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**PUBLIC HEALTH LEGAL PREPAREDNESS  
BRIEFING MEMORANDUM # 1<sup>1</sup>**

BIOTERRORISM SURVEILLANCE UNDER HIPAA'S PUBLIC HEALTH EXCEPTION<sup>2</sup>

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**ISSUE:** Do the new federal health information privacy regulations limit the disclosure of individually-identifiable health information by covered entities to public health authorities pursuant to bioterrorism or other reporting requirements?

**RESPONSE:** For the reasons set forth below, the HIPAA privacy regulations do not substantially limit these disclosures. In fact, the HIPAA privacy regulations encourage and support the disclosure of individually-identifiable data without specific, informed consent for public health purposes.

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<sup>1</sup>. On December 11, 2002, the CDC Public Health Law Program, the Association of State and Territorial Health Officials, and the National Association of County and City Health Officials sponsored a peer consultation workshop on selected legal and policy issues related to public health legal preparedness for bioterrorism. The *Center for Law and the Public's Health* hosted the workshop. This memorandum was prepared in response to an issue of shared interest to workshop participants.

<sup>2</sup>. This Memorandum is intended as a guide for use by public health attorneys and practitioners attending the Workshop. It is not intended to be, and cannot be relied upon to offer, specific legal advice.

Developed by the Department of Health and Human Services (DHHS) under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Privacy Rule sets forth standards for the use and disclosure of individually-identifiable health information (a.k.a. “*protected health information*” (PHI)) in paper or electronic form. PHI includes individually-identifiable information relating to individual medical 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 Rule principally because its use and exchange raise few individual privacy concerns.

The Rule governs the acts of *covered entities*. Covered entities include health data clearinghouses, health plans (insurers, Medicare, Medicaid), and health care providers (e.g. hospitals, physicians, laboratories)<sup>3</sup> who transmit any PHI in electronic form pursuant to certain financial and administrative transactions.<sup>4</sup> The Rule takes effect for most covered entities on **April 14, 2003**.

The practice of public health will be affected by the Rule in many ways. Presently, the *Center for Law and the Public’s Health* and others are working with the Epidemiology Program Office at the Centers for Disease Control and Prevention (CDC) to develop a practitioner’s guide on the impact of the Rule on public health. Final versions of this document, due to be completed in late March, 2003, will be widely circulated.

The Rule adopts a typical standard concerning disclosures of PHI outside the health care transaction setting. PHI shall not be disclosed without written authorization of the individual who is the subject of the information. Various public health provisions of the Rule, however, allow covered entities to disclose PHI without individual authorization to public health authorities for public health purposes.

Provided that a recipient of protected health information is a *public health authority*, the acquisition of identifiable health data for bioterrorism surveillance or other legitimate public health purposes is protected under these broad provisions, and thus does not require individual informed consent.

A *public health authority* is broadly 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

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<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. § 160.102.

public health matters as part of its official mandate.”<sup>5</sup>

Public health authorities include federal public health agencies (e.g., CDC, NIH, FDA, OSHA); tribal health agencies; state public health agencies (e.g. public health departments or divisions, state cancer registries, vital statistics departments); local public health agencies; and anyone acting under authorization from or pursuant to a contract with a public health authority.

The Rule allows disclosures of PHI to public health authorities without individual authorization when required by federal, tribal, state, or local laws,<sup>6</sup> or as permitted via common practice<sup>7</sup>. As HHS clarifies in its interpretation of these corresponding sections of the Rule:

The . . . Rule permits covered entities to disclose the amount and type of [PHI] that [are] needed for public health purposes. In some cases, the disclosure will be required by other law, in which case, covered entities may make the required disclosure pursuant to 45 CFR 164.512(a) of the Rule. For disclosures that are not required by law, covered entities may disclose, without authorization, the information that is reasonably limited to that which is minimally necessary to accomplish the intended purpose of the disclosure."

The Rule thus provides in Section 164.512(a) that disclosures of PHI may be made whenever they are required by law. This includes laws, like state public health reporting statutes, mandating disclosures of identifiable health data for public health purposes.

Pursuant to Section 164.512(b), public health authorities may acquire PHI from covered entities via permissive or discretionary disclosures under several categories, including:

- (1) When the public health authority is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or 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.
- (2) When the public health authority is authorized by law to receive reports of child abuse or neglect.

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

<sup>6</sup> 45 C.F.R. § 164.512(a).

<sup>7</sup> 45 C.F.R. § 164.512(b).

- (3) To a person subject to FDA jurisdiction for public health purposes related to the quality, safety, or effectiveness of an FDA-regulated product or activities.
- (4) To a person who is at risk of contracting or spreading a disease or condition if other law authorizes the covered entity to notify such individuals as necessary to carry out public health interventions or investigations.

In other circumstances, the Rule permits covered entities to disclose PHI without individual authorization for specific public responsibilities that may have public health implications, including:

- emergency circumstances;
- identification of the body of a deceased individual, or the cause of death;
- oversight of the healthcare system; and
- activities related to national defense and security.

Once PHI is disclosed to public health authorities pursuant to these provisions, it is no longer covered by the Privacy Rule, and may be maintained, used, and disclosed consistent with the laws, regulations, and policies applicable to the public health authority. Thus, provided that state law permits the sharing of such data by public health authorities across state boundaries, or among intrastate agencies, these disclosures may continue unabated by the Rule.

However, any non-governmental entity that performs services similar to government-supported public health agencies, 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>8</sup> This entity must follow the Rules requirements relating to patient consent, authorization, and opportunity to object or agree before disclosure by a covered entity is permitted.

The Rule expressly does not pre-empt (or override) state law requirements for any disclosures that has the “purpose[] of serving a compelling need related to public health, safety, or welfare,”<sup>9</sup> or “provides for the reporting of disease or injury . . . or for the conduct of public health surveillance, investigation, or intervention . . . .”<sup>10</sup> Thus, state or local law that permits covered entities to disclose identifiable information to public health authorities without individual informed consent remains intact.

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<sup>8</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/admnsimp/final/PvcPre03.htm>> (responding to the first comment listed).

<sup>9</sup> 45 C.F.R. § 160.203(a)(1)(iv).

<sup>10</sup> 45 C.F.R. § 160.203(c).

This further supports a public health authority's ability to collect protected health information without the patient's informed consent where state or local law allows.

While the HIPAA Rule does not limit disclosures of protected health information to public health authorities, covered entities may be required to log these and many other disclosures.<sup>11</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.

As a final note, some may confuse these findings to suggest that the Rule requires covered entities to report PHI to federal, tribal, state, or local public health authorities. This is not so. The regulations allow public health disclosures to be made, but the underlying authority for these disclosures lies in existing laws. Thus, the HIPAA regulations give way to existing public health reporting requirements, but do not create any new reporting requirements for covered entities.

In summary, the new HIPAA privacy Rule allows for (but does not require) the disclosure of PHI without specific, informed consent to public health authorities pursuant to bioterrorism or other reporting requirements.

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<sup>11</sup> 45 C.F.R. § 164.528(a).