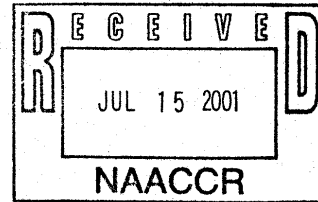




GEORGETOWN UNIVERSITY LAW CENTER



July 13, 2001

Holly L. Howe, PhD  
Executive Director  
North American Association of Central Cancer Registries  
2121 West White Oaks Dr, Suite C  
Springfield, Illinois 62704

Re: *Disclosure of Protected Health Information to Cancer Registries Under Federal Health Information Privacy Protections Pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA)*

Dear Dr. Howe:

Thank you for this opportunity to address on behalf of the North American Association of Central Cancer Registries (NAACCR) a prevailing, legal issue that has arisen pursuant to the new federal health information privacy standards developed by the Department of Health and Human Services (DHHS) with Congressional authorization under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

This issue may be succinctly stated as follows: *Do the new federal health information privacy regulations limit the disclosure of individually-identifiable health information (namely cancer data) by medical providers and others to cancer registries for public health uses?* For the reasons set forth below, I conclude that the HIPAA privacy regulations do not substantially limit these disclosures unless the recipient cancer registry is not a *public health authority* (as defined below). In fact, the HIPAA privacy regulations encourage and support the disclosure of individually-identifiable cancer data without specific, informed consent for public health purposes.

After Congress failed to meet a self-imposed deadline under HIPAA to enact a relevant privacy statute, DHHS assumed authority under the Act to develop regulations to protect the privacy of individually-identifiable health information. The regulations were finally approved by

President Bush on April 12, 2001.<sup>1</sup> The official, effective date of the regulations is April 14, 2001. Covered entities (discussed below) have two (2) years to fully comply (or by April 14, 2003), except for small health plans, who have until April 14, 2004 to comply.<sup>2</sup>

The HIPAA privacy regulations set forth privacy rules for the acquisition, use, storage, and disclosure of individually-identifiable health information (a.k.a. “*protected health information*”) in paper or electronic form. Protected health information includes individually-identifiable information relating to cancer diagnoses, tests, and treatments. If health information is non-identifiable (*i.e.*, it cannot be identified to any individual), it is not covered by the HIPAA privacy regulations principally because the use and exchange of such data raises little or no individual privacy concerns.

The regulations govern the acts of *covered entities*. Covered entities include health care providers (e.g. hospitals, physicians, laboratories)<sup>3</sup> who transmit any health information in electronic form pursuant to certain financial and administrative transactions.<sup>4</sup> Most hospitals and physicians typically rely on some form of electronic billing or information exchange, and thus fall under the requirements of the Act.

Concerning disclosures, the HIPAA privacy regulations set forth a standard rule: protected health information shall not be disclosed without the written, informed consent of the individual who is the subject of the information. However, DHHS recognizes several exceptions to this general rule to allow disclosures for various communal goods, including disclosures made for public health purposes.

The “public health” exemption states that a covered entity may disclose protected health information without specific, individual informed consent to a “*public health authority* that is authorized by law to collect and receive such information for the purpose of preventing and controlling disease, injury, or disability, including . . . reporting of disease . . . and the conduct of public health surveillance . . . .”<sup>5</sup> Provided that a cancer registry fits the definition of a *public health authority*, the registries’ acquisition of identifiable cancer data for surveillance or other

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<sup>1</sup> *Statement by DHHS Secretary Tommy G. Thompson Regarding the Patient Privacy Rule*. April 12, 2001.

<sup>2</sup> 66 Fed. Reg. 12434 (Feb. 26, 2001).

<sup>3</sup> 45 C.F.R. § 160.103 (defining *health care provider* in reference to two other acts as well as to include “any person or organization who furnishes, bills, or is paid for health care in the normal course of business”).

<sup>4</sup> 45 C.F.R. § 164.104.

<sup>5</sup> 45 C.F.R. § 164.512(b)(1)(i) (2001).

legitimate public health purposes is protected under the exemption, and thus does not require individual informed consent.

A *public health authority* is defined as an:

agency or authority of the United States, a State, a 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 . . . that is responsible for public health matters as part of its official mandate.<sup>6</sup>

This definition clearly applies to central or regional cancer or tumor registries operated by a state or local department of health, or as a freestanding, state-supported agency. A public health authority also includes some private sector entities that perform public health functions (like cancer surveillance) pursuant to a grant of authority or contract with a governmental public health agency.

*Since most cancer or tumor registries would be considered public health authorities, covered entities under HIPAA may disclose protected health information to these registries without the individual informed consent of each patient pursuant to the "public health" exemption to HIPAA general disclosure rule.*

However, any non-governmental entity that performs services similar to government-supported cancer registries, but is not acting under a grant of authority from or does not contract with a public agency, would likely not come under the exemption.<sup>7</sup> This entity must follow the regulation's requirements relating to patient consent, authorization, and opportunity to object or agree before disclosure by a covered entity is permitted.

This conclusion is affirmed by the pre-emption provisions in the HIPAA privacy regulations. The privacy regulations expressly do not pre-empt (or override) state law that "provides for the reporting of disease or injury . . . or for the conduct of public health surveillance [or] investigation . . ." <sup>8</sup> Thus, state law that permits covered entities to disclose identifiable information to cancer registries without individual informed consent remains intact. This further supports a cancer registry's ability to collect protected health information without the patient's informed consent where state law allows the registry to do so.

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<sup>6</sup> 45 C.F.R. § 164.501 (2001).

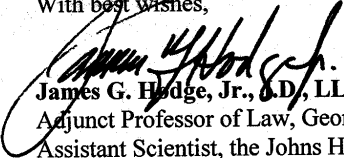
<sup>7</sup> See DHHS, *Section 164.512(b) -- Uses and Disclosures for Public Health Activities*, in *Section-by-Section Discussion of Comments, Preamble Part III of Standards of Privacy of Individually Identifiable Information* (June 28, 2001) <<http://aspe.hhs.gov/admsimp/final/PvcPre03.htm>> (responding to the first comment listed).

<sup>8</sup> 45 C.F.R. § 160.203 (2001).

While HIPAA does not limit disclosures of protected health information to cancer registries, the Act requires covered entities to log these and many other disclosures.<sup>9</sup> This minimal requirement preserves the individual's right to review an accounting of disclosures of their health information over a certain period of time (generally six years).

I hope that this opinion letter clarifies the effect of the new HIPAA privacy regulations concerning the disclosure of individually-identifiable health information to cancer registries from hospitals, physicians, laboratories, and other medical providers. In summary, the regulations allow for these disclosures without specific, informed consent provided the cancer registry is a public health authority. Please let me know your questions, comments, or concerns related to this opinion. You may reach me via email at [jhodge@jhps.edu](mailto:jhodge@jhps.edu), or via phone, (410) 955-7624.

With best wishes,



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<sup>9</sup> 45 C.F.R. § 164.528 (2001).