

April 8, 2015

To the Honorable members of the  
Vermont Senate Health Committee  
Sen. Claire Ayer, Chair  
Sen. Virginia "Ginny" Lyons, Vice Chair  
Sen. Anthony Pollina  
Sen. Dick McCormack  
Sen. Brian Collamore, Clerk

RE: H. 98 - An act relating to reportable disease registries and data

Dear Honorable Senators,

The Vermont Coalition for Vaccine Choice (VCVC) is dedicated to the preservation of health choice and informed consent for parents and all Vermonters. Thank you for hearing our concerns this morning.

We strongly believe that immunization registry data should be collected with written permission. However, Vermont's immunization registry as proposed, unlike other states, is mandatory and does not require permission from the health care consumer.

We oppose H98 due to the inconsistency and inequities across registries, and because there are insufficient privacy protections built into the immunization registry (section 3). While it may be thought that HIPAA will protect the private health information collected in the registries, according to the North American Association of Central Cancer Registries (NAACCR), public health reporting under the authority of state law is specifically exempted from HIPAA rules. Further, the Privacy Rule applies to disclosure of protected health information by "covered entities" as required by law; but state cancer registries are not covered entities. The NAACCR reports that typically state cancer registry authorizing legislation includes strict limits on use and disclosure of reported information.<sup>1</sup> Therefore it is imperative that all the proposed registries contain appropriately rigorous limits on the privacy, use and disclosure of reported information.

We would like to ask that this bill be amended for uniformity. For example, in the case of willful, malicious or negligent disclosure of immunization status, resulting in economic, bodily or psychological harm, we respectfully request equal penalties, the private right of action and misdemeanor crimes identical to those currently written only into the HIV-AIDS portion of the bill (subdivisions 1-4 of subsection (3) in Section 2 of the bill).

Regardless of your position on whether or not government recommended immunizations should be mandatory, we hope that you will agree that all health care consumers, regardless of infection (HIV), disease (cancer) or treatment (vaccination) status, deserve equal and respectful considerations under the law.

Thank you for your time and consideration.

Respectfully submitted,

Jennifer R. Stella, VT Coalition for Vaccine Choice, (802) 917 3230

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<sup>1</sup> <http://www.naacr.org/LinkClick.aspx?fileticket=y98X2meiX64%3D&tabid=120&mid=460>

Please note the attachments and further references:

1) Attachment:

The Vermont Medical Society excerpted information about Vermont's laws regarding medical records stating, "Under Vermont law, there is no general penalty or cause of action for wrongful release of confidential medical information."

2) The nuance: the private health information is covered under either FERPA or HIPAA, but once in the registry is covered by neither, necessitating clear and equitable protections under state law.

Privacy protection under FERPA (protects school records) (<https://www.nacweb.org/public/ferpa0808.htm>) and HIPAA (protects consumer information in the hands of provider and covered entities), but exceptions include Public Health and "covered entity" rules:

<http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/publichealth/index.html>

[http://www.hhs.gov/ocr/privacy/hipaa/faq/preemption\\_of\\_state\\_law/399.html](http://www.hhs.gov/ocr/privacy/hipaa/faq/preemption_of_state_law/399.html)

[http://www.hhs.gov/ocr/privacy/hipaa/faq/covered\\_entities/358.html](http://www.hhs.gov/ocr/privacy/hipaa/faq/covered_entities/358.html)

3) NAACCR Registry FAQ:

<http://www.naacr.org/LinkClick.aspx?fileticket=y98X2meiX64%3D&tabid=120&mid=460>

**Vermont Medical Society: <http://www.vtmd.org/consent-privacy-and-medical-records>**

Emphasis in bold by J. Stella, VCVC

**What liability or penalties could be imposed on a provider who wrongfully discloses the medical information of a Vermont patient?**

Under the HIPAA privacy rules and the HITECH Act, a civil penalty may be imposed by the U.S. Department of Health and Human Services Office of Civil Rights (OCR) ranging from \$100 to a maximum of \$1,500,000. The Vermont Attorney General's office, along with all states attorney generals, is authorized to enforce the HIPAA privacy regulations through injunction or civil penalties ranging from \$100 up to a maximum of \$25,000. Criminal penalties for certain egregious wrongful disclosures may be pursued by the U.S. Department of Justice as well.

**Under Vermont law, there is no general penalty or cause of action for the wrongful release of confidential medical information.** However, there is a statutory provision which imposes either a \$500 fine or up to one year of imprisonment for the wrongful disclosure of information related to hospitalization for mental illness. [18 V.S.A. §7103(c)]

**Although in other states a person harmed by a wrongful disclosure of medical information may have a cause of action for invasion of privacy, defamation or breach of contract or fiduciary trust, Vermont has no statutory law or reported case law which establishes a clear right or cause of action to the individual.**

**What enforcement authority does the Department of Health have?**

The Vermont Department of Health works collaboratively with health care practitioners and facilities in public/private partnerships to educate practitioners and to make them aware of reporting requirements, and to resolve obstacles to implementation of public health requirements. However, the Department also has significant enforcement authority.

There are a number of specific enforcement provisions related to reporting requirements. For example, a fine of up to \$500.00 may be imposed on anyone failing to comply with the fetal death reporting requirements.

Similarly, there are also enforcement provisions and authorizations to seek civil penalties related to willful, malicious and negligent disclosure of confidential communicable disease information. Negligent disclosures not authorized by law may be subject to a civil penalty of up to \$2500. Penalties range from \$10,000 to \$25,000 for willful and malicious disclosure.

For further information about these enforcement provisions practitioners can refer to the specific public health laws. See, 18 V.S.A. §§ 130, 131 (general), §1001 (communicable disease disclosure), §1918 (patient safety reports), §5225 (fetal death); and 26 V.S.A. §1317(e) (unprofessional conduct reports).



## NORTH AMERICAN ASSOCIATION OF CENTRAL CANCER REGISTRIES

# FREQUENTLY ASKED QUESTIONS AND ANSWERS ABOUT CANCER REPORTING AND THE HIPAA PRIVACY RULE

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## 1. What is the HIPAA Privacy Rule?

In 1996 the U.S. Congress passed a law requiring, among other things, uniform federal privacy protections for individually identifiable health information. This law is called the Health Insurance Portability and Accountability Act of 1996, or "HIPAA." The U.S. Department of Health and Human Services recently issued final regulations implementing the privacy provisions of HIPAA. These regulations are called the "Privacy Rule." Copies of the HIPAA Privacy Rule, as well as helpful explanatory materials, may be found at the HHS Office of Civil Rights website: <http://www.hhs.gov/ocr/hipaa/>.

## 2. What is a 'Public Health Authority' under HIPAA?

Under HIPAA, a 'Public Health Authority' refers to "an agency or authority of the United States, a State or territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate."<sup>1</sup> "...Such agencies are authorized by law to collect or receive such information for the purposes of preventing or controlling disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions."<sup>2</sup> Central cancer registries are considered public health authorities because state laws mandate their duties.

<sup>1</sup> 45 CFR 164.501

<sup>2</sup> 45 CFR 164.512

## 3. What is a 'Covered Entity' under HIPAA?

A 'Covered Entity' is a health care plan, a healthcare clearinghouse, or a health care provider who transmits any health information in electronic form for financial and administrative transactions. A 'health care provider' is "a provider of medical or health services, and any other person who furnishes, bills or is paid for health care in the normal course of business."<sup>1</sup>

<sup>1</sup> 45 CFR 160.103

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## NORTH AMERICAN ASSOCIATION OF CENTRAL CANCER REGISTRIES

### **4. Is it a violation of HIPAA for a covered entity to report information about cases of cancer to the state cancer registry?**

No. Reporting information about cases of cancer in accordance with the requirements of state authorizing statutes and regulations is permitted by HIPAA. The Privacy Rule contains a specific provision authorizing covered entities to disclose protected health information as required by law.<sup>1</sup> In fact, penalties for failure to comply with state reporting are specified in state law and often consist of significant fines.

<sup>1</sup>45 CFR 164.512(a)(1)

### **5. Since HIPAA is federal, will it override the state laws?**

No. HIPAA does not obstruct any state law that supports or mandates the reporting of diseases or injury for public health purposes.

### **6. Is there specific legal documentation that supports the requirement to release cancer patient information to any agency?**

Individual state laws and regulations document cancer reporting requirements. Central registries should consult their state laws and regulations regarding release of cancer patient information.

### **7. What, if any, are the consequences of not cooperating with state cancer registry requests for new cancer case information?**

HIPAA does not obstruct any state law that supports or mandates the reporting of diseases or injury for public health purposes. Penalties for failing to comply with state reporting are specified in the state law and often consist of significant fines.

### **8. Does HIPAA require covered entities to obtain written authorization from the individual before reporting protected health information to the state cancer registry?**

No. The provision of the Privacy Rule authorizing disclosure of protected health information as required by law is an exception to the requirement for written authorization.<sup>1</sup>

<sup>1</sup>45 CFR 164.512(a)(1)

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## NORTH AMERICAN ASSOCIATION OF CENTRAL CANCER REGISTRIES

### 9. How does HIPAA impact the data collection of non-reportable/benign diseases (i.e. benign brain, CIN III, Co-morbid conditions)?

HIPAA does not obstruct any state law that supports or mandates the reporting of any disease.

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### 10. Are private practice physicians still required to report new cancer cases?

Yes, in compliance with state reporting regulations. The central cancer registry has a reportable list that identifies which cancers are reportable, and all reportable cancers should be reported, as required by state law.

### 11. Will private practice physicians and hospitals be permitted to continue to provide follow-up and treatment information to hospital cancer registries without patient authorization?

Yes. Although private practice physicians and hospitals are health providers, and thus covered under the provisions of the HIPAA privacy regulations,<sup>1</sup> they may continue to provide cancer patient follow-up and treatment information to hospital cancer registries without patient authorization when both the physician and the hospital has or had a relationship with the patient.

Under the HIPAA Final Privacy Rule, private practice physicians and hospitals may disclose confidential patient information to hospitals for the purpose of treatment, payment and **health care operations** (emphasis added) (quality assessment/improvement is considered a health care operation). A business associate agreement is not required between a hospital and physician for such purposes (emphasis added).

#### **Section 164.506(c)(4), states, in relevant part, that**

"A Covered Entity may disclose protected health information to another covered entity for health care operations activities of the entity that receives the information, if each entity either has or had a relationship with the individual who is the subject of the protected health information being requested, the protected health information pertains to such relationship, and the disclosure is:

(i) For a purpose listed in paragraph (1) or (2) of the definition of health care operations Section 164.501 of the Privacy Rule defines health care operations and Paragraph (1) of the definition provides, in relevant part:

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(1) Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, **population-based activities related to improving health** (emphasis added) or reducing health care costs, protocol development, case management and case coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment.

Paragraph (2) of the definition provides, in relevant part:

(2) Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing, or credentialing activities.

Thus, as hospital cancer registries collect treatment and follow-up data in compliance with state law and for the purpose of “population-based activities related to improving health” this is a permitted disclosure without requirement of patient authorization. It may also be noted that many hospital cancer registries collect this information for “conducting quality assessment and improvement activities”, for “reviewing the competence or qualifications of health care professionals”, for “conducting training programs” and for “accreditation, certification, licensing, or credentialing activities”. All of these are specifically permitted in paragraphs (1) and (2) shown above.

Note that Section 164.506(c)(4) specifically provides for the ability of one covered entity to provide an individual's PHI to another covered entity, if the receiving covered entity “has or had” a relationship with the individual. This specific reference to the past tense is important since it means that a covered entity's ability to obtain information about a patient need not be “cut-off” if the patient no longer has a direct relationship with the covered entity.

While exchange of treatment and follow-up information is permitted without patient authorization under the provisions described above, an accounting of disclosure must still be maintained.

<sup>1</sup>45 CFR 160.103

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### **12. What if a patient does not want follow-up information to be collected?**

State-mandated cancer reporting typically does not require patient informed consent nor can individuals elect to be removed from reporting. In a state which allows the collection of follow-up cancer data for public health purposes, it can be collected regardless of consent from a patient.

### **13. Once HIPAA is in place, will pathology labs be able to continue to send new cancer case information to the state cancer registry?**

Yes. Public health reporting under the authority of state law is specifically exempted from HIPAA rules

### **14. If the government-authorized public health entity is not located in the same state as the covered entity, is it still ok under HIPAA to provide the data?**

Yes, it is not prohibited. In fact, the definition of a 'public health entity' was broadened in the section "Uses and Disclosures for Public Health Activities", which states specifically "...We broaden the scope of allowable disclosures ...by allowing covered entities to disclose protected health information not only to U.S. public health authorities but also, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority."<sup>1,2</sup>

<sup>1</sup> FR p. 82525

<sup>2</sup> 45 CFR 164.512

### **15. Are covered entities required to determine whether the information about cases of cancer reported to the state cancer registry is the "minimum necessary" information required to be disclosed?**

No. The Privacy Rule does include a general requirement that covered entities make reasonable efforts to limit the disclosure of protected health information to the minimum necessary to accomplish the intended purpose of the disclosure.<sup>1</sup> However, there is a specific exception to this requirement for disclosures that are required by law, such as the reporting of information about cases of cancer to the state cancer registry pursuant to state law and regulations.<sup>2</sup>

<sup>1</sup> 45 CFR 164.502(b)(1)

<sup>2</sup> 45 CFR 164.502(b)(2)(v)

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## NORTH AMERICAN ASSOCIATION OF CENTRAL CANCER REGISTRIES

### 16. What information is required for a covered entity to meet the Privacy Rule's verification requirements with respect to reporting information about cases of cancer to the state cancer registry?

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The Privacy Rule requires covered entities to verify a requester's identity before disclosing protected health information.<sup>1</sup> In the case of disclosure to a person acting on behalf of a public official, a covered entity that reasonably relies on a written statement on appropriate government letterhead that the requester is acting under the government's authority will fulfill this requirement.<sup>2</sup> The Privacy Rule also requires covered entities to verify the requester's authority.<sup>3</sup> A covered entity that reasonably relies on a written statement of the legal authority under which the information is requested will fulfill this requirement.<sup>4</sup> To assist covered entities in meeting the verification requirements, the state cancer registry may elect to provide a written statement to cancer reporting facilities with the aforementioned information.

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<sup>1</sup>45 CFR 164.514(h)(1)(i)

<sup>2</sup>45 CFR 164.514(h)(2)(ii)(C)

<sup>3</sup>45 CFR 164.514(h)(1)(i)

<sup>4</sup>45 CFR 164.514(h)(2)(iii)(A)

### 17. Are covered entities required to sign "business associate agreements" with regional or state cancer registries that perform on-site abstracting and cancer data reporting?

HIPAA requires business associate agreements with entities that carry out health care functions on behalf of covered entities, but state and regional registries are acting on behalf of the state when they provide on-site abstracting and reporting services, not the covered entity. Therefore, they are not business associates.

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### 18. Does HIPAA apply to the use or disclosure of information about cancer cases after it has been reported to the state cancer registry?

No. The Privacy Rule applies to disclosure of protected health information by covered entities as required by law; state cancer registries are not covered entities. However, state cancer registry authorizing legislation typically includes strict limits on use and disclosure of reported information.

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## NORTH AMERICAN ASSOCIATION OF CENTRAL CANCER REGISTRIES

### 19. Are covered entities required to provide individuals upon request with an accounting of any protected health information that the entity has disclosed about them to the state cancer registry?

Yes. The Privacy Rule requires covered entities to provide an accounting of disclosures of protected health information.<sup>1</sup> The accounting must include for each disclosure:

- The date of the disclosure
- The name of the entity or person who received the protected health information and, if known, the address of such entity or person
- A brief description of the protected health information disclosed
- A brief statement of the purpose of the disclosure that reasonably informs the individual of the basis for the disclosure or, in lieu of such statement, a copy of a written request for a disclosure under §164.502(a)(2)(ii) or 164.512, if any.<sup>1</sup>

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<sup>1</sup>45 CFR 164.528

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