

Houston Department of Health and Human Services
Bureau of Epidemiology Disease Reporting Packet – 2014

Dear Provider,

Thank you for inquiring about reporting to the Bureau of Epidemiology at the Houston Department of Health and Human Services. Timely reporting allows that Health Department to respond to and control potential disease outbreaks. Reporting also allows the Health Department to monitor disease trends in Houston.

The form (Morbidity Report Form) used to report most diseases to the Bureau of Epidemiology at the City of Houston Department of Health and Human Services is included in this packet. This form may be faxed to 832-393-5232. You may also call 832-393-5080, Monday to Friday between 8am to 5pm. This same number serves as our 24/7 Epidemiology on-call line. You may call this number outside of normal business hours to report diseases requiring immediate attention. Attached is the Texas Notifiable Conditions List.

In addition to the Morbidity Report Form, this packet also includes the STD and HIV reporting forms. These forms may be faxed to 832-393-5230. Please do not fax any report form indicating HIV/AIDS status. These can be mailed to:

Houston Department of Health and Human Services
8000 North Stadium
4th Floor Epidemiology
Houston, TX 77054

Thank you for your assistance,



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Division Director, Office of Surveillance and Public Health Preparedness

Houston Department of Health and Human Services

24/7/365 Disease Reporting Number

832-393-5080

For non-emergencies: call between 8am and 5pm from Monday to Friday. Diseases not requiring immediate attention can be faxed to 832-393-5232. Do not fax HIV/AIDS status information.

Helpful Websites:

Houston Department of Health and Human Services, Epidemiology and Disease Reporting

<http://www.houstontx.gov/health/Epidemiology/index.html>

Texas Department of State Health Services, Infectious Disease Home page

<https://www.dshs.state.tx.us/idcu/>

CDC HIPAA Privacy Rule Guidance

http://www.cdc.gov/nhsn/faqs/FAQ_HIPPARules.html

Several Texas laws (Health & Safety Code, Chapter 81, 84, and 87) require specific information regarding notifiable conditions be provided to the Texas Department of State Health Services (DSHS). Health care providers, hospitals, laboratories, schools, and others are required to report patients who are suspected of having a notifiable condition (Chapter 97, Title 25, Texas Administrative Code).

2014 Summary of Changes in the Texas Administrative Code

Regarding Notifiable Conditions

Newly reportable in 2014 (not notifiable in the 2013):

- Carbapenem-resistant Enterobacteriaceae
- Multi-drug resistant Acinetobacter

*See Multi-drug resistant organisms (MDRO). CRE and MDR-A reporting is covered and encouraged as a rare or exotic disease and will be specified by Texas Administrative Code (TAC) rule with an estimated effective date of April, 2014.

Renamed:

Severe acute respiratory syndrome (SARS) is now called Novel Coronavirus Causing Severe Respiratory Disease

The following are not notifiable (unless they meet the inclusion criteria of a reportable disease including outbreaks, exotic diseases, and unusual expression of disease) and their case definition is included in the 2014 EpiCase Criteria for ease of access to their case definition:

- Influenza, human isolates
- Norovirus
- Staphylococcus aureus, coagulase-positive, methicillin-or oxacillin-resistant (MRSA)
- Streptococcal toxic-shock syndrome

Texas Notifiable Conditions

24/7 Number for Immediately Reportable – 1-800-705-8868

Report confirmed and suspected cases.

Unless noted by *, report to your local or regional health department using number above or find contact information at <http://www.dshs.state.tx.us/idcu/investigation/conditions/contacts/>



A – I	When to Report	I – Y	When to Report
*Acquired immune deficiency syndrome (AIDS) ^{1,2}	Within 1 week	Influenza, Novel ²	Call Immediately
Amebiasis ³	Within 1 week	*Lead, child blood, any level & adult blood, any level ⁴	Call/Fax Immediately
Amebic meningitis and encephalitis ³	Within 1 week	Legionellosis ³	Within 1 week
Anaplasmosis ³	Within 1 week	Leishmaniasis ³	Within 1 week
Anthrax ^{3,5}	Call Immediately	Listeriosis ^{3,5}	Within 1 week
Arbovirus infection ^{3,6}	Within 1 week	Lyme disease ³	Within 1 week
*Asbestosis ⁷	Within 1 week	Malaria ³	Within 1 week
Babesiosis ³	Within 1 week	Measles (rubeola) ³	Call Immediately
*Botulism (adult and infant) ^{3,5,8}	Call Immediately	Meningococcal infections, invasive ^{3,5}	Call Immediately
Brucellosis ^{3,5}	Within 1 work day	Multi-drug resistant <i>Acinetobacter</i> (MDR-A) ^{9,10}	Call Immediately
Campylobacteriosis ³	Within 1 week	Mumps ³	Within 1 week
*Cancer ¹¹	See rules ¹¹	Pertussis ³	Within 1 work day
Carbapenem resistant <i>Enterobacteriaceae</i> (CRE) ^{9,12}	Call Immediately	*Pesticide poisoning, acute occupational ¹³	Within 1 week
Chagas' disease ³	Within 1 week	Plague (<i>Yersinia pestis</i>) ^{3,5}	Call Immediately
*Chancroid ³	Within 1 week	Poliomyelitis, acute paralytic ³	Call Immediately
Chickenpox (varicella) ¹⁴	Within 1 week	Poliovirus infection, non-paralytic ³	Within 1 work day
* <i>Chlamydia trachomatis</i> infection ³	Within 1 week	Q fever ³	Within 1 work day
*Contaminated sharps injury ¹⁵	Within 1 month	Rabies, human ³	Call Immediately
*Controlled substance overdose ¹⁶	Call Immediately	Relapsing fever ³	Within 1 week
Creutzfeldt-Jakob disease (CJD) ³	Within 1 week	Rubella (including congenital) ³	Within 1 work day
Coronavirus, novel causing severe acute respiratory disease ^{3,17}	Call Immediately	Salmonellosis, including typhoid fever ³	Within 1 week
Cryptosporidiosis ³	Within 1 week	Shigellosis ³	Within 1 week
Cyclosporiasis ³	Within 1 week	*Sillcosis ¹⁸	Within 1 week
Cysticercosis ³	Within 1 week	Smallpox ³	Call Immediately
*Cytogenetic results (fetus and infant only) ¹⁹	See rules ¹⁹	*Spinal cord injury ²⁰	Within 10 work days
Dengue ³	Within 1 week	Spotted fever group rickettsioses ³	Within 1 week
Diphtheria ³	Call Immediately	<i>Staph. aureus</i> , vancomycin-resistant (VISA and VRSA) ^{3,5}	Call Immediately
*Drowning/near drowning ²⁰	Within 10 work days	Streptococcal disease (group A, B, <i>S. pneumoniae</i>), invasive ³	Within 1 week
Ehrlichiosis ³	Within 1 week	*Syphilis – primary and secondary stages ^{1,21}	Within 1 work day
<i>Escherichia coli</i> infection, Shiga toxin-producing ^{3,5}	Within 1 week	*Syphilis – all other stages ^{1,21}	Within 1 week
*Gonorrhea ³	Within 1 week	<i>Taenia solium</i> and undifferentiated <i>Taenia</i> infection ³	Within 1 week
<i>Haemophilus influenzae</i> type b infections, invasive ³	Within 1 week	Tetanus ³	Within 1 week
Hansen's disease (leprosy) ³	Within 1 week	*Traumatic brain injury ²⁰	Within 10 work days
Hantavirus infection ³	Within 1 week	Trichinosis ³	Within 1 week
Hemolytic Uremic Syndrome (HUS) ³	Within 1 week	Tuberculosis (includes all <i>M. tuberculosis</i> complex) ^{3,22}	Within 1 work day
Hepatitis A (acute) ³	Within 1 work day	Tularemia ^{3,5}	Call Immediately
Hepatitis B, C, and E (acute) ³	Within 1 week	Typhus ³	Within 1 week
Hepatitis B identified prenatally or at delivery (acute & chronic) ³	Within 1 week	<i>Vibrio</i> infection, including cholera ^{3,5}	Within 1 work day
Hepatitis B, perinatal (HBsAg+ < 24 months old) ³	Within 1 work day	Viral hemorrhagic fever, including Ebola ³	Call Immediately
*Human immunodeficiency virus (HIV) infection ^{1,2}	Within 1 week	Yellow fever ³	Call Immediately
Influenza-associated pediatric mortality ³	Within 1 work day	Yersiniosis ³	Within 1 week

In addition to specified reportable conditions, any outbreak, exotic disease, or unusual group expression of disease that may be of public health concern should be reported by the most expeditious means available.

*See condition-specific footnote for reporting contact information

- Please refer to specific rules and regulations for HIV/STD reporting and who to report to at: <http://www.dshs.state.tx.us/hivstd/healthcare/reporting.shtm>.
- Labs conducting confirmatory HIV testing are requested to send remaining specimen to a CDC-designated laboratory. Please call 512-533-3132 for details.
- Reporting forms are available at <http://www.dshs.state.tx.us/idcu/investigation/forms/> and investigation forms at <http://www.dshs.state.tx.us/idcu/investigation/>. Call as indicated for immediately reportable conditions.
- For reporting information see <http://www.dshs.state.tx.us/lead/default.shtm>.
- Lab isolate must be sent to DSHS lab. Call 512-776-7598 for specimen submission information.
- Reportable Arbovirus infections include neuroinvasive and non-neuroinvasive California serogroup including Cache Valley and La Crosse, Eastern Equine (EEE), Dengue, Powassan, St. Louis Encephalitis (SLE), West Nile, and Western Equine (WEE).
- For reporting information see <http://www.dshs.state.tx.us/epitox/asbestos.shtm>.
- Report suspected botulism immediately by phone to 888-963-7111.
- CRE and MDR-A reporting is covered and encouraged as a rare or exotic disease and will be specified by Texas Administrative Code (TAC) rule with an estimated effective date of April 1, 2014. See proposed amendments at <http://www.sos.state.tx.us/texreg/pdf/backview/1206/1206prop.pdf>, 25 TAC §§97.1, 97.3, 97.4, 97.7.
- See additional reporting information at http://www.dshs.state.tx.us/IDCU/health/antibiotic_resistance/MDR-A-Reporting.doc.
- Please refer to specific rules and regulations for cancer reporting and who to report to at <http://www.dshs.state.tx.us/ctr/reporting.shtm>.
- See additional reporting information at http://www.dshs.state.tx.us/IDCU/health/antibiotic_resistance/Reporting-CRE.doc.
- For reporting information see <http://www.dshs.state.tx.us/epitox/Pesticide-Exposure/#reporting>.
- Call your local health department for a copy of the Varicella Reporting Form with their fax number. The Varicella (chickenpox) Reporting Form should be used instead of an Epi-1 or Epi-2 morbidity report.
- Not applicable to private facilities. Initial reporting forms for Contaminated Sharps at http://www.dshs.state.tx.us/idcu/health/infection_control/bloodborne_pathogens/reporting/.
- Contact local poison center at 1-800-222-1222. For instructions, see <http://www.dshs.state.tx.us/epidemiology/epipolison.shtm#rcsa>.
- Novel coronavirus causing severe acute respiratory disease includes previously reportable Severe Acute Respiratory Syndrome (SARS).
- For reporting information see <http://www.dshs.state.tx.us/epitox/sillcosis.shtm>.
- Report cytogenetic results, including routine karyotype and cytogenetic microarray testing (fetus and infant only). Please refer to specific rules and regulations for birth defects reporting and who to report to at http://www.dshs.state.tx.us/birthdefects/BD_LawRules.shtm.
- Please refer to specific rules and regulations for Injury reporting and who to report to at <http://www.dshs.state.tx.us/injury/rules.shtm>.
- Laboratories should report syphilis test results within 3 work days of the testing outcome.
- MTB complex includes *M. tuberculosis*, *M. bovis*, *M. africanum*, *M. canettii*, *M. microti*, *M. caprae*, and *M. pinnipedii*. See rules at <http://www.dshs.state.tx.us/idcu/disease/tb/reporting/>.

Texas Department of State Health Services – Business Hours 1-800-252-8239 / After Hours 888-963-7111



MORBIDITY REPORT FORM

Houston Department of Health and Human Services
8000 Nodh Stadium Drive Houston, Texas 77054

832-393-5080

Fax: (832)393-5232 [Do NOT fax HIV/AIDS-related patient information]



Reported By : _____ Date : _____

Case Number : _____

PATIENT DEMOGRAPHIC DATA

Last Name : _____ FirstName & MI : _____

DOB : _____ Age : _____ Sex : _____

Race/Ethnicity : _____ SocSecNumber : _____

Address : _____

City, Zipcode : _____ Home Phone : () --

Occupation/Work Place : _____ Tel: () --

School/Day Care Center : _____ Tel: () --

Parent/Contact Person : _____ Tel: () --

DISEASE DATA

Date of Onset: _____

REPORTABLE DISEASE/ORGANISM: _____

Species/serotype : _____

Source of Specimen	Date of Collection	Diagnostic test and Result	Source of Specimen	Date of Collection	Diagnostic test and Result
Specific Viral Hepatitis Studies		Anti-HAV IgM _____ Anti-HAV Total _____	Anti-HBc IgM _____ Anti-HBc Total _____ Anti-HBs _____ HbsAg _____ HbeAg _____	Anti-HCV _____ HCV RIBA _____ HCV RNA by PCR _____	AST/SGOT _____ ALT/SGPT _____

HOSPITAL or CLINIC DATA

Hospital/Clinic : _____ Attending Physician : _____

Medical RecNumber : _____ Address : _____

Date Admitted : _____

Date Discharged : _____ Pager/Phone : _____

Date Expired : _____ Other Physician : _____

Comments/patient history/risk factors:

Investigator: _____

FOR OFFICIAL USE ONLY

FILENO:	RPTBY :	HSA:	INTRV :	STATUS :
KMAP :	CENRCT:	DX :	OCCUP:	

CONFIDENTIAL STD MORBIDITY REPORT FORM



Houston Department of Health and Human Services
 ATTN: Bureau of Epidemiology – STD Surveillance 4th floor
 8000 North Stadium Drive Houston, Texas 77054
 Tel: (832)393-5080 Fax: (832)393-5233



Reported by: _____

Facility/Clinic: _____

Phone Number: _____

Date: _____

PATIENT DEMOGRAPHIC DATA

Last Name _____	First Name, MI _____	Sex _____	
DOB _____	Social Security # _____		
Race _____	Hispanic <input type="checkbox"/> Y <input type="checkbox"/> N		
Address _____	Home Phone () --		
City, State Zipcode _____	Other Phone () --		
Emergency Contact Name _____	Contact Phone () --		
Marital Status <input type="checkbox"/> Single <input type="checkbox"/> Married <input type="checkbox"/> Divorced <input type="checkbox"/> Widowed <input type="checkbox"/> Unknown			
Pregnancy Status <input type="checkbox"/> N/A <input type="checkbox"/> No <input type="checkbox"/> Yes (Expected delivery date ___/___/___) <input type="checkbox"/> Unknown (Last menstrual date ___/___/___)			
Reason for Test (STD related, prenatal, immigration, etc): _____			

DISEASE DATA

Check Reportable Disease(s)

Syphilis
 Gonorrhea
 Chlamydia
 Chancroid

List Signs and Symptoms: _____

Check Voluntary Disease(s)

Genital Herpes
 Genital Warts
 Non-specific Urethritis
 Pelvic Inflammatory Disease
 Trichomoniasis
 Other non-specific Vaginitis
 Mucopurulent Cervicitis
 Other _____

LABORATORY DATA

Date of Collection/Test	Diagnostic Test	Results	Laboratory

TREATMENT INFORMATION

Prior History of Treatment Yes No Unknown Date of Previous Treatment ___/___/___

Method of Prior Treatment _____

CURRENT TREATMENT INFORMATION:

Date (s) of Treatment	Method of Treatment / Dose	Provider

Notes/Comments/Patient History/Risk Factors:

Laboratory Data

HIV Antibody Test at Diagnosis (Indicate first test)

HIV-1 IFA	<input type="checkbox"/> Positive	<input type="checkbox"/> Negative	<input type="checkbox"/> Indeterminate
HIV-1 Western Blot	<input type="checkbox"/> Positive	<input type="checkbox"/> Negative	<input type="checkbox"/> Indeterminate
Rapid	<input type="checkbox"/> Positive	<input type="checkbox"/> Negative	<input type="checkbox"/> Indeterminate
HIV-1 EIA	<input type="checkbox"/> Positive	<input type="checkbox"/> Negative	<input type="checkbox"/> Indeterminate
HIV-1/2 EIA	<input type="checkbox"/> Positive	<input type="checkbox"/> Negative	<input type="checkbox"/> Indeterminate
HIV 2 EIA	<input type="checkbox"/> Positive	<input type="checkbox"/> Negative	<input type="checkbox"/> Indeterminate
HIV-2 Western Blot	<input type="checkbox"/> Positive	<input type="checkbox"/> Negative	<input type="checkbox"/> Indeterminate
HIV-1/2 Ag/Ab	<input type="checkbox"/> Positive	<input type="checkbox"/> Negative	<input type="checkbox"/> Indeterminate

Collection Date (mm/dd/yyyy) _____

HIV Detection Test (Record all tests)

HIV-1 P24 Antigen	<input type="checkbox"/> Positive	<input type="checkbox"/> Negative	<input type="checkbox"/> Indeterminate
HIV-1 Qualitative PCR (NAAT)	<input type="checkbox"/> Positive	<input type="checkbox"/> Negative	<input type="checkbox"/> Indeterminate
HIV-1 Proviral DNA (Qualitative)	<input type="checkbox"/> Positive	<input type="checkbox"/> Negative	<input type="checkbox"/> Indeterminate
Other _____	<input type="checkbox"/> Positive	<input type="checkbox"/> Negative	<input type="checkbox"/> Indeterminate

Collection Date (mm/dd/yyyy) _____

Immunologic Lab Tests

AT or closest to current diagnosis status	CD4 Counts _____ cells/ul
CD4 Percent _____ %	
First <200 L or <14%	CD4 Counts _____ cells/ul
CD4 Percent _____ %	

Collection Date (mm/dd/yyyy) _____

Viral Load Tests (Most recent test)

	Copies/ul	Log
HIV-1 RNA NASBA	_____	_____
HIV-1 RNA RT-PCR	_____	_____
HIV-1 RNA bDNA	_____	_____

Collection Date (mm/dd/yyyy) _____

Last documented negative HIV test? Date _____ / _____ / _____

Test Type _____

If HIV laboratory test not documented, is HIV diagnosis documented by a physician? Yes No Unknown If Yes, Date _____ / _____ / _____

Clinical

AIDS Indicator Diseases (O. I.)

Others

Clinical Record Reviewed: Yes No

	Def	Pres	Initial Date
O. I. _____	<input type="checkbox"/>	<input type="checkbox"/>	_____/_____/_____
O. I. _____	<input type="checkbox"/>	<input type="checkbox"/>	_____/_____/_____
O. I. _____	<input type="checkbox"/>	<input type="checkbox"/>	_____/_____/_____
O. I. _____	<input type="checkbox"/>	<input type="checkbox"/>	_____/_____/_____
O. I. _____	<input type="checkbox"/>	<input type="checkbox"/>	_____/_____/_____

For M. tuberculosis, pulmonary, RVCT Case Number: _____

Enter date patient was diagnosed as:

Asymptomatic: _____ / _____ / _____

Symptomatic (not AIDS): _____ / _____ / _____

If HIV tests were not positive or were not done, does the patient have an immunodeficiency that would disqualify him/her from AIDS case definition? Yes No Unknown.

Treatment / Services Referrals

Has this patient been informed of his/her infection? Yes No Unknown

This patient's partners will be notified about their HIV exposure and counseled by: Health Department Physician/Provider Patient Unknown

This patient is receiving or has been referred for HIV related medical services: Yes No N/A Unknown

This patient is receiving or has been referred for substance abuse treatment services: Yes No N/A Unknown

This patient received or is receiving antiretroviral therapy (ART): Yes No Unknown

This patient received or is receiving PCP prophylaxis: Yes No N/A Unknown

For Women

This patient is receiving or has been referred for gynecological or obstetrical services: Yes No Unknown

Is this patient currently pregnant? Yes No Unknown

Has this patient delivered live-born infants? Yes No Unknown (If yes, provide birth info below)

Child's Name: _____ Child's State ID Number: _____ Child's Date of Birth: _____ / _____ / _____

Child's Hospital of Birth: _____ City: _____ State: _____ County: _____ Country: _____

Child's Name: _____ Child's State ID Number: _____ Child's Date of Birth: _____ / _____ / _____

Child's Hospital of Birth: _____ City: _____ State: _____ County: _____ Country: _____

Testing and Treatment History (TTH)

Completion Method: Patient Interview MRR Provider Report PEMS Other Date information is collected: _____ / _____ / _____

EVER had previous positive HIV test? Yes No Refused Unk Date of very first positive HIV test: _____ / _____ / _____

EVER had a negative HIV test? Yes No Refused Unk Date of very last negative HIV test: _____ / _____ / _____

Number of negative HIV tests within 24 months before first positive _____ Refused Unk

(Dates of negative tests: _____ / _____ / _____; _____ / _____ / _____; _____ / _____ / _____)

Ever taken any ARV? Yes No Refused Unk If yes, list all ARV: _____ Date 1st use: _____ / _____ / _____ Date of last use: _____ / _____ / _____

Local Fields (For Office Use Only)

Lab Name of first HIV positive test: _____ Specimen Accession # of first positive test: _____ Collection date: _____ / _____ / _____

Field Record cut for PHFU: Yes (cut by HIV surveillance staff) Date FR cut _____ / _____ / _____ Other (cut by others) No

DISCLOSURES FOR PUBLIC HEALTH ACTIVITIES
[45 CFR 164.512(b)]

Background

The HIPAA Privacy Rule recognizes the legitimate need for public health authorities and others responsible for ensuring public health and safety to have access to protected health information to carry out their public health mission. The Rule also recognizes that public health reports made by covered entities are an important means of identifying threats to the health and safety of the public at large, as well as individuals. Accordingly, the Rule permits covered entities to disclose protected health information without authorization for specified public health purposes.

How the Rule Works

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).

Frequently Asked Questions

To see Privacy Rule FAQs, click the desired link below:

[FAQs on Public Health Uses and Disclosures](#)

[FAQs on ALL Privacy Rule Topics](#)

(You can also go to http://answers.hhs.gov/cgi-bin/hhs.cfg/php/enduser/std_alp.php, then select "Privacy of Health Information/HIPAA" from the Category drop down list and click the Search button.)