



# State of Wisconsin / OFFICE OF THE COMMISSIONER OF INSURANCE

*Jim Doyle, Governor*  
*Jorge Gomez, Commissioner*

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November 1, 2005

Senator Dale Schultz  
Senate Majority Leader  
Room 211 South, State Capitol  
P.O. Box 7882  
Madison, WI 53707-7882

Representative John Gard  
Speaker of the Assembly  
Room 211 West, State Capitol  
P.O. Box 8952  
Madison, WI 53708

## **RE: Social and financial impact report – Senate Bill 288/Assembly Bill 617**

Dear Senator Schultz and Representative Gard:

SB 288/AB 617 prohibits a health care plan from denying coverage for a health care service, item, or drug administered in a cancer clinical trial if the service, item, or drug would have been covered had it not been administered in a clinical trial and if the clinical trial meets certain requirements. As required in, s. 601.423, Wis. Stats., I am submitting a social and financial report on the proposed health insurance mandate.

### **Current Wisconsin Law**

Wisconsin Law does not currently require insurers pay costs associated with any clinical trial. Insurers are permitted to offer coverage for clinical trials and OCI has heard anecdotally that some insurers do provide coverage for some costs associated with clinical trials. OCI does not, however, have any specific data describing the extent of this coverage.

### **Proposed Coverage Changes**

SB 288/AB 617 would prohibit insurance contracts providing coverage of health care expenses from excluding coverage for any health care service, item, or drug for the treatment of cancer that is administered in a clinical trial if the policy, plan, or contract would have covered the health care service, item, or drug had it not been administered in a clinical trial. SB 288/AB 617 also applies to self insured health plans of local governments. Clinical trials covered under SB 288/AB 617 must satisfy two criteria established in the bill related to the purpose of the trial and approval by an acceptable organization.

### **Social and Financial Impact Statements**

Wisconsin Statute 601.423 requires OCI to prepare social and financial impact reports when any bill affecting a health insurance policy, plan or contract is introduced. This report is required to be submitted to the presiding officer of the house of the legislature in which the bill was introduced.

601.423 (1) Defines a health insurance mandate as a statute of this state which requires an insurance policy, plan or contract to do any of the following:

- (a) Permit a person insured under the policy, plan or contract to obtain treatment or services from a particular type of health care provider, including, but not limited to, requiring a health maintenance organization, preferred provider plan, limited service health organization or other plan to select a particular type of health care provider for participation in the plan.
- (b) Provide coverage for the treatment of a particular disease, condition or other health care need.
- (c) Provide coverage of a particular type of health care treatment or service, or of equipment, supplies or drugs used in connection with a health care treatment or service.
- (d) Provide coverage for particular persons because of their relation to the insured or legal status with respect to the insured, or for any other reason.

It is my opinion that SB 288/AB 617 meets the criteria specified in sec. 601.423 (1) (a), and (c) and is considered a health insurance mandate for the purpose of this social and financial impact statement. Coverage of routine medical costs of cancer clinical trials (or any clinical trial) are not currently required to be covered expense, although some insurance plans currently do cover these costs. Also, any complications that develop as a result of any clinical trial is not currently required to be covered. SB 288/AB 617 would require coverage for these costs.

### **Impact of Mandates**

Wisconsin has long benefited from a healthy and competitive insurance market. The state currently has one of the lowest uninsured rates (48 of 51) in the country, according to the U.S. Census Bureau. Prohibiting insurance contracts providing coverage of health care expenses from excluding coverage for any health care service, item, or drug for the treatment of cancer that is administered in a clinical trial could have an adverse effect on our current health insurance market. Traditionally, as the number of benefit mandates increase the cost of coverage rises, and as costs rise, fewer and fewer individuals and businesses can afford to insure.

It is difficult to project the actual impact of any mandate because of the factors involved. The structure of a benefit will affect, either positively or negatively, the level of consumer demand or utilization of service. For example, a limited benefit may lead consumers to decide not to seek treatment that is not vitally necessary. On the other hand, a generous benefit could lead to over utilization for a specific treatment simply because payment is available.

### **Social Impact Factors**

Fully insured group and individual health insurance products cover approximately 1.5 million state residents<sup>1</sup>. This is a dramatic decrease over the past decade in the number of Wisconsin residents who are insured under a commercial health insurance policy, representing less than 28% of Wisconsin's population. This mandate will expand coverage for those individuals.

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<sup>1</sup> Office of the Commissioner of Insurance (June 2005). *Health Insurance Coverage in Wisconsin* (PI-094 R 06/2005) p. 14. Madison, WI.

Individuals who are members of groups whose benefit plans are self-funded are exempt from state regulation by the Employee Retirement and Income Security Act of 1974 (ERISA) and will not be affected by SB 288/AB 617. Because self-funded plans do not have to offer state-mandated benefits, this option offers self-funded plans the opportunity to save on premium costs, or choose which benefits to offer. Anytime mandates are added to insurance products, it may increase the propensity of employer groups to switch to self-funding.

Self-funding of health benefits has historically been used mostly by larger employers, however; over the last decade, the number of medium employers shifting from fully insured to self-funded products has increased. Larger employers are able to spread these costs over a larger base when self-funding and typically do not experience the same impact. Increasing the cost disparity between insured and self-funded plans costs could increase the incidence of such switching.

Figure 1 below demonstrates this occurrence. While commercial insurance coverage has declined in Wisconsin since 2000, enrollment in self-funded health plans has grown by 32 percent. Enrollment in public insurance programs (Medicare, Medicaid, BadgerCare and HIRSP) has also increased 34% since 2000; however, it is less certain that health insurance mandates were the main factor in this shift. Wisconsin's ailing economy in 2000 and 2001 and the high cost of health care in general may have had more of an impact than mandates specifically.

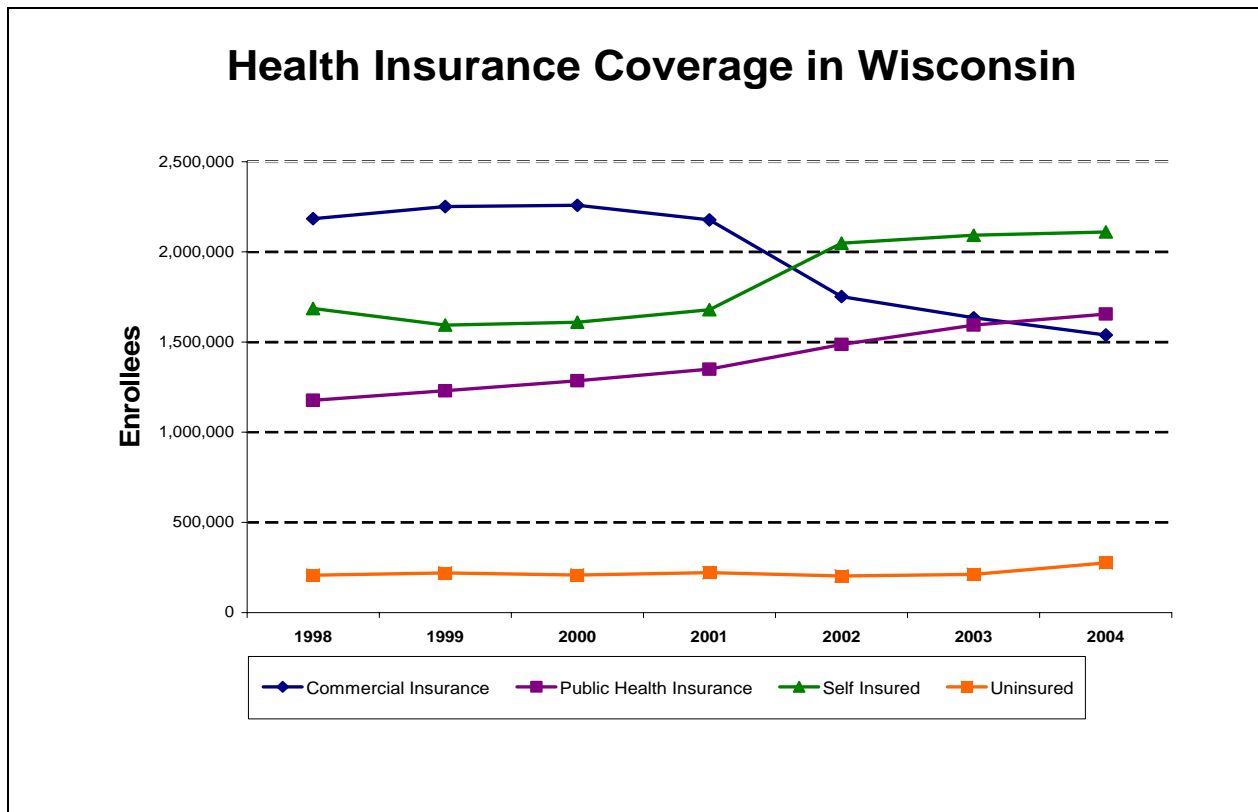


Figure 1. Health Insurance Coverage in Wisconsin 1998-2004.

(Source: OCI, DOA, DHFS)

According to the American Cancer Society, there were approximately 121,776 cases of cancer between 1996-2000<sup>2</sup> with 26,340 new cancer cases predicted for 2005.<sup>3</sup> Clinical trials have stringent eligibility requirements in order to obtain the proper study pool. The result of this is that there is a small pool of individuals with cancer who are actually eligible to participate in cancer clinical trials. A study printed in the *Journal of Clinical Oncology* in 2002 noted that with the exception of children and young adults aged 0-19 (30% to over 50%) only 1% to 2% of cancer patients participated in clinical trials.<sup>4</sup> For Wisconsin it was noted that between 1% and 1.99% of cancer patients were participating in cancer clinical trials.<sup>5</sup> Health insurance coverage seems to have a direct effect on participation in cancer clinical trials with over 71% of clinical trials participants having health insurance coverage, self-funded coverage included. This number jumps to over 94% when Medicare, Medicaid and Military participants are included.<sup>6</sup> It would appear that the biggest deterrent to participating in a cancer clinical trial is having no insurance coverage at all. The lack of a primary care provider or clinical oncology provider would be the logical reason this occurs.

### Financial Impact Factors

It is not possible to make a credible determination on the effect on future premiums to consumers, future health care costs or administrative costs to insurers. The variables involved in making assumptions on future costs to insurers and consumers, and the unique nature of individual clinical trials and the associated routine care costs make such estimates difficult, if not impossible. Although, as we have seen, most participants in cancer clinical trials have some type of insurance coverage, and some insurers are currently paying for some of the costs that would be required by SB 288/AB 617, OCI has no way of determining who is covered by whom and who is paying for what. Further, OCI does not have information on plan designs, premiums charged or cost sharing provisions for any of these participants. It is my belief that there is sufficient variety in these factors that making estimates is not possible. Additionally, OCI would not be able to estimate the percentage of clinical trial participants who are members of self-funded health insurance plans. Self-funded participants would need to be removed to make an accurate cost prediction.

There have been some national studies on the subject of costs of clinical trials. The *Journal of the American Medical Association* published a study in June of 2003 that showed that treatments for patients in cancer clinical trials were 6.5% higher. However, when only Phase III

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<sup>2</sup> American Cancer Society. *Wisconsin Facts and Figures 2003-2004. Table A: Cancer Incidence, Total Number of Cases and Averaged-Annual Age-Adjusted Rates by County, 1996-2000.* Retrieved from [http://www.cancer.org/downloads/COM/wisconsin\\_facts\\_and\\_figures.pdf](http://www.cancer.org/downloads/COM/wisconsin_facts_and_figures.pdf)

<sup>3</sup> American Cancer Society. *Cancer Facts and figures 2005.* Retrieved from <http://www.cancer.org/downloads/STT/CAFF2005f4PWSecured.pdf>

<sup>4</sup> W. B. Sateren, E. L. Trimble, et al. How Sociodemographics, Presence of Oncology Specialists, and Hospital Cancer Programs Affect Accrual to Cancer Treatment Trials. *Journal of Clinical Oncology*, Vol. 20, No 8 (April 15), 2002: pp 2109-2117 2109 10.1200/JCO.2002.08.056

<sup>5</sup> Ibid

<sup>6</sup> Ibid

trial participants costs were examined the costs were only 3.5% higher, while Phase I and Phase II costs were 12.8% higher.<sup>7</sup>

The insurance industry collected \$4.8 billion in direct earned premiums for group and individual health insurance products in Wisconsin 2004.<sup>8</sup> Health insurers paid \$4.2 billion in claims costs for 2004 in Wisconsin.<sup>9</sup> In order to have a 1% effect on premiums, SB 288/AB 617 would have to cost insurers an additional \$42 million in claim costs. Given the small pool of likely eligible participants for cancer clinical trials, it is unlikely that additional claims costs for routine medical care will approach this level, especially considering that some of these costs are already being paid out by insurers.

It is conceivable that utilization of clinical trials may increase due to the passage of SB 288/AB 617. As the earlier study in the *Journal of Clinical Oncology* pointed out, participation in cancer clinical trials is dependent on a number of factors including; unemployment levels, income levels, insurance coverage, proximity to clinical oncologists and oncology hospitals and HMO market penetration.<sup>10</sup> Clearly, ability to pay is a factor in deciding to participate in a clinical trial. Any increase in utilization will result in a short term cost increase. This must be weighed against a long term benefit from the successful completion of a trial that results in increased treatment options for patients that may save lives and reduce overall costs for future cancer patients.

### **Impact on the Uninsured**

According to Congressional Budget Office estimates - for every 1% increase in premiums, approximately 200,000 persons nationally could become uninsured. While it would be difficult to predict the number of persons affected, it is reasonable to assume that an increase in premium costs to small and medium-sized employers may have a negative impact on the number of people insured in Wisconsin.

Please contact Eileen Mallow at 266-7843 or Jim Guidry at 264-6239 if you have any questions regarding this report.

Sincerely,

Jorge Gomez  
Commissioner

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<sup>7</sup> D.P. Goldman, et al. *Incremental treatment costs in National Cancer Institute-sponsored clinical trials*. Rand Health, Santa Monica, CA. Published in the *Journal of the American Medical Association* (June 2003), JAMA, 2003 Jun 11, 289 (22): 2970-7.

<sup>8</sup> Office of the Commissioner of Insurance (2005). *Wisconsin Insurance Report Business of 2004*, Vol 136, p. 109. Madison, WI

<sup>9</sup> Ibid.

<sup>10</sup> W. B. Sateren, E. L. Trimble, et al