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Statutory Basis for Public Health Reporting Beyond Specific Diseases

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ABSTRACT *Statutory authority for public health surveillance is necessarily broad as previously uncharacterized diseases are regularly discovered. This article provides specific information about general disease reporting provisions in each state. The intent of these reporting laws and the Health Insurance Portability and Accountability Act Privacy Rule is to support this critical disease surveillance function for the benefit of the entire population.*

KEYWORDS *HIPAA public health provisions, Public health surveillance, Statutory authority.*

INTRODUCTION

A fundamental responsibility of the public health system in the United States is the prompt detection of, investigation of, and response to threats to the health of the population, whether these threats are due to known organisms, previously uncharacterized disease, or a covert deliberate terrorist event. Because of the recognition that previously uncharacterized diseases are regularly discovered, statutory authority for public health surveillance is necessarily broad to ensure that state and local public health personnel can fulfill their responsibility. The urgency of developing systems that might provide the earliest possible detection of a terrorist event has led public health and its partners to explore innovative surveillance approaches using their broad authority. At the same time, the process of implementing the recently promulgated Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule has compelled many health care providers, in an attempt to ensure a sound legal basis for disease reporting, to reexamine their process for reporting information to public health authorities. This article provides specific information about the general disease reporting provisions in each state and also shows that the intent of these reporting laws and the HIPAA Privacy Rule is to support this critical disease surveillance function for the benefit of the entire population.

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Background on the Health Insurance Portability and Accountability Act Privacy Rule

General Provisions Congress passed the HIPAA (HR 3103) and President Clinton signed it into law in 1996 (Pub L No. 104-191). The law was designed, among other purposes, to reduce the costs imposed on health care providers by encouraging the development of standardized electronic health information technologies. The law included a proviso for the development of new privacy safeguards designed to protect the security and confidentiality of health information. The proviso assigned Congress an August 1999 deadline for the development of these safeguards in the form of a comprehensive health privacy law. In the event Congress failed to meet this deadline, HIPAA directed the Department of Health and Human Services (HHS) to assume responsibility for privacy of health information in the form of regulatory action. When Congress failed to pass such privacy legislation, HHS began developing regulatory provisions to provide the privacy protections sought by Congress through HIPAA.

On November 3, 1999, HHS formally announced the draft privacy regulations designed to guarantee patients new rights and protections against the misuse or disclosure of their health information. This initial publication generated 52,000 public comments in response to the proposal. HHS reviewed these comments, revised the rule, and published the final Privacy Rule in December 2000, at the end of the Clinton administration. The Bush administration was concerned with the potential unintended consequences that the Privacy Rule would have on patient access and quality of care.

In an effort to ensure that the rule adequately addressed these issues, HHS opened the rule for an additional 30-day comment period in March 2001. The comment period generated an additional 11,000 comments on the rule. In August 2002, HHS completed its revisions to the Privacy Rule.[1]

The final rule continues to permit covered entities to disclose protected health information (PHI) without individual authorization directly to public health authorities, such as the Food and Drug Administration, the Occupational Safety and Health Administration, the Centers for Disease Control and Prevention, as well as state and local public health departments, for public health purposes.[2] The mandatory compliance date for organizations defined as covered entities under the Privacy Rule is April 14, 2003, with the exception of some small health plans, which have an additional year to comply with the regulations. The Privacy Rule is codified at 45 CFR Parts 160 and 164.

The applicability of the Privacy Rule is limited to organizations defined as covered entities or hybrid entities. Covered entities are health care providers who transmit health information in connection with certain electronic transactions, such as billing of health plans; individual or group health plans that provide or pay the cost of medical care; and health care clearinghouses, which are entities that convert health information received from another entity from nonstandard format or data content to standard format or data content or vice versa and may include billing services, repricing companies, and community health information systems. The rule also applies to sharing of information by covered entities with their business associates, which are organizations that use protected health information as they work on behalf of or provide certain services to covered entities. Finally, hybrid entities are covered entities that perform a breadth of health activities that include functions covered by the Privacy Rule and functions not covered by the Privacy Rule and that

designate their health care components. An example of a hybrid entity would be a state health department that administers Medicaid (a covered function) and public health programs (noncovered functions). Organizations that assume a hybrid entity classification apply the requirements of the Privacy Rule to their covered functions, but not to their noncovered functions.

The constraints imposed on or affecting covered entities, business associates, and hybrid entities focus specifically on the security and control of PHI. The definition of PHI is limited to a subset of health information specifically created or received by a covered entity and is related to (1) the past, present, or future physical or mental health or condition of an individual; (2) the provision of health care to an individual; and (3) the past, present, or future payment for the provision of health care to an individual. To fall within the PHI category, the information must identify an individual or contain enough information concerning an individual that there is a reasonable basis to believe that the information can be used to identify an individual. Employment and education records are generally excluded from the definition of PHI.

IMPLICATIONS FOR PUBLIC HEALTH

The Privacy Rule may have implications for public health practitioners in three areas: (1) the practice of public health including data collection; (2) research; and (3) when public health authorities are covered entities under the regulation. The remainder of this section focuses on the data collection aspect of the rule.

Generally, the disclosure of health information to public health authorities without consent or authorization is allowed by the regulation when the disclosure is required by law (federal, state, or local) or is authorized by law for a public health activity and purpose. The regulation itself does not require public health disclosures, but does not prevent an entity from complying with the relevant public health laws.

> In response to comments arguing that the provision (defining public health authority) is too broad we (OCR) note that section 1178[b] (of the Heath Insurance Portability and Accountability Act of 1996) of the Act, as explained in the NPRM, explicitly carves out protection for state public health laws. This provision states that: "[N]othing 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." In light of this broad congressional mandate not to interfere with current public health practices, we (OCR) believe the broad definition of "public health authority" is appropriate to achieve that end.[1(p86264)]

Public health activities are defined as "preventing or controlling disease, injury, or disability, including but not limited to, the reporting of disease, injury, vital events . . . , and the conduct of public health surveillance, . . . investigations, and . . . interventions"[2] and receiving child abuse and neglect reports. Such disclosure is authorized to public health authorities, an official of a foreign government acting in collaboration with a domestic public health authority, or a person exposed to or at risk of contracting or spreading disease if the public health authority is authorized by law to notify such persons. A public health authority is defined as

> an agency or authority of the US, 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 or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.[2]

While the public health activity for which the information is to be disclosed must be "authorized by law," the activity does not need to be specified by the law. For example, general authority to conduct public health surveillance is sufficient; the specific disease to be tracked or the information requested does not need to be named in the law. Once it is disclosed to the public health authority, the privacy and confidentiality of the information is no longer covered by the Privacy Rule unless the public health authority is also functioning as a covered entity under the rule. However, public health authorities generally are covered by other privacy and confidentiality laws, regulations, and policies, depending on their jurisdiction.

Protected health information disclosed for public health purposes must meet the minimum necessary provisions of the rule. However, covered entities may rely on the determination of a public official that the disclosure is the minimum necessary for the public health activity. Covered entities must provide their patients with a notice of their privacy policies and practices, which includes notification of uses and disclosures authorized by the rule for which they will be disclosing information. In addition, if requested by a patient, covered entities must provide an accounting of any public health disclosures it has made.

DISEASE REPORTING STATUTES AND SYNDROMIC SURVEILLANCE

The HIPAA Privacy Rule should not limit a state's ability to perform its public health functions. A primary function of the public health system is public health surveillance to determine the existence of cases of an illness and to disseminate data for the benefit of the community. Surveillance of nonspecific conditions or symptoms (syndromic surveillance) may provide an early warning of a large outbreak, terrorism, or other public health emergency. A public health authority continues to have the ability to conduct public health surveillance, based both on its "police power," the inherent power of a state to protect the health, safety, and welfare of the community, and on specific law.

One important aspect of public health surveillance, including syndromic surveillance, is disease reporting. Disease reporting, as with public health generally, is primarily a state and local function.* State disease reporting laws may be agent specific or general. All states have broad disease reporting laws that require the reporting of diseases of public health significance. This legal requirement is expressed in as many ways as there are states. Usually, the entities to which persons must report are state, local, or county health agencies or other health authorities. Each state requires, in pertinent part, the following to be reported:

> *Alabama*, Ala. Admin. Code r. 420-4-1-.04(7)(d) (2002), "cases of diseases of potential public health significance."

*Federal disease reporting requirements are generally limited to the mandatory reporting of ill passengers and deaths aboard cruise ships and other carriers.

Alaska, Alaska Admin. Code title 7, § 27.005(a) (2002), "epidemic outbreaks" and "an unusual incidence of infectious disease."

Arizona, Ariz. Admin. Code R9-6-202 (2002), "Outbreaks of foodborne/waterborne illness."

Arkansas, Ark. Reg. 007 05 003 (2002), "Occurrences which threaten the welfare, safety, or health of the public such as epidemic outbreaks."

California, Cal. Code Regs. title 17, § 2500 (2002), the "OCCURRENCE of ANY UNUSUAL DISEASE" and "OUTBREAKS of ANY DISEASE."

Colorado, 6 Colo. Code Regs. § 1009-1 (2002), "any unusual illness, or outbreak, or epidemic of illnesses which may be of public concern."

Connecticut, Conn. Agencies Regs. § 19a-36-A1 (2002), "other condition of public health significance."

Delaware, Del. Code Ann. title 16, § 130 (2002), "all cases of persons who harbor any illness or health condition that may be potential causes of a public health emergency."

Florida, Fla. Admin. Code Ann. r. 64D-3.002 (2002), "Any disease outbreak in a community, a hospital, or other institution, or a foodborne, or waterborne outbreak."

Georgia, Ga. Comp. R. & Regs. r. 290-5-3-.02 (2001), "Outbreaks or unusual clusters of disease (infectious and noninfectious)."

Hawaii, Haw. Admin. Rules § 11-156-3 (b) (2002), "Any communicable disease . . . occurring beyond usual frequency, or of unusual or uncertain etiology, including diseases which might be caused by a genetically engineered organism."

Idaho, Idaho Admin. Code 16.02.10.004 (2002), "Rare diseases and unusual outbreaks of illness which may be a risk to the public."

Illinois, Ill. Admin. Code title 77, § 690.295 (2002), "Any unusual case or cluster of cases"; and Ill. Admin. Code title, 77, § 690.800 (2002), "any suspected bioterrorist threat or events."

Indiana, Ind. Admin. Code. title 410, r. 1-2.3-47 (2002), "Unusual occurrence of disease" and "any disease . . . considered a bioterrorism threat."

Iowa, Iowa Admin. Code r. 641-1.3 (139A) (2002), "Outbreaks of any kind, unusual syndromes, or uncommon diseases."

Kansas, Kan. Admin. Regs. 28-1-2 (2002), "Any exotic or newly recognized disease, and any disease unusual in incidence or behavior, known or suspected to be infectious or contagious and constituting risk to the public health" and "The occurrence of a single case of any unusual disease or manifestation of illness that the health care provider determines or suspects may be caused by or related to a bioterrorist agent or incident."

Kentucky, 902 Ky. Admin. Regs. 2:020 (2002), "an extraordinary number of cases or occurrences of disease or condition."

Louisiana, Sanitary Code Ch. 2 § 2:003 (2002), "all cases of rare or exotic communicable disease, unexplained death, unusual cluster of disease and all outbreaks."

Maine, 10-144 Code ME R. Ch. 258 § 2 (2002), "Any pattern of cases or increased incidence of illness beyond the expected number of cases in a given

period, or cases which may indicate a newly recognized infectious agent, or an outbreak or related public health hazard."

Maryland, Md. Regs. Code title 10, § 06.01.03 (2002), "Outbreaks and Single Cases of Diseases of Public Health Importance."

Massachusetts, Mass. Regs. Code title 105 § 300.122 (2002), "Illness Believed to be Part of an Outbreak or Cluster."

Michigan, Mich. Admin. Code r. 325.173 (2002), "the unusual occurrence of any disease, infection, or condition that threatens the health of the public."

Minnesota, Minn. R. 4605.7050 (2002), "Any pattern of cases, suspected cases, or increased incidence of any illness beyond the expected number of cases in a given period."

Mississippi, Miss. Reg. 12 000 028 (2002), "Any Suspected Outbreak."

Missouri, Mo. Code Regs. title 19, § 20-20.020(3) (2002), "The occurrence of an outbreak or epidemic of any illness, disease or condition which may be of public health concern . . . [and] public health threats that could result from terrorist activities such as clusters of unusual diseases or manifestations of illness and clusters of unexplained deaths."

Montana, Mont. Admin. R. 37.114.203 (2002), "Any unusual incident of unexplained illness or death in a human or animal."

Nebraska, 173 Neb. Admin. Code Ch. 1 § 003 (2002), "Clusters, outbreaks or epidemics of any health problem, infectious or other, including food poisoning, influenza or possible bioterroristic attack; increased disease incidence beyond expectations; unexplained deaths possibly due to unidentified infectious causes; any unusual disease or manifestations of illness."

Nevada, Nev. Admin. Code ch. 441A, § 225 (2002), "Extraordinary occurrence of illness."

New Hampshire, N.H. Code Admin. R. Ann. [He-P] 301.02 (2002), "Unusual occurrence or cluster of illness which may pose a threat to the public's health,"

New Jersey, N.J. Admin. Code title 8, § 57-1.3 (2002), "Any outbreak or suspected outbreak, including, but not limited to, foodborne, waterborne, or nosocomial disease or a suspected act of bioterrorism."

New Mexico, N.M. Admin. Code title 7 § 4.3 (2002), "Illnesses suspected to be caused by the intentional or accidental release of biologic or chemical agents," "Acute illnesses of any type involving large numbers of persons in the same geographic area," and "Other conditions of public health significance."

New York, N.Y. Comp. Codes R. & Regs. title 10 § 2.1 (2002), "Any disease outbreak or unusual disease"

North Carolina, N.C. Admin. Code title 15A, r. 19A.0102 (2002), "all outbreaks or suspected outbreaks of foodborne illness"; and N.C. Admin. Code title 15A, r. 19A.0103 (2002), "a cluster of cases of a disease or condition . . . which represents a significant threat to the public health."

North Dakota, N.D. Admin. Code § 33-06-01-01 (2002), "Unusual cluster of severe or unexplained illnesses or deaths."

Ohio, Ohio Admin. Code § 3701-3-02 (2002), "Any unexpected pattern of cases, suspected cases, deaths or increased incidence of any other disease of major public health concern, because of the severity of disease or potential for

epidemic spread, which may indicate a newly recognized infectious agent, an outbreak, epidemic, related public health hazard or act of bioterrorism."

Oklahoma, Okla. Admin. Code § 3701-3-02 (2002), "Outbreaks of apparent infectious disease."

Oregon, Or. Admin. R. 333-018-0015 (2002), "Any known or suspected common-source outbreaks; any Uncommon Illness of Potential Public Health Significance."

Pennsylvania, 28 Pa. Code § 27.3 (2002), "Unusual occurrence of a disease, infection or condition."

Rhode Island, R.I. Code R. 14 040 002 (2002), "an outbreak of infectious disease or infestation, or a cluster of unexplained illness, infectious or non-infectious . . . Exotic diseases and unusual group expressions of illness which may be of public health concern."

South Carolina, S.C. Code Ann. § 44-29-10 (2002), "all cases of known or suspected contagious or infectious diseases . . . all cases of persons who harbor any illness or health condition that may be caused by chemical terrorism, bioterrorism, radiological terrorism, epidemic or pandemic disease, or novel and highly fatal infectious agents and might pose a substantial risk of a significant number of human fatalities or incidents of permanent or long-term disability."

South Dakota, S.D. Admin. R. 44:20:01:03 (2001), "Epidemics or outbreaks . . . and Unexplained illnesses or deaths of humans or animals."

Tennessee, Tenn. Comp. R. & Regs.1200-14-1.02 (2002), "Disease outbreaks, foodborne, waterborne, and all other."

Texas, 25 Tex. Admin. Code § 97.3 (2002), "any outbreak, exotic disease, and unusual group expressions of disease which may be of public health concern."

Utah, Utah Admin. Code 386-702 (2002), "Any sudden or extraordinary occurrence of infectious or communicable disease" and "Any disease occurrence, pattern of cases, suspect cases, or increased coincidence of any illness which may indicate an outbreak, epidemic or related public health hazard, including but not limited to suspected or confirmed outbreaks of foodborne or waterborne disease, newly recognized or re-emergent diseases or disease producing agents."

Vermont, Vt. Code R. 13 140 007 (2002), "Any unexpected pattern of cases, suspected cases, deaths or increased incidence of any other illness of major public health concern, because of the severity of illness or potential for epidemic spread, which may indicate a newly recognized infectious agent, an outbreak, epidemic, related public health hazard or act of bioterrorism."

Virginia, 12 Va. Admin. Code § 5-90-80 (2002), "Outbreaks, all (including foodborne, nosocomial, occupational, toxic substance-related, waterborne, and other outbreaks)."

Washington, Wash. Admin. Code § 246-101-301 (2002), "Disease of suspected bioterrorism origin" and "Other rare disease of public health significance."

West Virginia, W. Va. Code St. R. § 64-7-3 (2002), "An outbreak or cluster of any illness or condition—suspect or confirmed" and "Unexplained or ill-defined illness, condition, or health occurrence of potential public health significance."

Wisconsin, Wis. Admin. Code Ch. HFS 145, App. A (2002), "Suspected outbreaks of . . . acute or occupationally related diseases."

Wyoming, WY Rules and Regulations HLTH CHI Ch 1 s 5 (2002) and (http://wdhfs.state.wy.us/epiid/reportlist.pdf), "A cluster of unusual or unexplained illnesses or deaths and suspected biological incidents."

Many of these general disease reporting laws appear compatible with syndromic surveillance. Individual states, however, can determine whether their state disease reporting laws would authorize public health agencies to obtain ongoing data on relevant symptoms. These state reporting laws identify information that each state requires to be reported. The Privacy Rule would permit such reporting because the rule permits covered entities to disclose PHI if such disclosures are required by law. However, if these or other laws do not require covered entities to make these disclosures, other laws may authorize health departments to collect this type of data as discussed above. States would need to examine their specific statutory or regulatory provisions to determine whether a disclosure is required or authorized by law. For example, a law that broadly authorizes a public health authority to take whatever actions are necessary to protect the health of the public may be sufficient for this type of data collection. The more specific the law, the clearer a state's authority may be.

If, despite a health department's apparent authority to collect data on relevant symptoms, there is difficulty collecting such data, one possibility would be for the state legislature to consider revising and clarifying their disease reporting laws for syndromic surveillance purposes. Other options might include more regular enforcement of existing disease reporting laws and better education of providers on the public health significance of reporting nonspecific symptoms. For example, in some states, noncompliance with disease reporting laws is a misdemeanor punishable by fine or imprisonment, but it is unclear whether these laws are being enforced. Furthermore, compliance may not be occurring since physicians may see their first duty as protecting their individual patients and maintaining confidentiality, and patients themselves may be concerned with invasions of privacy and discrimination. Educational efforts, however, may help physicians and their patients to understand the benefit from detecting a covert bioterrorist event as rapidly as possible, when early detection can translate directly into lives saved.[3] Educational efforts could also include information about the policies and regulations ensuring the security and protection of information provided to public health authorities.

Finally, public health is committed to developing disease surveillance systems that minimize the burden to providers of reporting surveillance information, while incorporating highly stringent information security practices. Ideally, the net effect of these laws, regulations, and systems will be security for individual patient information and for the entire nation.

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