Testimony of the

Centers for Disease Control and Prevention (CDC)

on the implementation of the

HIPAA Privacy Rule in Public Health Practice

Prepared by the
CDC Health Information Privacy Office
for the Office of the Director

National Committee on Vital Health Statistics (NCVHS)
Subcommittee on Privacy and Confidentiality

Professor Mark A. Rothstein, J.D., Chair

November 19, 2003

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention

Atlanta, Georgia

The Centers for Disease Control and Prevention (CDC) and its tribal, state, and local partners have strongly supported the need for health information privacy protections within public health practice, health research, and clinical care. CDC staff have systematically shared their perspectives on protecting health information privacy with the Department of Health and Human Services (HHS) and others during the development of the Standards for Privacy of Individually Identifiable Health Information (Privacy Rule) promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). CDC has engaged multiple efforts to examine the impact of the Privacy Rule on public health practice, including (1) its internal creation of a coordinating, health information privacy office within CDC's Epidemiology Program Office (EPO); (2) the designation of a HIPAA Privacy Rule Coordinator also within EPO; and (3) extensive forums, meetings, correspondence, and discussions with national, state, tribal, and local partners in public health practice. On April 11, 2003, CDC staff and others published with HHS a national guidance document, HIPAA Privacy Rule and Public Health: Guidance from CDC and the U.S. Department of Health and Human Services as a Special Supplement to the Morbidity and Mortality Weekly Report (MMWR) (please refer to this document for additional information and key definitions supporting this testimony).[1]

As summarized in this guidance document, the Privacy Rule attempts to balance individual and communal interests in identifiable health data. The Rule provides a national standard for protecting individual privacy through provisions aimed at covered entities (e.g. health care providers, insurers, and data clearinghouses). It simultaneously recognizes the need for governmental health authorities and others responsible for protecting the public's health to access and use identifiable health information (or "protected health information," PHI) for public health purposes.

1 Centers for Disease Control and Prevention. HIPAA Privacy Rule and public health: guidance from CDC and the U.S. Department of Health and Human Services. MMWR 2003;52(Supl)[1-20].

Accordingly, the Rule (1) permits disclosures of PHI from covered entities to public health authorities for authorized public health activities (e.g., public health surveillance, investigations, and interventions) without individual written authorization; (2) allows public health authorities performing public health functions or activities to use or disclose PHI in their possession; (3) is deferential to public health authorities to determine the minimum necessary amount of PHI needed for a specific public health program; (4) leaves intact existing federal, tribal, state, and local public health reporting laws and other provisions authorizing data acquisition; and (5) allows existing public health information privacy laws and protections that do not interfere with or infringe upon national privacy protections to remain in effect. In sum, the Privacy Rule strongly supports the need for public health authorities to acquire, use, and disclose PHI, while at the same time protecting the privacy of this data through covered entities.

Though the Privacy Rule is conceived and structurally designed to minimize its impact on public health practice, it has presented challenges to public health authorities. Some of these challenges are directly related to significant misconceptions and misinterpretations of the Rule by covered entities and others. For example, some covered entities initially and incorrectly perceived that the Privacy Rule did not allow them to continue to provide PHI to public health authorities without individual written authorization. This and other misinterpretations are discussed in CDC's MMWR Guidance, and continue to be addressed by CDC through its health information privacy office, other internal staff, and CDC partners at the tribal, state, and local levels. Through these efforts, CDC is confident that unintended impacts to public health practice arising from the Privacy Rule have been and will continue to be negated.

Other impacts of the Privacy Rule on public health practice, however, are not related to misinterpretations. CDC notes that the affects of the Privacy Rule on public health practice have not been fully assessed, studied, nor conclusions drawn. Complete assessments may not be available

until after the first nine months of the Rule's implementation. Thus, this testimony does not provide conclusive evidence of the effects of the Rule, but rather legal and policy information supported in part by informal surveys and anecdotal information. As the Rule affects the ways that PHI is used and disclosed among covered entities and those performing covered functions, it may affect public health practice in internal and external ways.

Internally, public health practice is affected by the Rule's breadth. The Rule extends its coverage not just to those identified as "covered entities," but also to those who perform "covered functions," like the limited provision of health care services. Many state and local public health authorities provide basic health care services to some parts of the population (e.g., vaccinations provided to uninsured children through a county health department). That these services are performed in pursuit of a public health goal (e.g., increasing vaccination rates in the community) does not remove the activity from coverage under the Rule. Accordingly, if the public health authority also transmits PHI electronically as part of these services, these activities must comply with the Rule. This has led many state and local public health authorities to internally declare their hybrid entity status in accordance with the Rule, with various legal, financial, policy, and organizational consequences.

From an external perspective, assessing how the Rule affects the flow of PHI from covered entities to public health authorities is critical. The Rule clarifies the permissibility of sharing information between covered entities and public health authorities for public health or research purposes, yet questions on its external affects on public health practice and research include:

- *How extensively must a covered entity account for disclosures of PHI to a public health authority?* Covered entities have routinely resisted some public health data requests because they assert that they cannot meet the Rule's accounting requirement. HHS' Office for Civil

Rights (OCR) has offered flexible and favorable guidance that suggests that extensive accounting of public health disclosure is not always needed. Some covered entities, however, continue to incorrectly cite accounting requirements as a basis for failing to provide PHI to public health authorities.

- *What are the Rule's bases for disclosures of PHI to public health authorities?* Some covered entities confuse Section 164.512(a) of the Rule (allowing disclosures of PHI without written authorization when "authorized by law") and Section 164.512(b) (allowing permissive disclosures to public health authorities). These entities may inappropriately refuse to provide PHI because their collection by the public health authority is not directly supported by a mandatory state or local reporting law. Some state legislatures are considering amendments to state reporting laws to resolve controversies, particularly concerning syndromic surveillance. In the interim, some public health authorities lack critical health data.
- *How does the Privacy Rule impact the exchange of health data between public health authorities and educational institutions?* The Privacy Rule defers to the Family Educational Rights and Privacy Act of 1976 (FERPA) concerning privacy protections of education records. Yet, the nexus between the Privacy Rule and FERPA is unclear, particularly when a public health authority seeks identifiable health data from a school or a school maintains a health clinic. OCR is working with CDC on a FAQ to clarify these issues.
- *What are the distinctions between public health practice and research under the Privacy Rule?* Public health authorities may seek to collect PHI from covered entities for public health practice or for public health research, or both. The Privacy Rule has differing standards for PHI disclosed for public health or research purposes without sufficiently clarifying these distinctions. These distinctions are also problematic under federal human

subject research provisions (e.g., the Common Rule). Yet, under the Privacy Rule, some covered entities or institutional review boards (IRBs) may disagree with public heath authorities on the purpose of their data collection. Access to PHI may be initially denied or subject to additional requirements (e.g., specific informed consent, or a HIPAA research waiver of authorization). Additional problems arise when a covered entity knows that a public health authority anticipates using PHI for research although it is initially collected for public health purposes.

- *How can state and local public health agencies prepare for the Rule's complaint driven enforcement procedures?* Some agencies are concerned about the procedural and financial obligations to effectively respond to citizen complaints in their capacity as hybrid entities.
- *Is the Privacy Rule a per se standard for the liability of public health practitioners who may violate its provisions?* Potential or actual breaches of the Privacy Rule may withstand legal claims through state or local courts if the Rule is recognized as a national standard of care for the protection of the privacy of health data.

These and other questions on the impact of the Rule on public health practice have emerged in the initial months of its implementation. CDC will continue to work closely with HHS OCR, additional federal agencies, and its tribal, state, and local partners to monitor these issues. Where appropriate, the agency will respond through additional guidance based on OCR interpretations, research within and outside CDC, and support for external projects or research that may contribute to their resolution. Thank you for the opportunity to share this testimony with the National Committee on Vital Health Statistics' Subcommittee on Privacy and Confidentiality.