Thursday, January 22, 1:30-3:00PM
Concurrent Breakout Session

HIPAA and Birth Defects
Moderator: Larry Edmonds, Centers for Disease Control and Prevention, Atlanta, GA

Update on HIPAA and Birth Defects
Beverly Dozier, Centers for Disease Control and Prevention, Atlanta, GA

The deadline to comply with the Privacy Rule issued by the U.S. Department of Health and Human Services (HHS), as required by the Health Insurance Portability and Accountability Act (HIPAA) was April 14, 2003. This session will provide a quick overview of HIPAA and a more in depth analysis of its impact on birth defects surveillance since the deadline, and a discussion of some of the provisions of the Rule which need clarification. Specifically, we will address those provisions in the Rule affecting birth defects surveillance, such as minimum necessary access to data, data sharing, and grants of authority to covered entities to act as public health authorities for birth defects surveillance.

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HIPAA: Utah Birth Defect Network Experience and Perspective
Jean Hendrickson, Utah Department of Health, Salt Lake City, UT

The Utah Birth Defect Network [UBDN] instituted in 1994 is a statewide surveillance program functioning within the Utah Department of Health [UDOH]. Beginning in 1999, the goal was identification of all major structural malformations occurring in Utah pregnancy outcomes. With the adoption and implementation of the federal Privacy Rule [45 C.F.R., Parts 160 and 164] under the Health Insurance Portability and Accountability Act of 1996 [HIPAA], Public Law 104-191, the UBDN has been impacted even though it is not a "covered entity" to which the rule applies. The public health surveillance functions are expressly permitted by the rule. However, maintaining the uninterrupted functioning of the UBDN's public health activities required education and an understanding of many of the provisions in the Privacy Rule. The health information relied upon by the UBDN is initially created by health care providers who are covered entities under the Privacy Rule.

It is from this perspective that the UBDN decided upon a pro-active stance in its contacts with covered entities and in its interface with the disclosure standards of the Privacy Rule.

The UBDN needed a system which allowed it to continue its surveillance activities consistent with program objectives and which provided covered entities the assurance the UBDN respected the needs of covered entities concerning the disclosure standards imposed by the Privacy Rule.

Among the public health activities performed by the UBDN, its surveillance functions cause it to interface with covered entities and with the standards required by the Privacy Rule. It is a public health authority "authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including . . . 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." 45 C.F.R. § 164.512(b)(1)(i). Thus, disclosures of health information by covered entities to the UBDN are permitted. Moreover, disclosures "required by law" are also permitted by the Privacy Rule. 45 C.F.R. § 164.512(a). The Utah Health Code, under Title 26, provides authority for a variety of public health activities. Pursuant to the authority granted to the Health Department, Utah has a birth defect reporting rule requiring hospitals, birthing centers, and laboratories to report birth defects and birth-defect related test results. Utah Admin. Code R. 398-5. This framework provides important support for the UBDN to continue its surveillance functions post-HIPAA Privacy Rule implementation. Even so, the UBDN needed an outreach program to maintain effective and efficient working relationships with health care facilities and providers.

Even though the Privacy Rule does not govern the public health activities, it functionally governs how public health authorities interface with covered entities to acquire the health data the public health authorities are authorized to collect and receive. Covered entities are now, to varying degrees, sensitive to the many avenues through which protected health information may be disclosed to public health authorities. UBDN staff became aware of the health care community's lack of understanding of the UBDN's purpose and activities. If the UBDN were to maintain a successful relationship with the hospitals, birthing centers, laboratories, and other health care providers, it needed a method to raise awareness of the UBDN's activities and create a positive atmosphere.

Recognizing that its surveillance activities might be met with heightened wariness or even resistence, the UBDN prepared written communications referencing the appropriate state laws and rules and the disclosure provisions of the Privacy Rule.

In the beginning, a generic letter based upon a template was pressed into service. It addressed initial questions from covered entities during the initial Privacy Rule implementation phase. At this time many entities, public and private, were still grappling with the effect and application of the Privacy Rule. Over time, this letter was revised to include more information about the purpose and activities of the UBDN. As time passed, and as entities became more familiar with the Privacy Rule, more letters were crafted to address specific issues. However, it soon proved more effective to have a few, focused letters which addressed the most important points which needed to be stated. [Samples of these are included in the materials.]

An informational letter is still used to explain how the Privacy Rule should be read to permit continued surveillance activities. However, more information about surveillance activities needed to be disseminated to the health care community. The UBDN became aware that its existence and purpose were not well-understood in the health care community. The UBDN took this opportunity to prepare materials describing the program's objectives and the activities employed to achieve them. It is important that the health care community understand what the UBDN does if the UBDN is to maintain a cooperative relationship.

To dispel a common misunderstanding that patient consent would be required before a hospital or birthing center or other entity could disclose protected health information to the UBDN, the UBDN included references to the Privacy Rule and supporting legal authorities. The letter explains the intent of Congress not to interfere with public health reporting. It references the legal authority expressly authorizing reporting requirements of certain health information. In the case of mandatory birth defect reporting under Utah's reporting rule, those disclosures for public health activities would come within the exception for disclosures for which an authorization or an opportunity to agree or object is not required.

Another set of letters explains the routine contacts by UBDN abstractors monitoring the occurrence of all structural birth defects occurring in Utah. The UBDN abstractors contact the medical facility by letter or other means prior to a planned monitoring visit. This letter or contact states the purpose of the visit, the intended targets for review, and the legal references authorizing the disclosure requested. As the investigation of birth defects is a multistage process, hospitals, clinics, and doctors are sent focused requests for access to specified patient files as determined by the stage of inquiry. The UBDN employs letters stating the purpose of the record review, the legal basis authorizing such activity, and that the letter is placed in the file reviewed as evidence of the date the abstractor performed the surveillance function. Any reasonable requests to accommodate the medical records officers' needs for records control and accounting functions and which do not negatively impact the abstractors' efforts are welcomed.

In addition to the letters and explanatory materials used, the UBDN made personal contact with records officers and privacy officers to explain the surveillance activities. A protocol of procedures was jointly established. These procedures addressed the mutual concerns for proper identification of abstractors, security issues, confidentiality of records, and a notification system for scheduled visits by abstractors. This personal contact was crucial to the entire process. These contacts created the opportunity for the covered entity and the public health worker to express concerns, ask questions, and begin to understand the respective needs of each other.

Communication and education are key elements to successfully negotiating the unsettled landscape confronting both the health care community and the public health surveillance authorities. The initial personal contacts to identify issues and establish protocols are just the beginning; follow-up meetings were scheduled and will continue. These meetings allow the records officers and the privacy officers and the UBDN staff to evaluate the procedures instituted. Any problems can be promptly addressed by a joint solution. Particularly effective procedures can be translated to other facilities. The UBDN anticipates regular contact to continue and ongoing assessment of procedures put in place to address issues of health information access, use, and disclosure.