



## 2007 SENATE BILL 415

January 24, 2008 - Introduced by Senators SULLIVAN, KREITLOW, SCHULTZ, ROBSON, MILLER, COWLES, LEHMAN, KAPANKE, OLSEN, RISSER, ROESSLER, PLALE, HANSEN, LASSA, DARLING, TAYLOR and COGGS, cosponsored by Representatives SHILLING, WIECKERT, VRUWINK, SHERIDAN, MUSSER, RICHARDS, DAVIS, VAN AKKEREN, SUDER, HEBL, JESKEWITZ, BLACK, POPE-ROBERTS, MASON, MURTHA, GRIGSBY, HILGENBERG, YOUNG, SEIDEL, MOULTON, BENEDICT, BIES, TOWNSEND, BOYLE, PARISI, NEWCOMER, BERCEAU, MURSAU, SOLETSKI, A. OTT, A. WILLIAMS, FIELDS, GUNDERSON, NELSON, NERISON, SINICKI, GARTHWAITE, OWENS, HIXSON, WOOD, KAUFERT and WASSERMAN. Referred to Committee on Public Health, Senior Issues, Long Term Care and Privacy.

1     **AN ACT** *to amend* 146.82 (2) (a) 8.; and *to create* 20.435 (1) (ae), 255.01 (2m),  
2           255.01 (2n), 255.04 (3) (c), 255.04 (6), 255.04 (7), 255.04 (8), 255.04 (9) and  
3           255.04 (10) of the statutes; **relating to:** permitting a researcher, under certain  
4           conditions, access to cancer information reported to the Department of Health  
5           and Family Services, prohibiting certain other use or redisclosure of the  
6           information, creating civil liability for violation of the prohibitions, making an  
7           appropriation, and providing penalties.

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### *Analysis by the Legislative Reference Bureau*

Under current law, hospitals, physicians, and certain laboratories must report to the Department of Health and Family Services (DHFS) information concerning any person who is diagnosed as having cancer or a precancerous condition. Any information that DHFS receives under this requirement that could identify the person or a physician who submits the report is confidential as a patient health care record, except that DHFS may disclose the information to a central tumor registry in another state, if the person who is the subject of the information resides in the other state, or to a national tumor registry.

Beginning July 1, 2008, this bill permits DHFS to disclose otherwise confidential cancer report information to a researcher who requests it, by means of a written application to DHFS, for the purpose of studying cancer, cancer prevention,

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or cancer control or performing other cancer research. The application must include a written protocol for the proposed research, the researcher’s professional qualifications, documentation of approval of the research protocol by an institutional review board that meets certain requirements, and any information requested by DHFS. These conditions must be met before DHFS may approve the application and before DHFS may release the information. The bill authorizes DHFS to impose a reasonable fee on a researcher who obtains information. The fee must be commensurate with actual direct costs to DHFS and may be waived by DHFS. Cancer information obtained by DHFS or by a researcher is, under the bill, not subject to open records requirements. The bill specifically prohibits use of the information for a purpose other than for performance of research, disclosure of the information to a person who is not connected with performance of the research, and revealing in the final research product information that may identify a research subject, and creates penalties for violation and intentional violation of the prohibitions. Lastly, the bill creates civil liability to the research subject for any person who negligently or intentionally violates the prohibitions.

Because this bill creates a new crime or revises a penalty for an existing crime, the Joint Review Committee on Criminal Penalties may be requested to prepare a report concerning the proposed penalty and the costs or savings that are likely to result if the bill is enacted.

For further information see the *state* fiscal estimate, which will be printed as an appendix to this bill.

***The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:***

1           **SECTION 1.** 20.005 (3) (schedule) of the statutes: at the appropriate place, insert  
2           the following amounts for the purposes indicated:

				<b>2007-08</b>	<b>2008-09</b>
3					
4	<b>20.435</b>	<b>Health and family services, department</b>			
5		<b>of</b>			
6	(1)	PUBLIC HEALTH SERVICES PLANNING, REGULATION			
7		AND DELIVERY; STATE OPERATIONS			
8	(ae)	Cancer information	GPR     A	-0-	90,800

9           **SECTION 2.** 20.435 (1) (ae) of the statutes is created to read:

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1           20.435 (1) (ae) *Cancer information*. The amounts in the schedule for cancer  
2 information collecting, compiling, and disseminating under s. 255.04.

3           **SECTION 3.** 146.82 (2) (a) 8. of the statutes is amended to read:

4           146.82 (2) (a) 8. To the department under s. 255.04 and to the persons specified  
5 under s. 255.04 (3). The release of a patient health care record under this subdivision  
6 shall be limited to the information prescribed by the department under s. 255.04 (2).

7           **SECTION 4.** 255.01 (2m) of the statutes is created to read:

8           255.01 (2m) “Research” means a systematic investigation through scientific  
9 inquiry, including development, testing, and evaluation, that is designed to develop  
10 or contribute to generalizable knowledge.

11          **SECTION 5.** 255.01 (2n) of the statutes is created to read:

12          255.01 (2n) “Researcher” means a person who performs research.

13          **SECTION 6.** 255.04 (3) (c) of the statutes is created to read:

14          255.04 (3) (c) If all of the following conditions are met, a researcher who  
15 proposes to conduct research:

16           1. The researcher applies in writing to the department for approval of access  
17 to individually identifiable information under sub. (1) or (5) that is necessary for  
18 performance of the proposed research and the department approves the application.  
19 An application under this subdivision shall include all of the following:

20           a. A written protocol to perform research.

21           b. The researcher’s professional qualifications to perform the proposed  
22 research.

23           c. Documentation of approval of the research protocol by an institutional  
24 review board of a domestic institution that has a federalwide assurance issued by the

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1 office of human research protections of the federal department of health and human  
2 services.

3 d. Any other information requested by the department.

4 2. The proposed research is for the purpose of studying cancer, cancer  
5 prevention, or cancer control or performing other cancer research.

6 **SECTION 7.** 255.04 (6) of the statutes is created to read:

7 255.04 (6) The department may impose a reasonable fee on a researcher who,  
8 under sub. (3) (c), obtains information under sub. (1) or (5). The fee shall be  
9 commensurate with the actual direct costs to the department that are associated  
10 with collecting, compiling, and disseminating the information to the researcher and  
11 may be waived by the department.

12 **SECTION 8.** 255.04 (7) of the statutes is created to read:

13 255.04 (7) Information obtained by the department under sub. (1) or (5) or  
14 obtained by a person under sub. (3) (c) is not subject to inspection, copying, or receipt  
15 under s. 19.35 (1).

16 **SECTION 9.** 255.04 (8) of the statutes is created to read:

17 255.04 (8) No person to whom information is disclosed under sub. (3) (c) may  
18 do any of the following:

19 (a) Use the information for a purpose other than for the performance of  
20 research as specified in the application under sub. (3) (c) 1., as approved by the  
21 department.

22 (b) Disclose the information to a person who is not connected with performance  
23 of the research.

24 (c) Reveal in the final research product information that may identify an  
25 individual whose information is disclosed under sub. (3) (c).

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1           **SECTION 10.** 255.04 (9) of the statutes is created to read:

2           255.04 **(9)** Whoever violates sub. (8) (a), (b), or (c) is liable to the subject of the  
3 information for actual damages and costs, plus exemplary damages of up to \$1,000  
4 for a negligent violation and up to \$5,000 for an intentional violation.

5           **SECTION 11.** 255.04 (10) of the statutes is created to read:

6           255.04 **(10)** (a) Whoever intentionally violates sub. (8) (a), (b), or (c) may be  
7 fined not more than \$15,000 or imprisoned for not more than one year in the county  
8 jail or both.

9           (b) Any person who violates sub. (8) (a), (b), or (c) may be required to forfeit not  
10 more than \$100 for each violation. Each day of continued violation constitutes a  
11 separate offense, except that no day in the period between the date on which a  
12 request for a hearing is filed under s. 227.44 and the date of the conclusion of all  
13 administrative and judicial proceedings arising out of a decision under this  
14 paragraph constitutes a violation.

15           (c) The department may directly assess forfeitures under par. (b). If the  
16 department determines that a forfeiture should be assessed for a particular violation  
17 or for failure to correct the violation, the department shall send a notice of  
18 assessment to the alleged violator. The notice shall specify the alleged violation of  
19 the statute and the amount of the forfeiture assessed and shall inform the alleged  
20 violator of the right to contest the assessment under s. 227.44.

21           **SECTION 12. Nonstatutory provisions.**

22           (1) **CANCER INFORMATION.** The authorized FTE positions for the department of  
23 health and family services are increased by 1.0 GPR position on July 1, 2008, to be  
24 funded from the appropriation under section 20.435 (1) (ae) of the statutes, as

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1 created by this act, for the purpose of cancer information collecting, compiling, and  
2 disseminating.

3 **SECTION 13. Effective date.**

4 (1) This act takes effect on July 1, 2008.

5 (END)