CONTENTS

Introduction........................................ 13.2
  Purpose............................................ 13.2
  Policy............................................. 13.2

Health Insurance Portability and
Accountability Act (HIPAA) .............. 13.8
  Centers for Disease Control and Prevention
guidance on HIPAA............................. 13.8
  Ohio HIPAA policies............................ 13.8

National Guidelines....................... 13.9

Resources and References............... 13.10
Introduction

Purpose

Use this section to do the following:

- Determine what information and which records should be treated with confidentiality.
- Identify state policy for maintaining patient confidentiality.
- Take measures to ensure TB patients’ confidentiality.
- Determine when it is permissible to share information for public health reasons.

The protection of private patient information is commonly referred to as confidentiality. Confidentiality involves the protection of information revealed during patient–healthcare worker encounters, including all written or electronic records of these encounters. Confidentiality is an essential issue in many different aspects of tuberculosis (TB) control. Healthcare workers need to be aware of confidentiality issues that are relevant to patient–healthcare worker encounters, as well as to the collection, management, and sharing of information gathered on TB patients.¹

Policy

Healthcare workers should keep patient information in confidence and divulge it only with the permission of the patient, except as otherwise allowed by law.²

For roles and responsibilities, refer to the “Roles, Responsibilities, and Contact Information” topic in the Introduction.
Federal Laws and Regulations
45 CFR 164.512(b)

General Public Health Activities. The Privacy Rule permits covered entities to disclose protected health information, without authorization, to public health authorities who are legally authorized to receive such reports for the purpose of preventing or controlling disease, injury, or disability. This would include, for example, the reporting of a disease or injury; reporting vital events, such as births or deaths; and conducting public health surveillance, investigations, or interventions. See 45 CFR 164.512(b)(1)(i). Also, covered entities may, at the direction of a public health authority, disclose protected health information to a foreign government agency that is acting in collaboration with a public health authority. See 45 CFR 164.512(b)(1)(i). Covered entities who are also a public health authority may use, as well as disclose, protected health information for these public health purposes. See 45 CFR 164.512(b)(2).

A “public health authority” is an agency or authority of the United States government, a State, a territory, a political subdivision of a State or territory, or Indian tribe that is responsible for public health matters as part of its official mandate, as well as a person or entity acting under a grant of authority from, or under a contract with, a public health agency. See 45 CFR 164.501. Examples of a public health authority include State and local health departments, the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention, and the Occupational Safety and Health Administration (OSHA). Generally, covered entities are required reasonably to limit the protected health information disclosed for public health purposes to the minimum amount necessary to accomplish the public health purpose. However, covered entities are not required to make a minimum necessary determination for public health disclosures that are made pursuant to an individual’s authorization, or for disclosures that are required by other law. See 45 CFR 164.502(b).

For disclosures to a public health authority, covered entities may reasonably rely on a minimum necessary determination made by the public health authority in requesting the protected health information. See 45 CFR 164.514(d)(3)(iii)(A). For routine and recurring public health disclosures, covered entities may develop standard protocols, as part of their minimum necessary policies and procedures that address the types and amount of protected health information that may be disclosed for such purposes. See 45 CFR 164.514(d)(3)(i).
Other Public Health Activities. The Privacy Rule recognizes the important role that persons or entities other than public health authorities play in certain essential public health activities. Accordingly, the Rule permits covered entities to disclose protected health information, without authorization, to such persons or entities for the public health activities discussed below.

- **Child abuse or neglect.** Covered entities may disclose protected health information to report known or suspected child abuse or neglect, if the report is made to a public health authority or other appropriate government authority that is authorized by law to receive such reports. For instance, the social services department of a local government might have legal authority to receive reports of child abuse or neglect, in which case, the Privacy Rule would permit a covered entity to report such cases to that authority without obtaining individual authorization. Likewise, a covered entity could report such cases to the police department when the police department is authorized by law to receive such reports. See 45 CFR 164.512(b)(1)(ii). See also 45 CFR 512(c) for information regarding disclosures about adult victims of abuse, neglect, or domestic violence.

- **Quality, safety or effectiveness of a product or activity regulated by the FDA.** Covered entities may disclose protected health information to a person subject to FDA jurisdiction, for public health purposes related to the quality, safety or effectiveness of an FDA-regulated product or activity for which that person has responsibility. Examples of purposes or activities for which such disclosures may be made include, but are not limited to:
  - Collecting or reporting adverse events (including similar reports regarding food and dietary supplements), product defects or problems (including problems regarding use or labeling), or biological product deviations;
  - Tracking FDA-regulated products;
  - Enabling product recalls, repairs, replacement or lookback (which includes locating and notifying individuals who received recalled or withdrawn products or products that are the subject of lookback); and
  - Conducting post-marketing surveillance. See 45 CFR 164.512(b)(1)(iii). The “person” subject to the jurisdiction of the FDA does not have to be a specific individual. Rather, it can be an individual or an entity, such as a partnership, corporation, or association. Covered entities may identify the party or parties responsible for an FDA-regulated product from the product label, from written material that accompanies the product (know as labeling), or from sources of labeling, such as the Physician’s Desk Reference.

- **Persons at risk of contracting or spreading a disease.** A covered entity may disclose protected health information 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. For example, a covered health care provider may disclose
protected health information as needed to notify a person that (s)he has been exposed to a communicable disease if the covered entity is legally authorized to do so to prevent or control the spread of the disease. See 45 CFR 164.512(b)(1)(iv).

- **Workplace medical surveillance.** A covered health care provider who provides a health care service to an individual at the request of the individual’s employer, or provides the service in the capacity of a member of the employer’s workforce, may disclose the individual’s protected health information to the employer for the purposes of workplace medical surveillance or the evaluation of work-related illness and injuries to the extent the employer needs that information to comply with OSHA, the Mine Safety and Health Administration (MSHA), or the requirements of State laws having a similar purpose. The information disclosed must be limited to the provider’s findings regarding such medical surveillance or work-related illness or injury. The covered health care provider must provide the individual with written notice that the information will be disclosed to his or her employer (or the notice may be posted at the worksite if that is where the service is provided). See 45 CFR 164.512(b)(1)(v).

OCR HIPAA Privacy
December 3, 2002 Revised April 3, 2003
State Laws and Regulations
Ohio Revised Code 339.81

Confidential Information. Any information, data, and reports with respect to a case of tuberculosis that are furnished to, or procured by, a county or district tuberculosis control unit or the department of health shall be confidential and used only for statistical, scientific, and medical research for the purpose of controlling tuberculosis in this state. No physician, hospital, or other entity furnishing information, data, or reports pursuant to this chapter shall by reason of such furnishing be deemed to have violated any confidential relationship, be held to answer for willful betrayal of a professional confidence, or be held liable in damages to any person.

Effective Date: 10-10-2000

Ohio Administrative Code

3701-75-04
Confidentiality statutes The following federal statutes or regulations or state statutes and administrative rules make personal information maintained by the agency confidential and identify the confidential personal information within the scope of rules promulgated by this agency in accordance with section 1347.15 of the Revised Code and 3701-67-06 of the Administrative Code. (D) Protected health information: section 3701.17 of the Revised Code. (E) Information reported to the Ohio cancer incidence surveillance system: section 3701.262 of the Revised Code.

3701.17
Protected health information (A) As used in this section:

(1) "Prosecutor" has the same meaning as in section 2935.01 of the Revised Code.

(2) "Protected health information" means information, in any form, including oral, written, electronic, visual, pictorial, or physical that describes an individual’s past, present, or future physical or mental health status or condition, receipt of treatment or care, or purchase of health products, if either of the following applies:

(a) The information reveals the identity of the individual who is the subject of the information.

(b) The information could be used to reveal the identity of the individual who is the subject of the information, either by using the information alone or with other information that is available to predictable recipients of the information.

(B) Protected health information reported to or obtained by the director of health, the department of health, or a board of health of a city or general health district is confidential and shall not be released without the written consent of the individual who is the subject of the information unless the information is released pursuant to division (C)
of this section or one of the following applies:

(1) The release of the information is necessary to provide treatment to the individual and the information is released pursuant to a written agreement that requires the recipient of the information to comply with the confidentiality requirements established under this section.

(2) The release of the information is necessary to ensure the accuracy of the information and the information is released pursuant to a written agreement that requires the recipient of the information to comply with the confidentiality requirements established under this section.

(3) The information is released pursuant to a search warrant or subpoena issued by or at the request of a grand jury or prosecutor in connection with a criminal investigation or prosecution.

(4) The director determines the release of the information is necessary, based on an evaluation of relevant information, to avert or mitigate a clear threat to an individual or to the public health. Information may be released pursuant to this division only to those persons or entities necessary to control, prevent, or mitigate disease.

(C) Information that does not identify an individual is not protected health information and may be released in summary, statistical, or aggregate form. Information that is in a summary, statistical, or aggregate form and that does not identify an individual is a public record under section 149.43 of the Revised Code and, upon request, shall be released by the director.

(D) Except for information released pursuant to division (B)(4) of this section, any disclosure pursuant to this section shall be in writing and accompanied by a written statement that includes the following or substantially similar language: “This information has been disclosed to you from confidential records protected from disclosure by state law. If this information has been released to you other than in a summary, statistical, or aggregate form, you shall make no further disclosure of this information without the specific, written, and informed release of the individual to whom it pertains, or as otherwise permitted by state law. A general authorization for the release of medical or other information is not sufficient for the release of information pursuant to this section.”

Effective Date: 02-12-2004
Health Insurance Portability and Accountability Act (HIPAA)

Confidentiality of patient information has long been a requirement in the healthcare field and now has its own set of regulations, the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. The new regulations protect the privacy of certain individually identifiable health data, referred to as protected health information (PHI). PHI is individually identifiable health information that is transmitted or maintained in any form or medium (e.g., electronic, paper, or oral), but excludes certain educational and employment records.

Centers for Disease Control and Prevention Guidance on HIPAA

The Centers for Disease Control and Prevention (CDC) published the report “HIPAA Privacy Rule and Public Health: Guidance from CDC and the US Department of Health and Human Services” (MMWR 2003;52 [S-2]:1–12 at this hyperlink: http://www.cdc.gov/mmwr/preview/mmwrhtml/su5201a1.htm), to provide guidance in implementing the HIPAA requirements. In this report, the US Department of Health and Human Services (DHHS) recognized the importance of sharing PHI to accomplish essential public health objectives and to meet certain other societal needs (e.g., administration of justice and law enforcement).

Covered entities—which are health plans, healthcare clearinghouses, and healthcare providers who transmit health information in electronic form in connection with certain transactions—are permitted by the Privacy Rule to do the following:

- Share PHI for specified public health purposes. For example, covered entities may disclose PHI, without individual authorization, to a public health authority legally authorized to collect or receive the information for the purpose of preventing or controlling disease, injury, or disability.

- Make disclosures that are required by other laws, including laws that require disclosures for public health purposes.³

- Information specific to Ohio can be accessed at this hyperlink: http://infosec.ohio.gov/Portals/0/Docs/GuidetotheHIPAAPrivacyRule.pdf
National Guidelines

The following guidelines for protecting tuberculosis (TB) patients’ confidentiality are adapted from the National Tuberculosis Controllers Association’s (NTCA’s) and Centers for Disease Control and Prevention’s (CDC’s) “Guidelines for the Investigation of Contacts of Persons with Infectious Tuberculosis: Recommendations from the National Tuberculosis Controllers Association and CDC” (MMWR 2005;54[No. RR-15]).

When necessary, use a consent form. To create a consent form, refer to CDC’s form “Example of an Authorization for Disclosure of Medical Record Information” at: https://www.cdc.gov/tb/education/ssmodules/pdfs/7.pdf.

Table 1: HOW TO PROTECT CONFIDENTIALITY

<table>
<thead>
<tr>
<th>Conducting All Activities</th>
<th>▪ Make every attempt to ensure patient confidentiality.</th>
</tr>
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<tbody>
<tr>
<td>Training</td>
<td>▪ Participate in training on maintaining confidentiality and obtaining informed consent in accordance with local/state laws.</td>
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<tr>
<td>Interviewing Patients</td>
<td>▪ Interview the tuberculosis (TB) patient in a private setting.</td>
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<td></td>
<td>▪ Inform the patient about confidentiality rights.</td>
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<td></td>
<td>▪ Explain to a human immunodeficiency virus (HIV)-infected patient that HIV status will be kept confidential.</td>
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<td></td>
<td>▪ Consult with the patient to identify boundaries for confidentiality and obtain oral consent for any breaches in confidentiality.</td>
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<td></td>
<td>▪ If written consent is required, present the consent form to the patient in an appropriate manner and retain a copy in the patient’s medical record. If consent is refused, the TB program should develop a plan of action.</td>
</tr>
<tr>
<td>Conducting Site Investigations</td>
<td>▪ Plan site investigation procedures in advance of any visit, in consultation with and with the consent of the index patient, if possible.</td>
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<td></td>
<td>▪ Obtain agreement to maintain confidentiality from any site personnel who receive information about the identity of the index patient.</td>
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<tr>
<td>Communicating with the Press</td>
<td>▪ Maintain confidentiality in communications with the press.</td>
</tr>
<tr>
<td>Breaching Confidentiality</td>
<td>▪ Breach confidentiality only with approval of TB program administrators and with the consent of the TB patient, when possible.</td>
</tr>
</tbody>
</table>
Resources and References

Resources

- CDC. “HIPAA Privacy Rule and Public Health: Guidance from CDC and the US Department of Health and Human Services” (MMWR 2003;52[S-2]). Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/su5201a1.htm.


References


4 State of Ohio HIPAA website; http://infosec.ohio.gov/Portals/0/Docs/GuidetotheHIPAAPrivacyRule.pdf