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**TITLE 410 INDIANA STATE DEPARTMENT OF
HEALTH**

Proposed Rule
LSA Document #03-4

DIGEST

Amends 410 IAC 1-2.3-47 and 410 IAC 1-2.3-48 and adds 410 IAC 1-2.3-97.5 governing the reporting and control measures of communicable disease to add smallpox and complications related to vaccinations for smallpox. Effective 30 days after filing with the secretary of state.

410 IAC 1-2.3-47

410 IAC 1-2.3-48

410 IAC 1-2.3-97.5

SECTION 1. 410 IAC 1-2.3-47 IS AMENDED TO READ AS FOLLOWS:

410 IAC 1-2.3-47 Reporting requirements for physicians and hospital administrators

Authority: IC 16-41-2-1

Affected: IC 4-22-2-37.1; IC 16-21; IC 16-41-2-8; IC 25-22.5

Sec. 47. (a) It shall be the duty of each physician licensed under IC 25-22.5, and each administrator of a hospital licensed under IC 16-21, or the administrator's representative, to report all cases, and suspected cases of the diseases listed in subsection (d). Reporting of specimen results by a laboratory to health officials does not nullify the physician's or administrator's obligations to report said case.

(b) The report required by subsection (a) shall be made to the local health officer in whose jurisdiction the patient was examined at the time the diagnosis was made or suspected. If the patient is a resident of a different jurisdiction, the local health jurisdiction receiving the report shall forward the report to the local health jurisdiction where the patient resides. If a person who is required to report is unable to make a report to the local health officer within the time mandated by this rule, a report shall be made directly to the department within the time mandated by this rule.

(c) Any reports of diseases required by subsection (a) shall include the following:

(1) The patient's:

- (A) full name;
- (B) street address;
- (C) city;
- (D) zip code;
- (E) county of residence;
- (F) telephone number;
- (G) age or date of birth;
- (H) sex; and
- (I) race and ethnicity, if available.

(2) Date of onset.

(3) Diagnosis.

(4) Definitive diagnostic test results (for example, culture, IgM, serology, or Western Blot).

(5) Name, address, and telephone number of the attending physician.

(6) Other epidemiologically necessary information requested by the local health officer or the commissioner.

(7) Persons who are tested anonymously at a counseling and testing site cannot be reported using personal identifiers; rather, they are to be reported using a numeric identifier code. Age, race, sex, risk factors, and county of residence shall also be reported.

(8) Name, address, and telephone number of person completing report.

(d) The dangerous communicable diseases and conditions described in this subsection shall be reported within the time specified. Diseases or conditions that are to be reported immediately to the local health officer shall be reported by telephone or other instantaneous means of communication on first knowledge or suspicion of the diagnosis. Diseases that are to be reported within seventy-two (72) hours shall be reported to the local health officer within seventy-two (72) hours of first knowledge or suspicion of the diagnosis by telephone, electronic data transfer, other confidential means of communication, or official report forms furnished by the department. During evening, weekend, and holiday hours, those required to report should report diseases required to be immediately reported to the after-hours duty officer at the local health department. If unable to contact the after-hours duty officer locally, or one has not been designated locally, those required to report shall file their reports with the after-hours duty officer at the department at (317) 233-1325 or (317) 233-8115.

DANGEROUS COMMUNICABLE DISEASES AND CONDITIONS

Disease	When to Report (from probable diagnosis)	Disease Intervention Methods (section in this rule)
Acquired immunodeficiency syndrome	See HIV Infection/Disease	Sec. 76
Animal bites	Within 24 hours	Sec. 52
Anthrax	Immediately	Sec. 53
Babesiosis	Within 72 hours	Sec. 54
Botulism	Immediately	Sec. 55
Brucellosis	Within 72 hours	Sec. 56
Campylobacteriosis	Within 72 hours	Sec. 57
Chancroid	Within 72 hours	Sec. 58
Chlamydia trachomatis, genital infection	Within 72 hours	Sec. 59
Cholera	Immediately	Sec. 60
Cryptosporidiosis	Within 72 hours	Sec. 61
Cyclospora	Within 72 hours	Sec. 62
Diphtheria	Immediately	Sec. 63
Ehrlichiosis	Within 72 hours	Sec. 64
Encephalitis, arboviral, Calif. EEE, WEE, SLE, West Nile	Immediately	Sec. 65
Escherichia coli, infection (including E. coli 0157:H7 and other enterohemorrhagic types)	Immediately	Sec. 66
Gonorrhea	Within 72 hours	Sec. 67
Granuloma inguinale	Within 72 hours	Sec. 68
Haemophilus influenzae invasive disease	Immediately	Sec. 69
Hansen's disease (leprosy)	Within 72 hours	Sec. 70
Hantavirus pulmonary syndrome	Immediately	Sec. 71
Hemolytic uremic syndrome, postdiarrheal	Immediately	Sec. 66
Hepatitis, viral, Type A	Immediately	Sec. 72
Hepatitis, viral, Type B	Within 72 hours	Sec. 73
Hepatitis, viral, Type B, pregnant woman (acute and chronic), or perinatally exposed infant	Immediately (when discovered at or close to time of birth)	Sec. 73
Hepatitis, viral, Type C (acute)	Within 72 hours	Sec. 74
Hepatitis, viral, Type Delta	Within 72 hours	Sec. 73
Hepatitis, viral, unspecified	Within 72 hours	
Histoplasmosis	Within 72 hours	Sec. 75
HIV infection/disease	Within 72 hours	Sec. 76
HIV infection/disease, pregnant woman, or perinatally exposed infant	Immediately (when discovered at or close to time of birth)	Sec. 76
Legionellosis	Within 72 hours	Sec. 77

Leptospirosis	Within 72 hours	Sec. 78
Listeriosis	Within 72 hours	Sec. 79
Lyme disease	Within 72 hours	Sec. 80
Lymphogranuloma venereum	Within 72 hours	Sec. 81
Malaria	Within 72 hours	Sec. 82
Measles (rubeola)	Immediately	Sec. 83
Meningitis, aseptic	Within 72 hours	Sec. 84
Meningococcal disease, invasive	Immediately	Sec. 85
Mumps	Within 72 hours	Sec. 86
Pertussis	Immediately	Sec. 88
Plague	Immediately	Sec. 89
Poliomyelitis	Immediately	Sec. 90
Psittacosis	Within 72 hours	Sec. 91
Q Fever	Immediately	Sec. 92
Rabies in humans or animals (confirmed and suspect animal with human exposure)	Immediately	Sec. 93
Rabies, postexposure treatment	Within 72 hours	Secs. 93 and 52
Rocky Mountain spotted fever	Within 72 hours	Sec. 94
Rubella (German measles)	Immediately	Sec. 95
Rubella congenital syndrome	Immediately	Sec. 95
Salmonellosis, other than typhoid fever	Within 72 hours	Sec. 96
Shigellosis	Immediately	Sec. 97
Smallpox (variola infection)	Immediately	Sec. 97.5
Adverse events or complications due to smallpox vaccination (vaccinia virus infection) or secondary transmission to others after vaccination. This includes accidental implantation at sites other than the vaccination site, secondary bacterial infections at vaccination site, vaccinia keratitis, eczema vaccinatum, generalized vaccinia, congenital vaccinia, progressive vaccinia, vaccinia encephalitis, death due to vaccinia complications, and other complications requiring significant medical intervention.	Immediately	Sec. 97.5
Staphylococcus aureus, Vancomycin resistance level of MIC $\geq$ 8 μ g/mL	Immediately	Sec. 98
Streptococcus pneumoniae, invasive disease, and antimicrobial resistance pattern	Within 72 hours	Sec. 99
Streptococcus, Group A, invasive disease	Within 72 hours	Sec. 100
Streptococcus, Group B, invasive disease	Within 72 hours	Sec. 101
Syphilis	Within 72 hours	Sec. 102
Tetanus	Within 72 hours	Sec. 103
Toxic shock syndrome (streptococcal or staphylococcal)	Within 72 hours	Sec. 104
Trichinosis	Within 72 hours	Sec. 105
Tuberculosis, cases and suspects	Within Within 72 hours	Sec. 106
Tularemia	Immediately	Sec. 107
Typhoid fever, cases and carriers	Immediately	Sec. 108
Typhus, endemic (flea borne)	Within 72 hours	Sec. 109
Varicella, resulting in hospitalization or death	Within 72 hours	Sec. 110
Yellow fever	Within 72 hours	Sec. 111
Yersiniosis	Within 72 hours	Sec. 112
DANGEROUS BUT NOT COMMUNICABLE DISEASES AND CONDITIONS OF PUBLIC HEALTH SIGNIFICANCE		
	When to Report	Disease Intervention
Disease and Condition	(from probable diagnosis)	Methods
Pediatric venous blood lead > 10 μ g/dl in children less than or equal to 6 years of age	Within 1 week	Sec. 87

(e) Reporting of HIV infection/disease shall include classification as defined in the CDC Morbidity and Mortality Weekly Report, Volume 41, No. RR-17, 1993 Revised Classification System for HIV Infection and Expanded Surveillance Case Definition for AIDS among Adolescents and Adults. Reporting of HIV infection/disease in children less than thirteen (13) years of age shall include classification as defined in the CDC Morbidity and Mortality Weekly Report, Volume 43, No. RR-12, 1994 Revised Classification System for Human Immunodeficiency Virus Infection in Children Less Than 13 Years of Age. Supplemental reports shall be provided by the physician when an individual's classification changes. The CD4+ T-lymphocyte count and percentage, or viral load count, or both, shall be included with both initial and supplemental reports.

(f) The department, under the authority of IC 4-22-2-37.1, may adopt emergency rules to include mandatory reporting of emerging infectious diseases. Reports shall include the information specified in ~~section 47(c)~~ **subsection (c)** of this rule.

(g) Outbreaks of any of the following shall be reported immediately upon suspicion:

- (1) Any disease required to be reported under this section.
- (2) Diarrhea of the newborn (in hospitals or other institutions).
- (3) Foodborne or waterborne diseases in addition to those specified by name in this rule.
- (4) Streptococcal illnesses.
- (5) Conjunctivitis.
- (6) Impetigo.
- (7) Nosocomial disease within hospitals and health care facilities.
- (8) Influenza-like illness.
- (9) Unusual occurrence of disease.
- (10) Any disease (that is, anthrax, plague, tularemia, Brucella species, smallpox, or botulinum toxin) or chemical illness that is considered a bioterrorism threat, importation, or laboratory release.

(h) Failure to report constitutes a Class A infraction as specified by IC 16-41-2-8. (*Indiana State Department of Health; 410 IAC 1-2.3-47; filed Sep 11, 2000, 1:36 p.m.; 24 IR 339*)

SECTION 2. 410 IAC 1-2.3-48 IS AMENDED TO READ AS FOLLOWS:

410 IAC 1-2.3-48 Laboratories; reporting requirements

Authority: IC 16-41-2-1

Affected: IC 16-41-2-8

Sec. 48. (a) Each director, or the director's representative, of a medical laboratory in which examination of any specimen derived from the human body yields microscopic, bacteriologic, immunologic, serologic, or other evidence of infection by any of the organisms or agents listed in ~~section 48(d)~~ **subsection (d)** shall report such findings and any other epidemiologically necessary information requested by the department. HIV serologic results of tests performed anonymously in conjunction with the operation of a counseling and testing site registered with the department shall not be identified by name of patient, but by a numeric identifier code; for appropriate method to report such results, see subsection (b).

(b) The report required by subsection (a) shall, at a minimum, include the following:

- (1) Name, date, results of test performed, the laboratory's normal limits for that test, and the laboratory's interpretation of the test results.
- (2) Name of person and date of birth or age from whom specimen was obtained.
- (3) Name, address, and telephone number of attending physician, hospital, clinic, or other specimen submitter.
- (4) Name, address, and telephone number of the laboratory performing the test.

(c) This subsection does not preclude laboratories from testing specimens, which, when submitted to the laboratory, are identified by a numeric identifier code and not by name of patient. If testing of such a specimen, identified by numeric code, produces results that are required to be reported under this rule, the laboratory shall submit a report that includes the following:

- (1) Numeric identifier code, date, and results of tests performed.
- (2) Name and address of attending physician, hospital, clinic, or other.
- (3) Name and address of the laboratory performing the test.

(d) Laboratory findings demonstrating evidence of the following infections, diseases, or conditions shall be reported at least weekly to the department:

(1) Arboviruses, including, but not limited to, the following:

- (A) St. Louis.
- (B) California group.
- (C) Eastern equine.
- (D) Western equine.
- (E) West Nile.
- (F) Japanese B.
- (G) Yellow fever.

(2) Babesia species.

(3) Bacillus anthracis.

(4) Bordetella pertussis.

(5) Borrelia burgdorferi.

(6) Brucella species.

(7) Calymmatobacterium granulomatis.

(8) Campylobacter species.

(9) Chlamydia psittaci.

(10) Chlamydia trachomatis.

(11) Clostridium botulinum.

(12) Clostridium perfringens.

(13) Clostridium tetani.

(14) Corynebacterium diphtheriae.

(15) Coxiella burnetii.

(16) Cryptococcus neoformans.

(17) Cryptosporidium parvum.

(18) Cyclospora cayetanensis.

(19) Ehrlichia chaffeensis.

(20) Ehrlichia phagocytophila.

(21) Enteroviruses (coxsackie, echo, polio).

(22) Escherichia coli infection (including E. coli 0157:H7 and other enterohemorrhagic types).

(23) Francisella tularensis.

(24) Haemophilus ducreyi.

(25) Hantavirus.

(26) Hepatitis viruses:

(A) anti-HAV IgM;

(B) HbsAg or HbeAg or anti-HBc IgM;

(C) RIBA or RNA or Anti-HCV, or any combination;

(D) Delta.

(27) Haemophilus influenzae, invasive disease.

(28) Histoplasmosis capsulatum.

(29) HIV and related retroviruses.

(30) Influenza.

(31) Kaposi's sarcoma (biopsies).

(32) Legionella species.

(33) Leptospira species.

(34) Listeria monocytogenes.

(35) Measles virus.

(36) Mumps virus.

(37) Mycobacterium tuberculosis.

(38) Neisseria gonorrhoeae.

(39) Neisseria meningitidis, invasive.

(40) Pediatric blood lead tests (capillary and venous) equal to or greater than 10 µg/dl on children less than or equal to six (6) years of age.

- (41) Plasmodium species.
- (42) Pneumocystis carinii.
- (43) Rabies virus (animal or human).
- (44) Rickettsia species.
- (45) Rubella virus.
- (46) Salmonella species.
- (47) Shigella species and antimicrobial resistance pattern.
- (48) Smallpox (variola) virus.**
- ~~(48)~~ **(49)** Staphylococcus aureus, Vancomycin resistance equal to or greater than 8 µg/mL.
- ~~(49)~~ **(50)** Streptococcus pneumoniae, invasive disease, and antimicrobial resistance pattern.
- ~~(50)~~ **(51)** Streptococcus Group A (Streptococcus pyogenes), invasive disease.
- ~~(51)~~ **(52)** Streptococcus Group B, invasive disease.
- ~~(52)~~ **(53)** Treponema pallidum.
- ~~(53)~~ **(54)** Trichinella spiralis.
- ~~(54)~~ **(55)** Vibrio species.
- ~~(55)~~ **(56)** Yersinia species, including pestis, enterocolitica, and pseudotuberculosis.

(e) Laboratories may also report to the local health officer, but any such local report shall be in addition to reporting to the department. A laboratory may report by electronic data transfer, telephone, or other confidential means of communication. In lieu of electronic data transfer or reporting by telephone, a laboratory may submit a legible copy of the laboratory report, provided that the information specified in subsection (b) appears thereon. Whenever a laboratory submits a specimen, portion of a specimen, or culture to the department laboratory resource center for confirmation, phage typing, or other service, these reporting requirements will be deemed to have been fulfilled, provided that the minimum information specified in subsection (b) accompanies the specimen or culture.

(f) Laboratories shall submit all isolates of the following organisms to the department's microbiology laboratory for further evaluation:

- (1) Haemophilus influenzae, invasive disease.
- (2) Neisseria meningitidis, invasive disease.
- (3) E. coli 0157:H7 or sorbitol-negative E. coli isolates.
- (4) Staphylococcus aureus, Vancomycin resistance equal to or greater than 8 µg/mL.
- (5) Mycobacterium tuberculosis.
- (6) Listeria monocytogenes.
- (7) Salmonella from any site.

(g) Quarterly report the total number of blood lead test (capillary and venous) performed on children six (6) ~~or less~~ years of age **or less**.

(h) Reporting by a laboratory, as required by this section, shall not:

- (1) constitute a diagnosis or a case report; and
- (2) be considered to fulfill the obligation of the attending physician or hospital to report.

~~(i) Failure to report constitutes a Class A infraction as specified by IC 16-41-2-8. (Indiana State Department of Health; 410 IAC 1-2.3-48; filed Sep 11, 2000, 1:36 p.m.; 24 IR 342)~~

SECTION 3. 410 IAC 1-2.3-97.5 IS ADDED TO READ AS FOLLOWS:

410 IAC 1-2.3-97.5 Smallpox; specific control measures

Authority: IC 16-41-2-1

Affected: IC 16-41-2; IC 16-41-9

Sec. 97.5. The control measures for smallpox are to:

- (1) begin an investigation immediately by the department in conjunction with the local health officer to determine the possible sources of infection;**

(2) trace contacts of the known case; and

(3) determine the extent of the outbreak.

(Indiana State Department of Health; 410 IAC 1-2.3-97.5)

Notice of Public Hearing

Under IC 4-22-2-24, notice is hereby given that on July 2, 2003 at 2:00 p.m., at the Indiana State Department of Health, 2 North Meridian Street, Rice Auditorium, Indianapolis, Indiana the Indiana State Department of Health will hold a public hearing on proposed amendments governing the reporting and control measures of communicable disease to add smallpox and complications related to vaccinations for smallpox. Copies of these rules are now on file at the Indiana State Department of Health, 2 North Meridian Street, Information Services and Policy Commission, Third Floor and Legislative Services Agency, One North Capitol, Suite 325, Indianapolis, Indiana and are open for public inspection.

Gregory A. Wilson, M.D.
State Health Commissioner
Indiana State Department of Health