Memorandum

TO: Local Health Directors
Local Health Department HIPAA Coordinators
Local Health Department Nursing Directors
Universal Childhood Vaccination Distribution Program Participants

FROM: Leah Devlin, DDS, MPH, State Health Director and Director, Division of Public Health

SUBJECT: Impact of HIPAA on Immunization Records Sharing

August 1, 2003

This memorandum letter clarifies the effect of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule on North Carolina’s Immunization Registry (NCIR) and on NC State law governing immunization information sharing. The North Carolina Division of Public Health Immunization Branch is responsible for the NCIR.

The effects are as follows:

- The HIPAA Privacy Rule permits immunization providers to disclose immunization information, without an individual’s authorization, to the Immunization Branch (hence to the NCIR).
- North Carolina state law requires immunization providers to release immunization information, without an individual’s consent or authorization, to the Immunization Branch (hence to the NCIR) and to certain other types of organizations as defined by North Carolina law.
- HIPAA and the Privacy Rule do not interfere with the NC State law that defines the reporting and sharing of immunization information from providers to those organizations specified in NC law.
- The Division of Public Health Immunization Branch and the NCIR are not considered covered health care components under of the HIPAA Privacy Rule and also are not Business Associates as defined by HIPAA. The Division will not enter into Business Associate Agreements.

In summary, immunization information must continue to be shared as specified by North Carolina State law. However, it is the covered entity’s responsibility to otherwise safeguard and protect the information while it is their possession according to all applicable state and federal laws.

For the basis of these conclusions, please see the excerpts from the HIPAA Privacy Rules, NC Attorney General’s Office advisories and NC State law, which are attached to this memo.
The Division of Public Health is committed to fulfilling its responsibilities for protecting the public’s health and for public health oversight and monitoring according to federal and state law. Local providers serve essential and instrumental roles in the provision of prevention and treatment of disease and the Division is committed to continuing our public health partnerships with local providers in order to promote and ensure the public’s health.

Please feel free to contact my office if you have questions. You may also contact the DPH Privacy Official at HIPAA.DPH@ncmail.net or (919) 715-0411, if you would like additional clarification. Local public health department staff may also direct questions to the local public health department HIPAA Hotline at (919) 715-3358.

Thank you very much.

cc: Kevin Ryan, MD, MPH, Chief, Women’s and Children’s Health Section, Division of Public Health  
Beth Rowe-West, Branch Head, Immunization Branch, Division of Public Health  
Dennis Harrington, Chief, Administrative, Local, and Community Support Section NC Division of Public Health  
Chris Hoke, Chief, Legal and Regulatory Affairs, NC Division of Public Health  
Larry Forrister, Privacy Official, NC Division of Public Health  
Distribution, NC Division of Public Health

Attachments: Excerpts from HIPAA Privacy Rule and NC Attorney General advisory  
Excerpts from North Carolina Immunization Laws
Excerpts from HIPAA Privacy Rule and NC Attorney General advisory

The HIPAA Privacy Rule refers to the reporting of public health activities in 42 USC 130d-7(b):

Nothing in this part shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention.

The HIPAA Privacy Rule, CFR 160.203 (c), also includes the above provision for reporting of public health activities, such as immunizations, and excepts state public health laws from being preempted by the HIPAA Privacy Rule:

“A standard, requirement, or implementation specification adopted under this subchapter that is contrary to a provision of state law preempts the Provision of state law. This general rule applies, except if one or more of the following conditions is met: …

(c) The provision of State law, including procedures established under such law, as applicable, provides for the reporting of disease or injury, … or for the conduct of public health surveillance, investigation, or intervention.”

45 CFR 164.512(b)(1)(i) further permits a “covered entity” to disclose protected health information without an individual’s authorization for public health purposes to:

A public health authority that 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 …

The NC Attorney General’s Office issued an advisory letter to the Division Director and State Health Director about the effect of HIPAA on the Division’s continued ability to collect health information from covered entities. The letter concludes that the “Division meets the definition of a public health authority. Therefore, covered entities may disclose to the Division protected health information for the public health purposes … or if the law otherwise requires it. HIPAA does not prevent such disclosures; it authorizes them. Moreover, to the extent the information comes to the Division through a covered function, it may use that information for public health purposes.

Under the HIPAA Privacy Rule, local public health departments in North Carolina also meet the definition of public health authorities.

As part of its covered entity determination, the North Carolina Attorney General’s Office and the NC Division of Health and Human Services HIPAA Office have determined that the Division of Public Health Immunization Branch and the NC Immunization Registry are not covered health care components within the NC DHHS “hybrid entity.”
N.C.G.S.A. § 130A-153

(a) The required immunization may be obtained from a physician licensed to practice medicine or from a local health department. Local health departments shall administer required and State-supplied immunizations at no cost to the patient. The Department shall provide the vaccines for use by the local health departments. A local health department may redistribute these vaccines only in accordance with the rules of the Commission.

(b) Local health departments shall file monthly immunization reports with the Department. The report shall be filed on forms prepared by the Department and shall state, at a minimum, each patient's age and the number of doses of each type of vaccine administered.

(c) Immunization certificates and information concerning immunizations contained in medical or other records shall, upon request, be shared with the Department, local health departments, and the patient's attending physician. In addition, an insurance institution, agent, or insurance support organization, as those terms are defined in G.S. 58-39-15, may share immunization information with the Department. The Commission may, for the purpose of assisting the Department in enforcing this Part, provide by rule that other persons may have access to immunization information, in whole or in part.

(d) A physician or local health department may immunize a minor with the consent of a parent, guardian, or person standing in loco parentis to the minor. A physician or local health department may also immunize a minor who is presented for immunization by an adult who signs a statement that he or she is authorized by a parent, guardian, or person standing in loco parentis to the minor to obtain the immunization for the minor.
10A NCAC 19A.0406

NORTH CAROLINA ADMINISTRATIVE CODE
TITLE 10A. DEPARTMENT OF ENVIRONMENT AND NATURAL RESOURCES
CHAPTER 19. HEALTH: EPIDEMIOLOGY
SUBCHAPTER 19A. COMMUNICABLE DISEASE CONTROL
SECTION .0400. IMMUNIZATION
0406 ACCESS TO IMMUNIZATION INFORMATION

(a) Physicians, local health departments and the Department shall, upon request and without consent release the immunization information specified in Paragraph (b) of this Rule to the following organizations:
(1) schools K-12, whether public, private or religious;
(2) licensed and registered childcare facilities as defined in G.S. 110-86(3) and G.S. 110-101;
(3) Head Start;
(4) colleges and universities, whether public, private or religious;
(5) Health Maintenance Organizations; and
(6) Other state and local health departments outside of North Carolina.

(b) The following is the immunization information to be released to the organizations specified in Paragraph (a) of this Rule:

(1) name and address;
(2) name of the parent, guardian, or person standing in loco parentis;
(3) date of birth;
(4) gender;
(5) race and ethnicity;
(6) vaccine type, date and dose number administered;
(7) the name and address of the physician or local health department that administered each dose; and
(8) the existence of a medical or religious exemption determined by the Immunization Section to meet the requirements of G.S. 130A-156 and 15A NCAC 19A .0404 or G.S. 130A-157. If such a determination has not been made by the Immunization Section, the person shall have access to the certification of medical and religious exemptions required by G.S. 130A-156 or G.S. 130A-157 and 15A NCAC 19A .0404.