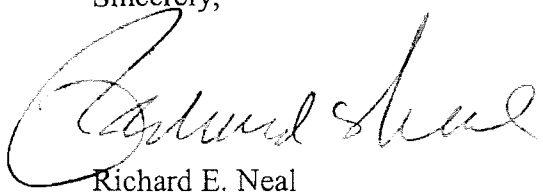
purchase to address the insured's *future* needs – to maintain quality of life during one's senior years. By contrast, health insurance is purchased to address *immediate* needs to improve or correct medical problems as of the effective date of coverage. Most health insurance is underwritten on a group basis; whereas most long-term care insurance is individually underwritten. Thus, medical underwriting is critical to long-term insurers' ability to continue to make products available at affordable prices.

HHS has recently recognized the critical importance of underwriting in the area of long-term care insurance. In that regard, I am attaching a recent study by the Society of Actuaries that discusses the adverse impact of the proposed GINA rules to long-term care insurance. Subjecting long-term care insurance to GINA's prohibitions on use and disclosure of genetic information may jeopardize the viability of the relatively new and innovative long- term care insurance market. Further, it may undermine Congress' initiatives that recognize the importance of long-term care insurance to American consumers' long range financial security.

I urge you to revise the proposed regulations to make clear that GINA does not apply to long-term care insurance and issuers of long-term care insurance products. Thank you for your attention to this matter and if you have any questions, please contact my counsel, Kara Getz, at 202-225-5601.

Sincerely,



Richard E. Neal
Member of Congress

JOHN KERRY
MASSACHUSETTS

COMMITTEES:
COMMERCE, SCIENCE, AND TRANSPORTATION
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SMALL BUSINESS

United States Senate
WASHINGTON, DC 20510–2102

December 8, 2011

The Honorable Kathleen Sebelius
Secretary
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Dear Secretary Sebelius:

I am writing regarding the Proposed Rule by the Department of Health and Human Services (HHS) to extend the Genetic Information Nondiscrimination Act's (GINA) prohibition on the disclosure and use of genetic information to long-term care insurance.

I have heard from Massachusetts long term care insurers about concerns that this Proposed Rule would be particularly damaging, both to insurers and the insured. As you are aware, premium rates for voluntary long term care insurance plans are based on characteristics of the insured population that indicate their actuarial risk. However, if high- and low-risk populations are indistinguishable to the insurer, they pay the same rates. It could then become necessary to raise premium rates to cover the unforeseen expenses of the high-risk population. This in turn could pressure the low-risk population to leave the plan and exacerbate adverse selection issues.

I understand the Senate Health, Education, Labor and Pensions Committee's report on GINA explicitly stated that long-term care insurance was not subject to GINA's prohibition on the disclosure and use of genetic information to long-term care insurance. As you work to promulgate the Final Rule, I respectfully request that you consider Congressional intent and any unintended negative consequences that could occur as a result of the Proposed Rule.

Thank you for your consideration of this request.

Sincerely,

John F. Kerry

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