➢ Hearing Records ... HR

** 07hr_sb0415_SC-PHSILTCP_pt01

WISCONSIN STATE LEGISLATURE ... PUBLIC HEARING COMMITTEE RECORDS

2007-08

(session year)

Senate

(Assembly, Senate or Joint)

Committee on Public Health, Senior Issues, Long Term Care and Privacy

(SC-PHSILTCP)

(FORM UPDATED: 07/02/2010)

COMMITTEE NOTICES ...

➢ Committee Reports ... CR
**

➢ Executive Sessions ... ES
**

➢ Public Hearings ... PH
**

➢ Record of Comm. Proceedings ... RCP
**

INFORMATION COLLECTED BY COMMITTEE FOR AND AGAINST PROPOSAL ...

➢ Appointments ... Appt
**

Name:

➢ Clearinghouse Rules ... CRule
**

➢ Hearing Records ... HR (bills and resolutions)
**

➢ Miscellaneous ... Misc
**

( )

Vote Record

Committee on Public Health, Senior Issues, Long Term Care and Privacy

Date: 2/20/08

Moved by: Cowles Seconded by: Carpenter

AB ____ SB 415 Clearinghouse Rule ____

AJR ____ SJR ____ Appointment ____

AR ____ SR ____ Other ____

A/S Amdt (1)

A/S Amdt ____ to A/S Amdt ____

A/S Sub Amdt ____

A/S Amdt ____ to A/S Sub Amdt ____

A/S Amdt ____ to A/S Amdt ____ to A/S Sub Amdt ____

Be recommended for:

☐ Passage ☒ Adoption ☐ Confirmation ☐ Concurrence ☐ Indefinite Postponement

☐ Introduction ☐ Rejection ☐ Tabling ☐ Nonconcurrence

Committee Member	Aye	No	Absent	Not Voting
Senator Tim Carpenter, Chair	☐	☒	☐	☐
Senator Spencer Coggs	☐	☒	☐	☐
Senator Pat Kreitlow	☐	☒	☐	☐
Senator Dale Schultz	☒	☐	☐	☐
Senator Robert Cowles	☒	☐	☐	☐
Totals:	2	3		

☐ Motion Carried ☒ Motion Failed

Vote Record

Committee on Public Health, Senior Issues, Long Term Care and Privacy

Date: 2/20/08

Moved by: Kreitlow Seconded by: Schultz

AB _____ SB 415 Clearinghouse Rule _____

AJR _____ SJR _____ Appointment _____

AR _____ SR _____ Other _____

A/S Amdt _____

A/S Amdt _____ to A/S Amdt _____

A/S Sub Amdt _____

A/S Amdt _____ to A/S Sub Amdt _____

A/S Amdt _____ to A/S Amdt _____ to A/S Sub Amdt _____

Be recommended for:

☒ Passage ☐ Adoption ☐ Confirmation ☐ Concurrence ☐ Indefinite Postponement

~~☐ Introduction~~ ☐ Rejection ☐ Tabling ☐ Nonconcurrence

Committee Member	Aye	No	Absent	Not Voting
Senator Tim Carpenter, Chair	☒	☐	☐	☐
Senator Spencer Coggs	☒	☐	☐	☐
Senator Pat Kreitlow	☒	☐	☐	☐
Senator Dale Schultz	☒	☐	☐	☐
Senator Robert Cowles	☐	☒	☐	☐
Totals:	4	1	____	____

☐ Motion Carried ☐ Motion Failed


FORWARD

Gundersen Lutheran

Testimony Presented by
Dr. Alcee Jumonville and Emily Hiatt
Gundersen Lutheran Health System
Office: (608) 775-3588
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EAHiatt@gundluth.org

February 6, 2008

To the Members of the Senate Committee on Public Health, Senior Issues, Long Term Care and Privacy,

Thank you for considering SB 415, *The Cancer Research Advancement Act*. Gundersen Lutheran Health System is privileged to testify in support of this legislation.

The bill updates existing Wisconsin law governing the state cancer registry to allow for release of patient-identifiable cancer registry data to researchers who meet the bill's conditions.

This bill can help Wisconsin's researchers achieve life-saving discoveries in cancer detection and treatment, and most importantly, help ensure every cancer patient has the best fighting chance against this horrific disease.

In adopting the bill's changes, Wisconsin will more completely satisfy compliance with U.S. Public Law 102-515, the "Cancer Registries Amendment Act," which governs state cancer registries seeking CDC funding.

BACKGROUND

This bill began with a physician, Dr. Richard Ellis, at Gundersen Lutheran's Norma J. Vinger Center for Breast Care in La Crosse, Wisconsin. Dr. Ellis is conducting research on ways to detect and diagnose breast cancer earlier. We know that when a woman is diagnosed with breast cancer early, she has as much as a 92% chance of surviving. But when a woman is diagnosed late, with 'Stage IV' breast cancer, her chance of surviving drops to 7%. For this reason, Dr. Ellis has been studying for five years his patients and their outcomes to identify more effective ways of detecting cancer earlier. But in completing this research, Dr. Ellis ran into an obstacle with Wisconsin's cancer registry statute. He couldn't get the data he needed.

We found that Wisconsin's cancer registry statute lacks a provision allowing for release of patient-identifiable cancer registry data to researchers. After some additional research, we discovered 45 other states across the country allow for release of this patient-identifiable cancer registry data to their researchers, making Wisconsin one of only five states that does not. (See Appendix 1 for a complete list).

With Wisconsin's strong tradition of achievement in scientific and medical research, we were surprised that our state cancer registry was less research-conducive than the rest of the country.

So, we set out to update the Wisconsin Cancer Registry statute, by writing a bill that will enable the registry to share patient-identifiable data with researchers who meet the bill's conditions.

Dr. Ellis believes his research will provide a national model for breast care that would achieve better patient outcomes and reduce costs associated with treating breast cancer. But in order to complete and publish his research findings, he needs to verify his research with data contained in the Wisconsin Cancer Registry, specifically, to identify the number of times he missed a cancer diagnosis, called a "false negative." With this information, his research can be sure it has identified all of the best methods for diagnosing breast cancer as early as possible.

Dr. Ellis is just one of many researchers in Wisconsin conducting important and potentially lifesaving cancer research. Updating the cancer registry in this way will enable cancer researchers across the state (and for years to come) to conduct cancer research on the same level as the rest of the nation - bringing Wisconsin's cancer research in line with the other scientific research Wisconsin has become known for across the globe.

STATEWIDE SUPPORT

We started working on this bill one year ago. We've worked with the Department of Health and Family Services and the patient advocacy community, including the Wisconsin Cancer Council, the Wisconsin Breast Cancer Coalition and the American Cancer Society who have all pledged their support for the legislation.

As you can see by the attached letter of support (Appendix 2), this measure is supported by medical and research institutions across the state, including the University of Wisconsin School of Medicine and Public Health, Marshfield Clinic, the Medical College of Wisconsin, Gundersen Lutheran, the Wisconsin Medical Society, the Wisconsin Collaborative on Healthcare Quality, Ministry Health Care, and others.

To date, there are no groups or organizations in opposition to the bill. Naturally, people have questions about protection of patient confidentiality. We'll discuss this topic below. Our federal laws were written both to encourage research and protect patient confidentiality - and this bill is an example of how we can advance cancer research while ensuring strict compliance with state and federal laws regarding patient confidentiality.

RESEARCH AND PROTECTING PATIENT CONFIDENTIALITY

Public Law 102-515, or the "Cancer Registries Amendment Act," was passed by the 102nd U.S. Congress in 1992 to establish a national program of cancer registries (See Appendix 4). The Law allows the Secretary of Health and Human Services to fund state cancer registries that meet the requirements set forth by the Act.

Two of the eight requirements of Public Law 102-515 are relevant to this discussion. They directly support research using confidential cancer registry data. So much so, that any cancer registry seeking federal funding must provide:

> *(vi) for a means by which confidential case data may in accordance with State law be disclosed to cancer researchers for the purposes of cancer prevention, control and research;*

(vii) for the authorization or the conduct, by the statewide cancer registry or other persons and organizations, or studies utilizing statewide cancer registry data, including studies of the sources and causes of cancer, evaluations of the cost, quality, efficacy, and appropriateness of diagnostic, therapeutic, rehabilitative, and preventative services and programs relating to cancer and any other clinical, epidemiological, or other cancer research.

- Public Law 102-515, 102nd United States Congress. The Cancer Registries Amendment Act of 1992. As reprinted by the U.S. Department of Health and Human Services.

Public Law 102-515 explicitly supports research using cancer registry data. Our bill will amplify and further satisfy Wisconsin's compliance with Public Law 102-515 by providing for a means to complete sections VI and VII, increasing our chances for securing additional federal funding.

There are a number of protocols in this bill that will prevent misuse of cancer registry data and ensure protection of patient confidentiality as guided by state and federal law.

First, according to this bill, researchers must receive authorization of a Federalwide Assurance-Holding (FWA) Institutional Review Board (IRB). The process is heavily regulated by the federal government and a process that is challenging for even the most well qualified researchers. Full details on FWA-holding IRBs can be found on the U.S. Department of Health and Human Services website (http://www.hhs.gov/ohrp/assurances/assurances_index.html) (See also Appendix 3). Only researchers who receive this authorization can access the cancer registry data, pending the researcher also meets the bill's other requirements. The researcher must present documentation of this FWA-holding IRB authorization to the Wisconsin Department of Health and Family Services (DHFS) as part of his or her application for the cancer registry data.

Next, the researcher must provide to DHFS his or her qualifications. This step will provide the Department with information on the researcher's qualifications, employer, sponsoring organization, and past experiences conducting research with protected patient information.

Additionally, the researcher must provide the protocol for his or her research. This protocol must include a description of the means by which the researcher will ensure total protection of the confidential cancer registry data he or she is given. If the researcher compromises the cancer registry data in any way, the researcher is held to the bill's criminal and civil liabilities.

The researcher's protocol must also include the names, affiliations, and qualification of those within the research study who will also have access to the researcher's cancer registry data. Anyone whose name is not included in the research protocol cannot legally access the researcher's confidential cancer registry data. If they accessed the data, they would be subject to the penalties provided in the bill which are both criminal and civil.

If the researcher attempts to disclose in his protocol that he intends to share or publish any confidential cancer registry data in a manner that is inconsistent with protection of patient confidentiality or the intent of this legislation, the Department of Health and Family Services can deny or amend the researcher's request. Again, if a researcher compromises the cancer registry data in any way, the researcher is subject to criminal and civil penalties.

Furthermore, the bill prohibits publicly revealing information that may serve to identify the individual whose information was released from the cancer registry. In this bill, "public" means any person beyond those outlined within the researcher's original application and research

protocol. Only aggregate, de-identified information can be shared publicly or with persons outside of those identified in the researcher's application and research protocol approved by the Department. If the researcher or the researcher's organization uses the patient-identifiable information in any business competitive manner not expressly approved by the Department, the researcher and/or organization will be in violation of the statute, HIPAA and punished accordingly.

Additionally, the bill provides that in the Rule-Making process the Department of Health and Family Services may make any additional requirements on the researchers. The Wisconsin Cancer Reporting System within the Department of Health and Family Services is acutely focused on protecting the confidential patient information contained within their registry; the forms and requirements that will be developed in the Rule-Making process will be stringent and thorough.

Finally, and most significantly, the protections and guidelines that HIPAA and the HHS Common Rule have established regarding both protection of confidential patient information as well as the conduct of research using confidential patient information, will ensure maximum protection of confidential cancer registry data.

While HIPAA governs how the researchers must handle the confidential patient information, the U.S. Health and Human (HHS) Common Rule on Protection of Human Subjects governs how the cancer registry handles the data contained within their registry. The cancer registry is allowed to release patient-identifiable cancer registry data in accordance with the HHS Common Rule, which sets criteria for IRB approval of research.

The criteria for an IRB waiver through the HIPAA Privacy Rule are consistent with the criteria for IRB waiver of informed consent under the Common Rule HHS Protection of Human Subjects Regulations, which applies in this case. In short, any researcher seeking access to cancer registry data will need to demonstrate to the Department that the researcher has received an IRB waiver of Authorization for their research in accordance with existing federal law.

As touched on above, the federal legal infrastructure for using patient-identifiable information in research is already well established (See Attachment). Our legislation operates within the existing federal infrastructure and rules on the subject, and, as outlined in the above section, we added a number of additional protections.

FISCAL NOTE, FEDERAL MATCHING DOLLARS

This bill includes a Fiscal Note which provides for 1.0 FTE at a cost of just more than $90,000.

We have an opportunity to capture federal matching dollars as a result of this Fiscal Note. For every dollar Wisconsin puts towards its cancer registry, the federal government can match 3 to 1. In other words, if we appropriate $90,000 to the Wisconsin Cancer Reporting System, we have the opportunity to capture more than $270,000 in federal matching dollars.

The severe staffing shortages occurring at the Wisconsin Cancer Reporting System (WCRS) underscore the importance of this funding. According to the Centers for Disease Control, Wisconsin's cancer registry is the fourth *worst* in the nation for staffing levels. Our annual caseload per cancer registry staff is more than 4,000 cases per person (See Appendix 5).

It has become apparent that the requirements created by this legislation would be significant and therefore additional staff would be needed to ensure compliance with the bill.

It would be unfortunate to succeed in making this data available for cancer research, but because of workload at the WCRS, researchers would have to wait years to get the data they requested. Timely receipt of cancer registry data is basic to the scientific validity of a researcher's study.

The medical community has agreed to help fund this position through user fees. The researchers who request and receive the cancer registry data will pay a "user fee" reasonable and commensurate with actual and direct costs associated with the bill. The hope is that these user fees will generate enough revenue to cover the cost of the FTE.

However, the amount of revenue the user fees will generate cannot be accurately predicted until we have a better understanding of exactly the number of research requests the registry will receive after this legislation is enacted. Because we want to be sure the position is funded, the fiscal note would be funded through General Purpose Revenue (GPR) and the user fees would go to repay the general fund.

Again, we see this as an opportunity for Wisconsin to capture 3-to-1 federal matching dollars for enhanced cancer research and cancer reporting in Wisconsin, helping us also to meet the public health goals of Healthy Wisconsin 2010.

A FINAL WORD

The Cancer Research Advancement Act will enhance and support important cancer research in Wisconsin's hospitals, clinics, and medical and educational research centers by allowing for release of cancer registry data to researchers.

This bill will ensure women, men, and children in Wisconsin have the best fighting chance against this horrific disease. It will help us move toward our ultimate goal – a cure.

Thank you for considering this legislation. We hope we have the opportunity to report back to you regarding the cancer research that was made possible because of your support for this legislation.

Survey of U.S. Cancer Registries: Encouraging Research in Cancer Screening, Diagnosis, and Treatment

Cancer Registries that Allow Release of Identifiable Patient Information to Researchers	
Alabama	Montana
Alaska	Nebraska
Arizona	New Hampshire
Arkansas	New Mexico
California	North Carolina
Colordao	North Dakota
Florida	Ohio
Georgia	Oklahoma
Hawaii	Oregon
Idaho	Pennsylvania
Illinois	Rhode Island
Indiana	South Carolina
Iowa	South Dakota
Luisiana	Tennessee
Maine	Texas
Maryland	Utah
Massachusetts	Vermont
Michigan	Virginia
Mississippi	Washington
Missouri	West Virginia

Cancer Registries that Allow Restricted Release for Research
Connecticut (For "public health planning")
Delaware (To "cancer control agencies")
Minnesota (Physician consent)
Nevada (Patient consent)
New York (Patient consent or government funded)

Cancer Registries that Do Not Allow Research
Kansas
Kentucky
New Jersey
Wisconsin
Wyoming

APPENDIX 2

January 15, 2008

To the Members of the Wisconsin Legislature,

Medical research in Wisconsin has been a source of great pride for our State. The groundbreaking research in our hospitals, clinics and universities has established Wisconsin as a leader in medicine and science.

With cancer, in particular, research is critical. For Wisconsin's men, women and children, research can mean the difference between surviving cancer and becoming a victim of cancer. In stark contrast to Wisconsin's great tradition of medical research, currently 45 other States have more research-conducive cancer registry statutes than Wisconsin. Because of the way our state law was written 30 years ago, the Wisconsin Cancer Registry is restricted in its ability to aid cancer research in our State. As a result, medical researchers across Wisconsin are unable to access the data needed to conduct or complete their research.

For instance, a Wisconsin woman diagnosed with late-stage breast cancer has only a 7% change for survival after five years, whereas a Wisconsin woman diagnosed with early-stage breast cancer has a 92% chance for survival after five years. Dr. Richard Ellis, a radiologist at Gundersen Lutheran in La Crosse, is conducting this research; he's identifying ways to detect and diagnose cancer earlier to save lives. He can't complete his research until he can access data contained in the Wisconsin Cancer Registry. He is just one example out of many researchers and medical professionals in Wisconsin conducting important cancer research.

The Cancer Research Advancement Act to amend the Wisconsin Cancer Registry will enhance and support important cancer research in Wisconsin's hospitals, clinics, and medical and educational research centers by allowing for release of cancer registry data to researchers. This bill will ensure the women, men, and children who are our patients receive optimal care and treatment. It will allow our researchers to publish their findings and outcomes on a national and international level.

Most of all, this bill will help us move toward our ultimate goal – a cure.

As physicians, nurses, medical professionals, and researchers working each day to alleviate cancer's toll in Wisconsin, we urge you to support this bill and ask you to stand beside us as we push to improve cancer research in Wisconsin.

Sincerely,

Jeffrey Thompson, MD
Chief Executive Officer & Pediatrician
Gundersen Lutheran

Gundersen Lutheran

Doug Reding, MD
Vice President & Hematologist/Oncologist
Marshfield Clinic

MARSHFIELD CLINIC

Robert Golden, MD
Dean, UW School of Medicine and Public Health
Vice Chancellor Medical Affairs
UW-Madison

University of Wisconsin
SCHOOL OF MEDICINE
AND PUBLIC HEALTH

T. Michael Bolger, J.D.
Chief Executive Office & President
Medical College of Wisconsin

MEDICAL COLLEGE OF WISCONSIN

Rance Hafner, MD
Chairperson
Wisconsin Cancer Council

Wisconsin Cancer Council

American Cancer Society

Michael A. Schmidt
President, St. Joseph's Hospital
Ministry Health Care

Saint Joseph's Hospital
Ministry Health Care
Sponsored by Sisters of the Sorrowful Mother

C.M. Chumbley, MD, MBA
President & CEO
Medical Associates Health Centers

medical associates
health centers

Susan L. Turney, MD, MS, FACMPE, FACP
Chief Executive Officer/ Executive Vice President

Wisconsin Medical Society
Your Doctor. Your Health.

Chris Queram
President and CEO
Wisconsin Collaborative for Healthcare Quality

WCHQ
Wisconsin Collaborative for Healthcare Quality

Paul Robey, MD
Medical Director
Lakeshore Medical Clinic

Lakeshore Medical Clinic

Code of Federal Regulations
TITLE 45
PUBLIC WELFARE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
PART 46
PROTECTION OF HUMAN SUBJECTS
[PDF 215 KB]
* * *
Revised June 23, 2005
Effective June 23, 2005
* * *

Basic HHS Policy for Protection of Human Research Subjects

Subpart A -- Sec.

	To what does this policy apply?
46.101	
46.102	Definitions.
46.103	Assuring compliance with this policy--research conducted or supported by any Federal Department or Agency.
46.104-46.106	[Reserved]
46.107	IRB membership. IRB functions and operations.
46.108	
46.109	IRB review of research.
46.110	Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.
46.111	Criteria for IRB approval of research. Review by institution.
46.112	Suspension or termination of IRB approval of research.
46.113	
46.114	Cooperative research.
46.115	IRB records.
46.116	General requirements for informed consent.
46.117	Documentation of informed consent.
46.118	Applications and proposals lacking definite plans for involvement of human subjects.
46.119	Research undertaken without the intention of involving human subjects.
46.120	Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.
46.121	[Reserved]
46.122	Use of Federal funds.
46.123	Early termination of research support: Evaluation of applications and proposals.
46.124	Conditions.

Subpart B -- Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research

Sec.

	To what do these regulations apply?
46.201	
46.202	Definitions.
46.203	Duties of IRBs in connection with research involving pregnant women, fetuses, and neonates.
46.204	Research involving pregnant women or fetuses.
46.205	Research involving neonates.
46.206	Research involving, after delivery, the placenta, the dead fetus or fetal material.
46.207	Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant

women, fetuses, or neonates.

Subpart C -- Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

Sec.

46.301 Applicability.
46.302 Purpose.
46.303 Definitions.
46.304 Composition of Institutional Review Boards where prisoners are involved.
46.305 Additional duties of the Institutional Review Boards where prisoners are involved.
46.306 Permitted research involving prisoners.

Subpart D -- Additional Protections for Children Involved as Subjects in Research

Sec.

46.401 To what do these regulations apply?
46.402 Definitions.
46.403 IRB duties.
46.404 Research not involving greater than minimal risk.
46.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.
46.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
46.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.
46.408 Requirements for permission by parents or guardians and for assent by children.
46.409 Wards.

Authority: 5 U.S.C. 301; 42 U.S.C. 289(a).

Editorial Note: The Department of Health and Human Services issued a notice of waiver regarding the requirements set forth in part 46, relating to protection of human subjects, as they pertain to demonstration projects, approved under section 1115 of the Social Security Act, which test the use of cost--sharing, such as deductibles, copayment and coinsurance, in the Medicaid program. For further information see 47 FR 9208, Mar. 4, 1982.

http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

Public Law 102-515
102d Congress

An Act

Oct. 24, 1992
[S. 3312]

Entitled the "Cancer Registries Amendment Act".

Cancer Registries Amendment Act.
Diseases.
Health and health care.
42 USC 201 note.
42 USC 280e note.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Cancer Registries Amendment Act".

SEC. 2. FINDINGS AND PURPOSE.

(a) FINDINGS.—Congress finds that—

(1) cancer control efforts, including prevention and early detection, are best addressed locally by State health departments that can identify unique needs;

(2) cancer control programs and existing statewide population-based cancer registries have identified cancer incidence and cancer mortality rates that indicate the burden of cancer for Americans is substantial and varies widely by geographic location and by ethnicity;

(3) statewide cancer incidence and cancer mortality data, can be used to identify cancer trends, patterns, and variation for directing cancer control intervention;

(4) the American Association of Central Cancer Registries (AACCR) cites that of the 50 States, approximately 38 have established cancer registries, many are not statewide and 10 have no cancer registry; and

(5) AACCR also cites that of the 50 States, 39 collect data on less than 100 percent of their population, and less than half have adequate resources for insuring minimum standards for quality and for completeness of case information.

(b) PURPOSE.—It is the purpose of this Act to establish a national program of cancer registries.

SEC. 3. NATIONAL PROGRAM OF CANCER REGISTRIES.

Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by adding at the end the following new part:

"PART M—NATIONAL PROGRAM OF CANCER REGISTRIES

42 USC 280e.

"SEC. 399H. NATIONAL PROGRAM OF CANCER REGISTRIES.

"(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control, may make grants to States, or may make grants or enter into contracts with academic or nonprofit organizations designated by the State to operate the State's cancer registry in lieu of making a grant directly to the State, to support the operation of population-based, statewide cancer registries in order to collect, for each form of in-situ and invasive cancer (with the exception of basal cell and squamous cell carcinoma of the skin), data concerning—

69-139 O - 92 (515)

"(1) demographic information about each case of cancer;

"(2) information on the industrial or occupational history of the individuals with the cancers, to the extent such information is available from the same record;

"(3) administrative information, including date of diagnosis and source of information;

"(4) pathological data characterizing the cancer, including the cancer site, stage of disease (pursuant to Staging Guide), incidence, and type of treatment; and

"(5) other elements determined appropriate by the Secretary.

"(b) MATCHING FUNDS.—

"(1) IN GENERAL.—The Secretary may make a grant under subsection (a) only if the State, or the academic or nonprofit private organization designated by the State to operate the cancer registry of the State, involved agrees, with respect to the costs of the program, to make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that is not less than 25 percent of such costs or $1 for every $3 of Federal funds provided in the grant.

"(2) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION; MAINTENANCE OF EFFORT.—

"(A) Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

"(B) With respect to a State in which the purpose described in subsection (a) is to be carried out, the Secretary, in making a determination of the amount of non-Federal contributions provided under paragraph (1), may include only such contributions as are in excess of the amount of such contributions made by the State toward the collection of data on cancer for the fiscal year preceding the first year for which a grant under subsection (a) is made with respect to the State. The Secretary may decrease the amount of non-Federal contributions that otherwise would have been required by this subsection in those cases in which the State can demonstrate that decreasing such amount is appropriate because of financial hardship.

"(c) ELIGIBILITY FOR GRANTS.—

"(1) IN GENERAL.—No grant shall be made by the Secretary under subsection (a) unless an application has been submitted to, and approved by, the Secretary. Such application shall be in such form, submitted in such a manner, and be accompanied by such information, as the Secretary may specify. No such application may be approved unless it contains assurances that the applicant will use the funds provided only for the purposes specified in the approved application and in accordance with the requirements of this section, that the application will establish such fiscal control and fund accounting procedures as may be necessary to assure proper disbursement and accounting of Federal funds paid to the applicant under subsection (a) of this

section, and that the applicant will comply with the peer review requirements under sections 491 and 492.

"(2) ASSURANCES.—Each applicant, prior to receiving Federal funds under subsection (a), shall provide assurances satisfactory to the Secretary that the applicant will—

"(A) provide for the establishment of a registry in accordance with subsection (a);

"(B) comply with appropriate standards of completeness, timeliness, and quality of population-based cancer registry data;

"(C) provide for the annual publication of reports of cancer data under subsection (a); and

"(D) provide for the authorization under State law of the statewide cancer registry, including promulgation of regulations providing—

"(i) a means to assure complete reporting of cancer cases (as described in subsection (a)) to the statewide cancer registry by hospitals or other facilities providing screening, diagnostic or therapeutic services to patients with respect to cancer;

"(ii) a means to assure the complete reporting of cancer cases (as defined in subsection (a)) to the statewide cancer registry by physicians, surgeons, and all other health care practitioners diagnosing or providing treatment for cancer patients, except for cases directly referred to or previously admitted to a hospital or other facility providing screening, diagnostic or therapeutic services to patients in that State and reported by those facilities;

"(iii) a means for the statewide cancer registry to access all records of physicians and surgeons, hospitals, outpatient clinics, nursing homes, and all other facilities, individuals, or agencies providing such services to patients which would identify cases of cancer or would establish characteristics of the cancer, treatment of the cancer, or medical status of any identified patient;

"(iv) for the reporting of cancer case data to the statewide cancer registry in such a format, with such data elements, and in accordance with such standards of quality timeliness and completeness, as may be established by the Secretary;

"(v) for the protection of the confidentiality of all cancer case data reported to the statewide cancer registry, including a prohibition on disclosure to any person of information reported to the statewide cancer registry that identifies, or could lead to the identification of, an individual cancer patient, except for disclosure to other State cancer registries and local and State health officers;

"(vi) for a means by which confidential case data may in accordance with State law be disclosed to cancer researchers for the purposes of cancer prevention, control and research;

"(vii) for the authorization or the conduct, by the statewide cancer registry or other persons and organizations, of studies utilizing statewide cancer registry data,

including studies of the sources and causes of cancer, evaluations of the cost, quality, efficacy, and appropriateness of diagnostic, therapeutic, rehabilitative, and preventative services and programs relating to cancer, and any other clinical, epidemiological, or other cancer research; and

"(viii) for protection for individuals complying with the law, including provisions specifying that no person shall be held liable in any civil action with respect to a cancer case report provided to the statewide cancer registry, or with respect to access to cancer case information provided to the statewide cancer registry.

"(d) RELATIONSHIP TO CERTAIN PROGRAMS.—

"(1) IN GENERAL.—This section may not be construed to act as a replacement for or diminishment of the program carried out by the Director of the National Cancer Institute and designated by such Director as the Surveillance, Epidemiology, and End Results Program (SEER).

"(2) SUPPLANTING OF ACTIVITIES.—In areas where both such programs exist, the Secretary shall ensure that SEER support is not supplanted and that any additional activities are consistent with the guidelines provided for in subsection (c)(2) (C) and (D) and are appropriately coordinated with the existing SEER program.

"(3) TRANSFER OF RESPONSIBILITY.—The Secretary may not transfer administration responsibility for such SEER program from such Director.

"(4) COORDINATION.—To encourage the greatest possible efficiency and effectiveness of Federally supported efforts with respect to the activities described in this subsection, the Secretary shall take steps to assure the appropriate coordination of programs supported under this part with existing Federally supported cancer registry programs.

"(e) REQUIREMENT REGARDING CERTAIN STUDY ON BREAST CANCER.—In the case of a grant under subsection (a) to any State specified in section 399K(b), the Secretary may establish such conditions regarding the receipt of the grant as the Secretary determines are necessary to facilitate the collection of data for the study carried out under section 399C.

"SEC. 399I. PLANNING GRANTS REGARDING REGISTRIES. 42 USC 280e-1.

"(a) IN GENERAL.—

"(1) STATES.—The Secretary, acting through the Director of the Centers for Disease Control, may make grants to States for the purpose of developing plans that meet the assurances required by the Secretary under section 399B(c)(2).

"(2) OTHER ENTITIES.—For the purpose described in paragraph (1), the Secretary may make grants to public entities other than States and to nonprofit private entities. Such a grant may be made to an entity only if the State in which the purpose is to be carried out has certified that the State approves the entity as qualified to carry out the purpose.

"(b) APPLICATION.—The Secretary may make a grant under subsection (a) only if an application for the grant is submitted to the Secretary, the application contains the certification required in subsection (a)(2) (if the application is for a grant under such subsec-

tion), and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

42 USC 280e–2.

"SEC. 399J. TECHNICAL ASSISTANCE IN OPERATIONS OF STATEWIDE CANCER REGISTRIES.

"The Secretary, acting through the Director of the Centers for Disease Control, may, directly or through grants and contracts, or both, provide technical assistance to the States in the establishment and operation of statewide registries, including assistance in the development of model legislation for statewide cancer registries and assistance in establishing a computerized reporting and data processing system.

42 USC 280e–3.

"SEC. 399K. STUDY IN CERTAIN STATES TO DETERMINE THE FACTORS CONTRIBUTING TO THE ELEVATED BREAST CANCER MORTALITY RATES.

"(a) IN GENERAL.—Subject to subsections (c) and (d), the Secretary, acting through the Director of the National Cancer Institute, shall conduct a study for the purpose of determining the factors contributing to the fact that breast cancer mortality rates in the States specified in subsection (b) are elevated compared to rates in other States.

"(b) RELEVANT STATES.—The States referred to in subsection (a) are Connecticut, Delaware, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, Vermont, and the District of Columbia.

"(c) COOPERATION OF STATE.—The Secretary may conduct the study required in subsection (a) in a State only if the State agrees to cooperate with the Secretary in the conduct of the study, including providing information from any registry operated by the State pursuant to section 399H(a).

"(d) PLANNING, COMMENCEMENT, AND DURATION.—The Secretary shall, during each of the fiscal years 1993 and 1994, develop a plan for conducting the study required in subsection (a). The study shall be initiated by the Secretary not later than fiscal year 1994, and the collection of data under the study may continue through fiscal year 1998.

"(e) REPORT.—Not later than September 30, 1999, the Secretary shall complete the study required in subsection (a) and submit to the Committee on Energy and Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the findings and recommendations made as a result of the study.

42 USC 280e–4.

"SEC. 399L. AUTHORIZATION OF APPROPRIATIONS.

"(a) REGISTRIES.—For the purpose of carrying out this part, the Secretary may use $30,000,000 for each of the fiscal years 1993 through 1997. Out of any amounts used for any such fiscal year, the Secretary may obligate not more than 25 percent for carrying out section 399I, and not more than 10 percent may be expended for assessing the accuracy, completeness and quality of data collected, and not more than 10 percent of which is to be expended under subsection 399J.

"(b) BREAST CANCER STUDY.—Of the amounts appropriated for the National Cancer Institute under subpart 1 of part C of title IV for any fiscal year in which the study required in section 399K is being carried out, the Secretary shall expend not less than $1,000,000 for the study.".

Approved October 24, 1992.

Authorization extended through 1998.

State Registry Caseload Per Staff (sorted by descending ratio)

Registry	Annual Est. Caseload	Staff (FTE)	Ratio = caseload/staff
California*	138,000	13.49	10230
Florida	150000	22	6818
Washington*	35000	7	5000
Michigan	59000	14	4214
Wisconsin	**26000**	**6.4**	**4063**
Pennsylvania	78000	20.25	3852
Indiana	28883	8	3610
Ohio	56000	22	2545
Massachusetts	55000	21.9	2511
Illinois	62000	25	2480
Virginia	32696	13.5	2422
Georgia	36000	17.25	2087
Oregon	20500	10	2050
Nebraska	9000	5	1800
Tennesee	35000	19.5	1795
New York	96000	54.2	1771
Alabama	**23000**	**13**	**1769**
Missouri	**28000**	**16.75**	**1672**
Texas	92,753	56	1656
South Dakota	4000	2.5	1600
Arizona	**23000**	**14.75**	**1559**
Colorado	19700	13	1515
Idaho	6200	4.5	1378
Maine	8500	6.5	1308
Oklahoma	17500	13.5	1296
North Carolina	35000	27.5	1273
Rhode Island	6500	5.25	1238
New Hampshire	7221	6	1204
Montana	5000	4.5	1111
Kansas	13000	12	1083
Arkansas	14026	15	935
Delaware	4500	5	900
Kentucky	22500	25	900
Minnesota	**24000**	**28**	**857**
North Dakota	3200	3.8	842
Vermont	3300	4	825
Louisiana	22158	43	515
Alaska	2100	4.5	467
Wyoming	2688	7	384
Wash DC	3000	9	333
Mean Ratio			2111
Median Ratio			1580

Note: Iowa (SEER)-50 staff

Source: State Profiles provided at CDC NPCR Program Manager's Meeting, March 2006, Atlanta, GA

Note: Staff includes all full-time, part-time, state, federal and contract employees listed in profiles

Note: part-time listings were estimated at .5 FTE for these calculations

* only NPCR-funded staff listed in report. Data on additional state or SEER-funded staff not available

Profiles were not provided for the following states: Connecticut, Hawaii, Iowa, Maryland, Mississippi, Nevada, New Jersey, South Carolina, Utah, and West Virginia


FORWARD

State of Wisconsin
Department of Health and Family Services

Jim Doyle, Governor
Kevin R. Hayden, Secretary

February 7, 2008

TO: Senate Committee on Public Health, Senior Issues, Long Term Care and Privacy
FROM: Katie Plona, DHFS legislative liaison
RE: Senate Bill 415

Good afternoon. I'm Katie Plona, legislative liaison for the Department of Health and Family Services. With me today is Laura Stephenson, who is the Program Director for the Wisconsin Cancer Reporting System in the Division of Public Health. Senator Carpenter and committee members, thank you for the opportunity to testify in favor of Senate Bill 415.

I would like to use my time before the committee to provide some background about the cancer registry at DHFS.

The Wisconsin Cancer Reporting System, established in 1976 by the Legislature, is Wisconsin's only statewide cancer registry. It has 7.9 FTE/LTE/contract positions that are 75-percent funded through a federal cancer grant and 25-percent funded by GPR to meet the federal grant's requirement for state "maintenance of effort" and matching funds. The program has been serving the state of Wisconsin in a number of valuable ways for more than 30 years:

- We have provided aggregate data on the burden of cancer in Wisconsin through its annual report and other specifically focused reports and studies;
- Provided de-identified datasets to researchers in Wisconsin and around the country for more in-depth research;
- Provided confidential information for approved research, as allowed by the current Wisconsin statute;
- Provided aggregate data to include in national and international publications.

Currently, identifiable data from the cancer registry is not available outside of DHFS with two exceptions: to a nationally recognized tumor registry, which is the National Program of Cancer Registries within the Centers of Disease Control and Prevention or to another state central cancer registry. Our registry would contain information about patients who are residents of another state if they have had their cancer diagnosis in Wisconsin.

The restriction on data release was a standard precaution in the 1970s and 1980s when our system started. But, it has proven to be increasingly insufficient to meet the needs of qualified cancer researchers in Wisconsin and around the country. The cancer research arena has broadened in the last decade, but Wisconsin's cancer laws have not been updated to meet those needs.

In 1992, the U.S. Congress passed Public Law 102-515, allowing for the creation of a National Program of Cancer Registries. The main purpose of this law was to establish central cancer registries in states that did not have one and to improve and enhance cancer registries that were already in existence, such as Wisconsin's registry. In the area of cancer data release, the Public Law, under criterion VI, requests that state registries have "a means by which confidential case data may in accordance with State law be disclosed to cancer researchers for the purposes of cancer prevention, control and research."

Many states established cancer registries through this law, and when doing so, wrote statutes that allowed access to confidential cancer data for qualified researchers following the guidelines in the federal law. SB 415 allows for increased release while still protecting the confidentiality of the data as defined in other parts of the current state statue.

We have worked closely with the bill's authors, key research institutions and organizations in Wisconsin to develop the specific provisions and definitions used in SB 415. We greatly appreciate how receptive they have been to work with the Department.

We support this legislation because it will increase opportunities for important research. Additionally, there are key provisions in the bill that I would like to highlight:

1. SB 415 authorizes 1.0 FTE in the registry to conduct the work needed to meet the increased demands for data this legislation will generate. Currently, the Wisconsin registry is the fourth lowest staffed registry in the country. The Wisconsin staff's current focus is to meet the national requirements for data completeness, timeliness and quality. Allowing increased access to data for research without providing the necessary staff to complete the requests would put an undue burden on current staff and the completeness, quality and timeliness of data requests would suffer.

   This GPR-funded position will also improve the registry's ability to meet the CDC grant's maintenance of effort requirement that I mentioned earlier and the additional required match component. The requirement is one dollar of non-federal funding for every three dollars of federal funding. In addition, the proposed annual $90,000 allocated to this position will allow the registry, based on the 3:1 match calculations, to annually request three times that amount, $27,000, in additional federal funding in future grant applications. Unfortunately, additional federal funding is limited and not a guarantee. Still, this legislation creates the potential for Wisconsin to receive more federal funds.

2. SB 415 defines "research" and "researcher" in a way that meets federal standards for these definitions.

3. SB 415 includes specific requirements for materials to be provided to the Department when requesting data that inform the Department about the nature of the research request, the protections for the data and the researcher's qualifications.

4. It creates civil and criminal penalties for misuse of the data.

5. It includes language that follows the federal Public Law 102-515 criterion for release of confidential data to researchers by limiting release only for the purpose of studying cancer, cancer prevention or control.

6. It does not alter any other part of the statute that discusses confidentiality of data.

7. It includes language protecting the data from open records requirements.

Thank you again for the opportunity to testify regarding SB 415. Laura and I are available to answer any questions you may have about the cancer registry or the Department's position on the bill.


FORWARD

Testimony of State Representative Steve Wieckert

Senate Bill 415 – Cancer Registry

Senate Committee on Public Health, Senior Issues, Long Term Care and Privacy
Room 330 Southwest – February 7, 2008

Thank you Mr. Chairman and members of the committee for holding a hearing on this important subject.

In so many ways, cancer is public enemy number one for our citizens' health and many times our citizens' survival.

This bill would promote and encourage the advancement of cancer research by allowing researchers greater access to more specific information on the existing cancer registry in Wisconsin which is officially referred to as the Wisconsin Cancer Reporting System.

Especially in three general areas regarding the background of the patient where they were living, their age, etc. as well as the type of cancer they have and the stage that it is in and third the type of treatment that is being administered is all valuable in understanding the causes and the effectiveness of cures of cancer.

This bill has adequate safeguards to make sure this information is used appropriately and will allow cancer researchers more information and research data needed in the fight to find ways to cure and prevent cancer. This bill has a broad coalition of democrats and republicans from both houses. I thank Sen. Sullivan and Rep. Schilling for doing the research necessary to put this bill together in such an efficient way.

I would be happy to answer any questions.


FORWARD

University of Wisconsin
Paul P. Carbone
Comprehensive Cancer Center

University of Wisconsin
School of Medicine and Public Health

To: Senate Committee on Public Health, Senior Issues, Long Term Care and Privacy

From: Amy Trentham-Dietz, PhD

Subject: Senate Bill 415

Date: February 7, 2008

Hello. My name is Amy Trentham-Dietz. I am an associate professor in Population Health Sciences at the University of Wisconsin-Madison and a Member of the Paul P. Carbone Comprehensive Cancer Center.

There are a few points I would like to bring to your attention today in support of Senate Bill 415, also called the Cancer Research Advancement Act.

I would like to first testify in support of the tremendous value of the Wisconsin Cancer Reporting System. This population registry is the only way we have to monitor the burden of cancer in the state. Trends in the Wisconsin data tend to mirror the ones observed in national data. This is reassuring because this shows that our data are not limited by incomplete reporting that invalidates its use for research or surveillance. Our high-quality data allow us to monitor for unexpected increases or decreases in the numbers of cancer cases here at home. For example, we can assess how cancer rates are different according to geographic location within the state. Past studies have examined where women were most likely to be diagnosed with advanced-staged breast cancers within Wisconsin, showing us where screening mammography efforts should be targeted so that more women have their breast cancers diagnosed earlier to improve their chances for cure and long-term survival.

My second point is that I believe Wisconsin citizens are supportive of expanding cancer research. I have been doing cancer research at the University of Wisconsin, working closely with registry staff, for over a decade. I routinely feel grateful that I am conducting research in Wisconsin because of the tremendous support that cancer patients provide for cancer studies. We often achieve 70, 80, or even 90% participation rates in our studies because men and women around our state are committed to reducing the burden of cancer. High participation rates are critical so that we can be assured that our study groups are representative of the targeted patient groups and our studies are not biased because they are missing important subgroups of people. Our study participation rates are the envy of researchers in other states.

Lastly, I want to urge you to support the fiscal note. The staff members at the registry are deeply committed to fulfilling the registry's mandate. As I've already said, I've been interacting with registry staff for over a decade. As others have spoken today (or will speak today), registry staff are very busy with collecting data and providing data summaries to the Centers for Disease Control (the CDC) and the North American Association of Central Cancer Registries. The

Wisconsin registry is understaffed relative to other comparable sized states and even states with smaller populations. While data collection and data utilization are both important goals for the registry, providing datasets to researchers is necessarily the second step, with registry staff concentrating most of their efforts on data collection and consolidation. Last year I submitted 7 data requests to the registry corresponding to research studies supported by the National Cancer Institute, the CDC, the Susan G Komen for the Cure Breast Cancer Foundation, the Wisconsin Partnership Fund for a Healthy Future, and the Carbone Cancer Center. It has taken 3 months, 6 months, or even longer to receive the data for these requests. I want to emphasize that I believe the registry staff are committed to supporting research and would have provided these data to me sooner if they only had the time. It is essential that the fiscal note is included with this bill. In light of current delays in data requests, I am concerned that the registry will not have the capacity to handle an expansion in access to the cancer data for research purposes.

As we in Madison and Milwaukee and LaCrosse and elsewhere around the state expand our efforts to support public health, I hope that you will support both this bill and its associated fiscal note because Senate Bill 415 will translate to improvements in our ability to prevent, detect, and treat cancer all across Wisconsin.

Thank you for your attention.


FORWARD

1000 North Oak Avenue
Marshfield, WI 54449-5777
715-387-5511
Fax 715-387-5240

MARSHFIELD CLINIC®

February 7, 2008

Senate Committee on Public Health, Senior Issues, Long-Term Care and Privacy
Wisconsin State Capitol
Madison, WI 53707

Dear Chairman Carpenter and Members of the Senate Public Health Committee:

Please allow me to introduce myself, I am Dr. Humberto Vidaillet, a cardiologist specializing in electrical disorders of the heart and Director of Marshfield Clinic's Research Foundation, part of the Marshfield Clinic system. I am writing on behalf of the Marshfield Clinic system in **support** of ***Senate Bill 415-Cancer Research Advancement Act.***

To briefly tell you a bit about the Marshfield Clinic system:

- Marshfield Clinic is a 501(c) (3) not-for-profit health care system.
- Our mission is "to provide high-quality health care to all who access our system regardless of payer source; to engage in basic science and clinical research to improve patients' lives; and to train the next generation of physicians through undergraduate and graduate medical education."
- Marshfield Clinic is a physician-led, not owned, integrated outpatient health care system with a 20-county primary service area in North Central Wisconsin.
- We currently have 41, soon to be 47, clinics and facilities in this region, with almost 800 physicians and approximately 6,500 additional employees.
- We provide primary, secondary, and tertiary health care to **all** who access our system. In FY 2007, Marshfield Clinic saw approximately 365,800 unique patients.

An integral part of the Marshfield Clinic System is the Marshfield Clinic Research Foundation. Founded in 1959, the Research Foundation was initially involved in the diagnosis of agricultural related diseases. Currently there are 24 full-time PhD Scientists and 160 support staff involved in over 400 research studies funded by various Federal and State Agencies including the National Institute of Health, National Cancer Institute, and Centers for Disease Control.

Marshfield Clinic has approximately 30 medical, pediatric, surgical, and radiation oncology specialists on staff who actively participate in oncology clinical trials. Approximately 400 Marshfield Clinic system patients are enrolled annually in cancer clinical trials. Those 400 patients and other patients from other centers in the state and outside of the state are participating in over 100 clinical trials, which continue to seek patient inclusion.

For more than 30 years, Marshfield Clinic and Marshfield Clinic Research Foundation have participated in the Community Clinical Oncology Program sponsored by the National Cancer Institute. This initiative was founded to translate state of the art cancer research to community clinical practices in rapid times spreading high-quality cancer care throughout Wisconsin beyond our 2 major metropolitan areas.

SB 415, authored by Sen. Sullivan and Rep. Schilling, will allow researchers and clinicians involved in cancer care in Wisconsin to access with appropriate safeguards the Wisconsin Cancer Reporting System (WCRS). This data will allow researchers and clinicians in Wisconsin to track cancer clusters in parts of the state, to access incidence and prevalence data statewide of rare and common forms of cancer and to follow patients' response to therapy.

Having this kind of population-based cancer data available will help Wisconsin achieve part of its Healthy Wisconsin 2010 and beyond goals of reducing the incidence of cancer and deaths due to it.

SB 415 will make critical state based cancer statistics accessible to a larger cadre of cancer treatment specialists and researchers.

Marshfield Clinic urges you to support SB 415.

Sincerely,

Humberto Vidaillet, M.D.
Director of Marshfield Clinic Research Foundation

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FORWARD

Date?

To: Senator Tim Carpenter, Chair, and Senate Committee on Public Health, Senior Issues, Long Term Care, and Privacy
From: J. Frank Wilson, M.D., FACR, FASTRO
Re: Senate Bill 415

Senator Carpenter and Senate Colleagues:

I am writing to express support for Senate Bill 415. This bill, combined with the fiscal note attached, plays a critical role in supporting cancer research, prevention, and care in Wisconsin.

In 1976, the Wisconsin Cancer Reporting System was established to track all cancer cases diagnosed in the state of Wisconsin. Hospitals and physicians are required to report cases using a standardized method. In 2002, this meant that 26,180 cases were reported. This information, along with that from the rest of the nation, forms the reference base for cancer-related research, treatment advances, and prevention efforts. As the President of the National Cancer Registrars' Association, Dr. Healy of Memorial Sloan-Kettering said, "A network of cancer registries can be our most potent new weapon against cancer. Today, thousands of people are living as a result of the type of information we collect and analyze." This includes Wisconsin citizens, *your constituents*, of all ages, colors and creeds.

The Centers for Disease Control's stated goal in supporting Cancer Registries is "to prevent and control cancer and improve patient care." This is achieved "by providing evidence-based information to physicians that is used to assess the efficacy of varying diagnostic and therapeutic methods and options and to plan, review, and update standards of care." In other words, a complete, up-to-date, and accessible registry is essential for the citizens of our state to receive proven preventive services, the most effective screening measures, and optimal life-saving treatment. This bill would play a crucial role in protecting the health of Wisconsin citizens by allowing researchers access to the information in the registry while also maintaining the privacy of individuals. It also adds one FTE to the WCRS staff. This final component is absolutely critical for several reasons:

- The Wisconsin Cancer Reporting System staff have done and are doing an outstanding job and were recognized in 2004 by the CDC for their work; they are already working as efficiently as possible.
- Wisconsin's registry has the fifth highest caseload per staff among all states with over 4000 cases a year for each staff member being registered. This is twice the national average.
- Minnesota has slightly fewer cancer cases each year, but over four times the staff that Wisconsin does. Other states with comparable caseloads are Alabama with 1800 cases per staff member, Missouri with 1700, and Arizona with 1600.
- Understaffing will limit the ability of the registry to be maintained and used effectively in several ways:

- The current National Program of Cancer Registries funding cycle, which began last year, requires all states to employ more than one Certified Tumor Registrar (CTR). Wisconsin currently can not meet this standard, jeopardizing our federal funding;
- Reporting in Wisconsin varies between facilities because, unlike New York and other states, we do not require that every cancer case report be prepared by a CTR. This additional position would improve data quality and thereby improve research outcomes;
- WCRS staff provide assistance in training and electronic reporting and would be even more involved in monitoring and education with the measures contained in this bill. Current staff levels are simply insufficient to do all of this with the quality and timeliness that a necessary function of this magnitude merits.

The contents of this bill, including the addition of a staff member, are also consistent with the Wisconsin Comprehensive Cancer Control Plan. The addition of a staff member and the availability of data to researchers are critical in achieving several priorities identified in the Plan. Among the most important of these is improved collection of data on racial and ethnic minorities. African American, Latino, and Native American patients bear a disproportionate burden of cancer mortality. In particular, they are less likely to be alive five years after a cancer diagnosis. If we are serious about closing health disparities in the State of Wisconsin, we must support legislation such as this that gives researchers, public health officials, and administrators the tools they need to provide better care for minority populations.

Members of the committee, please support this bill, including the addition of one FTE to the WCRS staff. It is an investment in the health and future of the citizens of Wisconsin.

Sincerely,

J. Frank Wilson M.D.

J. Frank Wilson, M.D., FACR, FASTRO
Immediate Past Chairman, Wisconsin Cancer Council
Chairman and Bernard & Miriam Peck Professor of Radiation Oncology
Director Emeritus, Cancer Center
Medical College of Wisconsin


FORWARD

JIM SULLIVAN
STATE SENATOR

Date?

5TH SENATE DISTRICT

Wisconsin State Senate

Testimony of Senator Jim Sullivan
Senate Bill 415
Senate Committee on Public Health, Senior Issues, Long Term Care and Privacy

Good afternoon committee members, and thank you for your attention to SB 415, legislation that will help researchers study cancer and cancer prevention.

The Wisconsin Cancer Reporting System (WCRS) is a repository for all diagnoses of cancer and precancerous (tumors of the central nervous system) conditions in Wisconsin. It was established in 1976 by the Wisconsin Legislature, and continues to operate today under rules established over thirty years ago.

Senate Bill 415 will update Wisconsin law to allow the Wisconsin Cancer Reporting System to provide confidential data to qualified researchers for the purpose of cancer research, prevention and control. Currently the WCRS is only able to provide researchers that do not meet the current statutes access to de-identified data that is not always sufficient for their research. Sometime researchers need more specific data to complete and validate their research, and that is the purpose of SB 415. SB 415 will allow the WCRS to release confidential, patient-identifiable data to qualified researchers for the purpose of studying cancer or cancer prevention.

Numerous safeguards are built in to ensure the information is protected and only used for the purpose of studying cancer. These safeguards include a rigorous application process, approval by an institutional review board (IRB), and civil and criminal penalties for misuse of data.

Organizations from around the state have endorsed this legislation, including the American Cancer Society, Medical College of Wisconsin, Gunderson Lutheran Health System, University of Wisconsin School of Medicine and Public Health, Marshfield Clinic, Wisconsin Cancer Council, Wisconsin Medical Society, Wisconsin Collaborative for Healthcare Quality, St. Joseph's Hospital, Wisconsin Association of Health Plan, Lakeshore Medical Clinic, Medical Associates Health Center and more.

Medical research has been a source of great pride in Wisconsin, and this bill will help move research towards the ultimate goal: a cure. Wisconsin is one of only five states that does not currently release patient-identifiable data. We all want to find a cure for cancer, and it is time for Wisconsin to join other states and give our researchers the tools they need in order to do their work. I ask for your support of SB 415.

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