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TITLE 410 INDIANA STATE DEPARTMENT OF HEALTH

Proposed Rule
LSA Document #05-189

DIGEST

Amends 410 IAC 1-2.3-47 and 410 IAC 1-2.3-48 to establish requirements for case management of a child with lead poisoning and delete the reporting and other requirements for blood lead levels from 410 IAC 1-2.3. Adds 410 IAC 29 to establish rules regarding the reporting, monitoring, and preventive procedures to protect from lead poisoning. Repeals 410 IAC 1-2.3-87. Effective 30 days after filing with the Secretary of State.

IC 4-22-2.1-5 Statement Concerning Rules Affecting Small Businesses

1. Estimate of the number of small businesses, classified by industry sector, that will be subject to the proposed rule.

The Indiana State Department of Health (ISDH) lists 120 laboratories that have recently reported blood lead tests to ISDH under current statute and rule. This number is greatly inflated by laboratories that have multiple listings. Most blood lead analyses are performed by a small number of major reference laboratories. ISDH does not believe that small businesses routinely perform these analyses.

2. Estimate of the average annual reporting, record keeping, and other administrative costs that small businesses will incur to comply with the proposed rule.

The proposed rule does not add any annual reporting, record keeping, or other administrative costs for small businesses to comply with the rule.

3. Estimate of the total annual economic impact that compliance with the proposed rule will have on all small businesses subject to the rule.

The proposed rule does not increase the economic impact on small businesses for complying with the blood lead reporting provisions.

4. Statement justifying any requirement or cost that is imposed on small businesses by the rule; and not expressly required by the statute authorizing the agency to adopt this rule of any other state or federal law.

Universal reporting of blood lead test results to ISDH is required by IC 16-41-39.4-3 and information required to be reported for blood lead tests is specified in the Communicable Disease Rule at 410 IAC 1-2.3-47. Electronic reporting of test data is required under IC 16-41-39.4-3 for laboratories that performed more than 50 tests in the previous calendar year. Data are used for epidemiology and for initiating case management service delivery where necessary. No additional requirement or cost to small businesses will result from this rule.

5. Regulatory Flexibility Analysis

A. Establishment of less stringent compliance or reporting requirements for small businesses.

The proposed rule combines the universal reporting requirement for blood lead test results under IC 16-41-39.4-3 with the information required to be reported for blood lead test results in the Communicable Disease Rule at 410 IAC 1-2.3-47. The proposed rule therefore consolidates and clarifies these two directives. Less stringent reporting requirements would result in incomplete epidemiological information and would decrease ISDH's ability to reduce the incidence of childhood lead poisoning in Indiana. Less stringent reporting requirements would also result in some lead-poisoned children not receiving case management and environmental follow-up services.

The electronic reporting requirement under IC 16-41-39.4-3 allows low volume laboratories to continue to provide test reports on paper.

B. Establishment of less stringent schedules of deadlines for compliance or reporting requirements for small business.

The proposed rule does not change the schedule or deadlines for reporting blood lead test information to ISDH. Less stringent reporting deadlines would result in unacceptable delays in initiating case management and environmental follow-up services for lead-poisoned children.

C. Consolidation or simplification of compliance or reporting requirements for small businesses.

The proposed rule does not require that any additional information be reported to ISDH. Low volume laboratories may continue to report on paper.

D. Establishment of performance standards for small businesses instead of design or operational standards imposed on other regulated entities by the rule.

No design or operational standards are imposed by the proposed rule.

E. Exemption of small businesses from part of all of the requirements of costs imposed by the rule.

Exemption of small businesses from universal reporting of blood lead levels is inappropriate because this information is used for epidemiology and to initiate case management and environmental services. Low volume laboratories are exempt from the electronic reporting requirement.

Conclusion:

The proposed rule consolidates and clarifies existing statutory and regulatory language on reporting of blood lead levels to ISDH. Less stringent reporting requirements would result in some children not receiving services and incomplete data for epidemiology. The proposed rule does not require any additional costs for small businesses.

410 IAC 1-2.3-47
410 IAC 1-2.3-48
410 IAC 1-2.3-87
410 IAC 29

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:

(1) physician licensed under IC 25-22.5; and ~~each~~

(2) 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:
  (A) culture;
  (B) IgM;
  (C) serology; or
  (D) Western Blot.

(5) **The** 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. **The following shall also be reported:**

(A) Age.

(B) Race.

(C) Sex.

(D) Risk factors. ~~and~~

(E) County of residence. ~~shall also be reported.~~

(8) **The** name, address, and telephone number of **the** 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 μg/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 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~~

~~Disease and Condition~~	~~When to Report (from probable diagnosis)~~	~~Disease Intervention Methods~~
~~Pediatric venous blood lead > 10 µg/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 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:
(A) anthrax;
(B) plague;
(C) tularemia;
(D) Brucella species;
(E) smallpox; or
(F) 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; filed Oct 23, 2003, 4:10 p.m.: 27 IR 865)*

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:
(1) microscopic;
(2) bacteriologic;
(3) immunologic;
(4) serologic; or

(5) other;

evidence of infection by any of the organisms or agents listed in subsection (d) shall report ~~such~~ **the** 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 **the** name of **the** patient, but by a numeric identifier code. For **the** appropriate method to report ~~such~~ **the** results, see subsection (b).

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

(1) **The:**

(A) name, date, **and** results of **the** test performed; ~~the~~

(B) laboratory's normal limits for that test; and ~~the~~

(C) laboratory's interpretation of the test results.

(2) **The** name of **the** person and **the** date of birth or age **of the person** from whom **the** specimen was obtained.

(3) **The** name, address, and telephone number of **the:**

(A) attending physician;

(B) hospital;

(C) clinic; or

(D) other specimen submitter.

(4) **The** 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 **the** name of **the** 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) **The** numeric identifier code, date, and results of tests performed.

(2) **The** name and address of **the:**

(A) attending physician;

(B) hospital;

(C) clinic; or

(D) other.

(3) **The** 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:
(A) E. coli 0157:H7; and
(B) 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)~~ **(40)** Plasmodium species.
~~(42)~~ **(41)** Pneumocystis carinii.
~~(43)~~ **(42)** Rabies virus (animal or human).
~~(44)~~ **(43)** Rickettsia species.
~~(45)~~ **(44)** Rubella virus.
~~(46)~~ **(45)** Salmonella species.
~~(47)~~ **(46)** Shigella species and antimicrobial resistance pattern.
~~(48)~~ **(47)** Smallpox (variola) virus.
~~(49)~~ **(48)** Staphylococcus aureus, Vancomycin resistance equal to or greater than **eight** (8) µg/mL.
~~(50)~~ **(49)** Streptococcus pneumoniae, invasive disease, and antimicrobial resistance pattern.
~~(51)~~ **(50)** Streptococcus Group A (Streptococcus pyogenes), invasive disease.
~~(52)~~ **(51)** Streptococcus Group B, invasive disease.
~~(53)~~ **(52)** Treponema pallidum.
~~(54)~~ **(53)** Trichinella spiralis.
~~(55)~~ **(54)** Vibrio species.
~~(56)~~ **(55)** Yersinia species, including **the following:**
(A) Pestis.
(B) Enterocolitica. ~~and~~
(C) 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~~ **Instead** 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 sorbital-negative E. coli isolates.
(4) Staphylococcus aureus, Vancomycin resistance equal to or greater than **eight** (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) years of age or less.~~

~~(h)~~ **(g)** 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.
(Indiana State Department of Health; 410 IAC 1-2.3-48; filed Sep 11, 2000, 1:36 p.m.: 24 IR 342; filed Oct 23, 2003, 4:10 p.m.: 27 IR 869)

SECTION 3. 410 IAC 29 IS ADDED TO READ AS FOLLOWS:

ARTICLE 29. REPORTING, MONITORING, AND PREVENTIVE PROCEDURES FOR LEAD POISONING

Rule 1. Definitions

410 IAC 29-1-1 Applicability
Authority: IC 16-41-39.4-1
Affected: IC 16-41-39.4

Sec. 1. The definitions in this rule apply throughout this article. *(Indiana State Department of Health; 410 IAC 29-1-1)*

410 IAC 29-1-2 "At-risk" defined
Authority: IC 16-41-39.4-1
Affected: IC 16-41-39.4

Sec. 2. "At-risk" means a child is at-risk if that child:
(1) lives in or regularly visits a house or other structure built before 1978;
(2) has a sibling or playmate who has been lead poisoned;
(3) has frequent contact with an adult who:
(A) works in an industry; or
(B) has a hobby;
that uses lead;
(4) is an immigrant or refugee or has recently lived abroad;
(5) is a member of a minority group;
(6) is a Medicaid recipient;
(7) uses medicines or cosmetics containing lead; or
(8) lives in a geographic area that increases the child's probability of exposure to lead.
(Indiana State Department of Health; 410 IAC 29-1-2)

410 IAC 29-1-3 "Capillary blood lead test" defined
Authority: IC 16-41-39.4-1
Affected: IC 16-41-39.4

Sec. 3. "Capillary blood lead test" means a blood lead test for which the blood sample was drawn using a finger lance to break the skin, followed by:

(1) drawing the blood from the cut into a capillary tube or other collection device; or

(2) placing drops of blood onto a piece of filter paper.

(Indiana State Department of Health; 410 IAC 29-1-3)

410 IAC 29-1-4 "Case management" defined

Authority: IC 16-41-39.4-1

Affected: IC 16-41-39.4

Sec. 4. "Case management" means the process of providing, overseeing, and coordinating lead poisoning services, including, but not limited to, the following:

(1) Outreach and identification of children with EBLLs.

(2) Child case management service planning and resource identification.

(3) Child case management service implementation and coordination.

(4) Monitoring of child case management service delivery, program advocacy, and program evaluation.

(Indiana State Department of Health; 410 IAC 29-1-4)

410 IAC 29-1-5 "Case manager" defined

Authority: IC 16-41-39.4-1

Affected: IC 16-41-39.4

Sec. 5. "Case manager" means a person authorized by a health department and trained by the department or its designated representative within six (6) months of hire or the effective date of this rule to perform case management protocols developed by the state. *(Indiana State Department of Health; 410 IAC 29-1-5)*

410 IAC 29-1-6 "Child case management service implementation and coordination" defined

Authority: IC 16-41-39.4-1

Affected: IC 16-41-39.4

Sec. 6. "Child case management service implementation and coordination" means the following:

(1) For confirmed blood lead levels between zero (0) and nine and nine-tenths (9.9) μg/dL, the following:

(A) Notify the child's primary medical provider within ten (10) working days of receipt of test results by the local health officer.

(B) Provide educational materials to the parents or family of the child regarding prevention of lead poisoning.

(C) Any additional actions the local health officer believes will assist the family in preventing the child's blood lead level from increasing.

(2) For confirmed elevated blood lead levels between ten (10) and fourteen and nine-tenths (14.9) μg/dL, begin child case management services within ten (10) working days after receipt of test results, including the following:

(A) Notify the child's primary medical provider within five (5) working days of receipt of test results and ensure coordination of long term services and retesting.

(B) Arrange for testing of all children under seven (7) years of age living in the home.

(C) Conduct an initial home visit to include the following:

(i) A medical, developmental, and behavioral history.

(ii) Lead education, including medical effects and environmental sources.

(iii) A determination of potential household exposures.

(iv) An evaluation of the risk of other family members, including pregnant women.

(v) A nutrition assessment or referral for nutrition assessment.

(vi) A developmental assessment or referral for developmental assessment.

(vii) Referrals to other social services as appropriate.

(D) Provide an environmental inspection to include the following:

(i) A risk assessment of the child's primary and secondary addresses within ten (10) working days after receipt of test results if the structure was built before 1978, to include the following:

(AA) A complete risk assessment including recommendations to mitigate identified lead hazards.

(BB) A written report to the family and the owner if the family does not own the home.

(CC) Education of the family and the owner on lead hazards in the home and measures to protect the child from further poisoning.

(ii) An environmental investigation, including the following:

(AA) Identification and evaluation of nonstructural exposure sources within the child's environment.

(BB) Presentation of results of the environmental investigation, including recommendations for reducing or eliminating exposure.

(CC) Education of the family on hazards found and education on temporary and permanent measures to protect the child from further exposure.

(E) If the risk assessment finds lead hazards, immediately provide written notice to the property owner of the lead hazards and required remediation options. The notice should include the risk assessment. The property owner is given a reasonable time to implement recommendations for remediating lead hazards within sixty (60) days. A clearance examination is conducted to establish the efficacy of remediation.

(F) Provide continuing child case management services until case closure as appropriate to the child's case and not less frequently than one (1) contact every three (3) months, to include the following:

(i) Monitoring blood lead levels by retesting according to section 5 of this rule and notification of the primary medical provider of the results and ensuring blood lead testing of other children and pregnant women residing in the home.

(ii) Monitoring and evaluation of other aspects of the child's case, including, but not limited to, the following:

(AA) Additional home visits to monitor the child's progress and to identify needs that may arise from changes in primary and secondary addresses, housing condition, family composition, occupations of family members, child's activities, child's development, medical condition, nutrition, and use of nonprescription medications or household goods.

(BB) Contacts with other service providers to monitor and evaluate service delivery, appropriateness, and efficacy.

(3) For confirmed elevated blood lead levels between fifteen (15) and nineteen and nine-tenths (19.9) µg/dL, initiate actions as in subdivision (1), and child case management services begin within five (5) working days after receipt of test results.

(4) For confirmed elevated blood lead levels between twenty (20) and forty-four and nine-tenths (44.9) µg/dL, initiate child case management services within five (5) working days after receipt of test results and all actions as in subdivision (1) with the following changes:

(A) Notify the child's primary medical provider immediately and ensure coordination of long term services and follow-up testing.

(B) Initiate risk assessment of the child's primary and secondary addresses within five (5) working days after receipt of test results if the structure was built before 1978.

(5) For confirmed elevated blood lead levels between forty-five (45) and sixty-nine and nine-tenths (69.9) µg/dL, initiate child case management services within twenty-four (24) hours after receipt of test results and all actions as in subdivision (1) with the following changes:

(A) Notify the child's primary medical provider immediately and ensure coordination of long term services and follow-up testing.

(B) Initiate a risk assessment of the child's primary and secondary addresses within two (2) working days after receipt of test results if the structure was built before 1978.

(C) Chelation therapy followed by a venous blood lead test one (1) month after completion of therapy as follows:

(i) Chelation therapy may be conducted at the child's home if the home does not have any lead hazards.

(ii) If the home has lead hazards, the child must be admitted to a hospital and chelation therapy performed at the hospital.

(6) For confirmed elevated blood lead level greater than or equal to seventy (70) µg/dL, initiate child case management services immediately after receipt of test results and all actions as in subdivision (1) with the following changes:

(A) Notify the child's primary medical provider immediately and ensure coordination of long term services and follow-up testing.

(B) Initiate a risk assessment of the child's primary and secondary addresses within twenty-four (24) hours after receipt of test results if the structure was built before 1978.

(C) Treatment of the child's EBLL as a medical emergency.

(D) Admission of the child to a hospital for chelation therapy.

(E) Obtain a venous blood lead test one (1) month after completion of therapy.

(Indiana State Department of Health; 410 IAC 29-1-6)

410 IAC 29-1-7 "Child case management service planning and resource identification" defined

Authority: IC 16-41-39.4-1

Affected: IC 16-41-39.4

Sec. 7. "Child case management service planning and resource identification" means:
(1) implementing a system to provide child case management services; and
(2) identifying resources and services in the community that can be utilized in child case management.
(Indiana State Department of Health; 410 IAC 29-1-7)

410 IAC 29-1-8 "Clearance examination" defined
Authority: IC 16-41-39.4-1
Affected: IC 16-41-39.4

Sec. 8. "Clearance examination" means an activity as defined in 326 IAC 23 conducted to establish proper completion of remediation. *(Indiana State Department of Health; 410 IAC 29-1-8)*

410 IAC 29-1-9 "Confirmatory testing" defined
Authority: IC 16-41-39.4-1
Affected: IC 16-41-39.4

Sec. 9. "Confirmatory testing" means conducting additional blood lead level tests on children with initial capillary blood lead tests as follows:
(1) Initial blood lead level zero (0) to nine and nine-tenths (9.9) μg/dL requires no confirmatory test.
(2) Confirm initial blood lead levels of ten (10) to nineteen and nine-tenths (19.9) μg/dL within two (2) months of receiving test results by the venous or capillary method.
(3) Confirm initial blood lead levels of twenty (20) to forty-four and nine-tenths (44.9) μg/dL within one (1) week of receiving test results by the venous or capillary method.
(4) Confirm initial blood lead levels of forty-five (45) μg/dL and over with a venous test within twenty-four (24) hours of receiving test results.
(Indiana State Department of Health; 410 IAC 29-1-9)

410 IAC 29-1-10 "Confirmed blood lead test" defined
Authority: IC 16-41-39.4-1
Affected: IC 16-41-39.4

Sec. 10. "Confirmed blood lead test" means either of the following:
(1) Two (2) consecutive capillary blood lead tests not more than twelve (12) weeks apart.
(2) A single venous blood lead test.
(Indiana State Department of Health; 410 IAC 29-1-10)

410 IAC 29-1-11 "Confirmed elevated blood lead level" or "CEBLL" defined
Authority: IC 16-41-39.4-1
Affected: IC 16-41-39.4

Sec. 11. "Confirmed elevated blood lead level" or "CEBLL" means a blood lead level of ten (10) μg/dL or higher that has been verified by a confirmed blood lead test. *(Indiana State Department of Health; 410 IAC 29-1-11)*

410 IAC 29-1-12 "Department" defined
Authority: IC 16-41-39.4-1
Affected: IC 16-41-39.4

Sec. 12. "Department" means the Indiana state department of health. *(Indiana State Department of Health; 410 IAC 29-1-12)*

410 IAC 29-1-13 "Elevated blood lead level" or "EBLL" defined
Authority: IC 16-41-39.4-1
Affected: IC 16-41-39.4

Sec. 13. "Elevated blood lead level" or "EBLL" means a blood lead level of ten (10) μg/dL or higher. *(Indiana State Department of Health; 410 IAC 29-1-13)*

410 IAC 29-1-14 "Environmental inspection" defined
Authority: IC 16-41-39.4-1
Affected: IC 16-41-39.4

Sec. 14. "Environmental inspection" means the following:
(1) An environmental investigation.
(2) A risk assessment of the child's primary and secondary addresses.
(Indiana State Department of Health; 410 IAC 29-1-14)

410 IAC 29-1-15 "Environmental investigation" defined
Authority: IC 16-41-39.4-1
Affected: IC 16-41-39.4

Sec. 15. "Environmental investigation" means an identification of lead hazards from any nonstructural source, including the following:
(1) Identification and evaluation of nonstructural exposure sources within the child's environment.
(2) Presentation of results of the environmental investigation, including recommendations for reducing or eliminating exposure.
(3) Education of the family on:
(A) hazards found; and
(B) temporary and permanent measures;
to protect the child from further exposure.
(Indiana State Department of Health; 410 IAC 29-1-15)

410 IAC 29-1-16 "Family" defined
Authority: IC 16-41-39.4-1
Affected: IC 16-41-39.4

Sec. 16. "Family" means the caregivers and household of a child. *(Indiana State Department of Health; 410 IAC 29-1-16)*

410 IAC 29-1-17 "Local health officer" defined
Authority: IC 16-41-39.4-1
Affected: IC 16-41-39.4

Sec. 17. "Local health officer" means the local health officer or the local health officer's designated representative. *(Indiana State Department of Health; 410 IAC 29-1-17)*

410 IAC 29-1-18 "Monitoring of child case management service delivery, program advocacy, and program evaluation" defined
Authority: IC 16-41-39.4-1
Affected: IC 16-41-39.4

Sec. 18. "Monitoring of child case management service delivery, program advocacy, and program evaluation" means the following:
(1) Tracking the provision of case management services.
(2) Securing resources adequate to support local efforts.
(3) Measuring program outputs.
(Indiana State Department of Health; 410 IAC 29-1-18)

410 IAC 29-1-19 "Outreach and identification" defined
Authority: IC 16-41-39.4-1
Affected: IC 16-41-39.4

Sec. 19. "Outreach and identification" means the following:

(1) The promotion of awareness of the health effects of lead, techniques for preventing lead poisoning, and techniques for treating lead poisoning and providing lead hazard education in the local health officer's jurisdiction through activities including, but not limited to, training staff on issues relevant to lead poisoning effects, prevention, and treatment, including, but not limited to, the following:

(A) Housing.

(B) Environment.

(C) Testing.

(2) Raising awareness in the community of lead hazards for those included in at-risk categories.

(3) Providing consultation and education to the local medical community.

(4) Providing consumer alerts and consumer education regarding lead hazards, including products for purchase in the community.

(5) Determining the magnitude of lead poisoning in their jurisdictions through activities including, but not limited to, the following:

(A) Ensuring blood lead testing of children at risk for lead poisoning.

(B) Partnering with:

(i) children's and maternal nutrition and health programs;

(ii) education programs and institutions;

(iii) community action agencies;

(iv) housing authorities;

(v) physicians; and

(vi) other partners, such as schools and community and faith-based organizations;

involved in the care of children to ensure screening and testing of all at-risk children.

(C) Partnering with local officials to determine high-risk geographic areas in order to target testing of children at risk for lead poisoning.

(Indiana State Department of Health; 410 IAC 29-1-19)

410 IAC 29-1-20 "Remediation" defined

Authority: IC 16-41-39.4-1

Affected: IC 16-41-39.4

Sec. 20. "Remediation" means actions that constitute either:

(1) abatement; or

(2) interim control;

of a lead hazard as defined in 326 IAC 23. *(Indiana State Department of Health; 410 IAC 29-1-20)*

410 IAC 29-1-21 "Retesting" defined

Authority: IC 16-41-39.4-1

Affected: IC 16-41-39.4

Sec. 21. "Retesting" means additional testing to monitor a child's blood lead level over time, with specific intervals depending on whether a child's blood lead level has or has not decreased, as follows:

(1) If the child's blood lead level has not decreased by at least three (3) μg/dL within at least a three (3) month period, retest as follows:

(A) In three (3) months for results between zero (0) and fourteen and nine-tenths (14.9) μg/dL.

(B) In two (2) months for results between fifteen (15) and nineteen and nine-tenths (19.9) μg/dL.

(C) In one (1) month for results between twenty (20) and twenty-four and nine-tenths (24.9) μg/dL.

(D) In two (2) weeks for results between twenty-five (25) and forty-four and nine-tenths (44.9) μg/dL.

(E) By the venous method one (1) month after completion of chelation therapy for results greater than forty-five (45) μg/dL.

(2) If the child's blood lead level has decreased by at least three (3) μg/dL within at least a three (3) month period, retest as follows:

(A) In six (6) months for results between zero (0) and fourteen and nine-tenths (14.9) μg/dL.

(B) In three (3) months for results between fifteen (15) and nineteen and nine-tenths (19.9) μg/dL.

(C) In two (2) months for results between twenty (20) and twenty-four and nine-tenths (24.9) μg/dL.

(D) In one (1) month for results between twenty-five (25) and forty-four and nine-tenths (44.9) µg/dL.

(E) By the venous method one (1) month after completion of chelation therapy for results greater than forty-five (45) µg/dL.

(Indiana State Department of Health; 410 IAC 29-1-21)

410 IAC 29-1-22 "Risk assessment" defined
Authority: IC 16-41-39.4-1
Affected: IC 16-41-39.4

Sec. 22. "Risk assessment" means an assessment of lead hazards from any structural source by a licensed risk assessor consistent with 326 IAC 23 to include the following:

(1) A complete risk assessment including recommendations to mitigate identified lead hazards.

(2) A written report to the family and the owner if the family does not own the home.

(3) Education of the family and the owner on the following:

(A) Lead hazards in the home.

(B) Measures to protect children from further poisoning.

(Indiana State Department of Health; 410 IAC 29-1-22)

410 IAC 29-1-23 "Risk assessor" defined
Authority: IC 16-41-39.4-1
Affected: IC 16-41-39.4

Sec. 23. "Risk assessor" means a person licensed by the state to conduct risk assessments consistent with section 15 of this rule. *(Indiana State Department of Health; 410 IAC 29-1-23)*

410 IAC 29-1-24 "Unconfirmed elevated blood lead level" or "UEBLL" defined
Authority: IC 16-41-39.4-1
Affected: IC 16-41-39.4

Sec. 24. "Unconfirmed elevated blood lead level" or "UEBLL" means a blood lead level of ten (10) µg/dL or greater that has not yet been subject to confirmatory testing. *(Indiana State Department of Health; 410 IAC 29-1-24)*

410 IAC 29-1-25 "Venous blood lead test" defined
Authority: IC 16-41-39.4-1
Affected: IC 16-41-39.4

Sec. 25. "Venous blood lead test" means a blood lead test for which the blood sample was drawn using venipuncture. *(Indiana State Department of Health; 410 IAC 29-1-25)*

Rule 2. Case Management and Testing

410 IAC 29-2-1 Case management
Authority: IC 16-41-39.4-1
Affected: IC 16-41-39.4

Sec. 1. Local health officers shall ensure the provision of case management to all children under seven (7) years of age in their jurisdictions, including the following:

(1) Outreach and identification of EBLL children.

(2) Child case management service planning and resource identification.

(3) Confirmatory testing.

(4) Child case management service implementation and coordination.

(5) Retesting.

(6) Monitoring of child case management service delivery, program advocacy, and program evaluation.

(Indiana State Department of Health; 410 IAC 29-2-1)

410 IAC 29-2-2 Case closure
Authority: IC 16-41-39.4-1
Affected: IC 16-41-39.4

Sec. 2. The department or local health officer may close cases under either of the following conditions:
(1) A case may be designated "case complete" if:
(A) referrals have been made to individuals and agencies for long term developmental, environmental, and medical follow-up; and
(B) the child has two (2) or more consecutive confirmed blood lead tests for which the BLL is less than ten (10) µg/dL in a six (6) month period, and environmental lead hazards have been remediated and passed a dust clearance test.
(2) A case may be designated "administratively closed" for any of the following reasons:
(A) The child moves to another state and a case referral has been made to the appropriate state lead poisoning prevention program. This referral must be made not later than ten (10) working days after the case manager learns of the move, and the department shall keep the case open until the case is confirmed as received by the state to which it has been transferred.
(B) The child moves to another county in Indiana and a case referral has been made to the appropriate local health department. This referral must be made not later than ten (10) working days after the case manager learns of the move, and the department shall keep the case open until the case is confirmed as received by the local health department to which it has been transferred.
(C) The child reaches his or her seventh birthday and referrals have been made to individuals and agencies for long term developmental, environmental, and medical follow-up.
(D) The child can no longer be located or contacted and five (5) attempts have been made to contact the child during a twenty-six (26) week closure window according to the following action periods:
(i) At least one (1) telephone call to the parent or guardian after the first four (4) weeks of the twenty-six (26) week closure window.
(ii) At least one (1) letter to the parent or guardian between nine (9) and thirteen (13) weeks into the twenty-six (26) week closure window.
(iii) At least one (1) certified letter to the parent or guardian between thirteen (13) and twenty-one (21) weeks into the twenty-six (26) week closure window.
(iv) At least one (1) attempted home visit to the child's last known address after twenty-four (24) weeks into the twenty-six (26) week closure window.
Actions completed later than the action period shall be recorded against the twenty-six (26) week closure window in the week in which they were performed.
(E) Case management is blocked for religious or other legally recognized reasons, and documentation of these reasons is on file.
(F) The death of the child.
(Indiana State Department of Health; 410 IAC 29-2-2)

Rule 3. Reporting

410 IAC 29-3-1 Reporting of blood lead test results
Authority: IC 16-41-39.4-1
Affected: IC 16-41-39.4

Sec. 1. (a) A person that examines the blood of an individual for the presence of lead must report to the department the results of the examination not later than one (1) week after completing the examination. The report must include at least the following:
(1) With respect to the individual whose blood is examined, the following:
(A) Full name.
(B) Date of birth.
(C) Gender.
(D) Full address, including street address, city, and zip code.
(E) County of residence.
(F) Race and ethnicity.
(G) Parent's or guardian's name and phone number, where applicable.

(H) Any other information that is required to be included to qualify to receive federal funding.
(2) With respect to the examination, the following:
(A) The date.
(B) The type of blood test performed.
(C) The person's normal limits for the test.
(D) The results of the test.
(E) The person's interpretation of the results of the test.
(3) The names, addresses, and telephone numbers of the following:
(A) The person examining the blood.
(B) The attending physician, hospital, clinic, or other specimen submitter.

(b) If a person required to report under subsection (a) has submitted more than fifty (50) results in the previous calendar year, the person must submit subsequent reports in an electronic format determined by the department. *(Indiana State Department of Health; 410 IAC 29-3-1)*

410 IAC 29-3-2 Reporting of case information
Authority: IC 16-41-39.4-1
Affected: IC 16-41-39.4

Sec. 2. (a) Local health officers shall ensure that case information is reported to the department for children less than seven (7) years of age who have an elevated blood lead level.

(b) Case management activities shall be reported electronically or using the forms designated by the department.

(c) Case closure activities shall be reported electronically or using forms designated by the department. *(Indiana State Department of Health; 410 IAC 29-3-2)*

410 IAC 29-3-3 Reporting of housing information
Authority: IC 16-41-39.4-1
Affected: IC 16-41-39.4

Sec. 3. Local health officers shall ensure that addresses associated with children with elevated blood lead levels and gathered after July 1, 2002, are provided to federal, state, and local organizations covered by 24 CFR Subpart A, Part 35. *(Indiana State Department of Health; 410 IAC 29-3-3)*

Rule 4. Prevention and Remediation

410 IAC 29-4-1 Prevention or remediation
Authority: IC 16-41-39.4-1
Affected: IC 16-41-39.4

Sec. 1. Local health officers may do the following:
(1) Enter upon and inspect private property, at proper times after due notice, in regard to the possible presence, source, and cause of lead poisoning and lead hazards.
(2) Order what is reasonable and necessary to prevent lead poisoning or remediate lead hazards.
Remediation shall be followed by dust clearance examination. *(Indiana State Department of Health; 410 IAC 29-4-1)*

SECTION 4. 410 IAC 1-2.3-87 IS REPEALED.

Notice of Public Hearing

Under IC 4-22-2-24, notice is hereby given that on May 9, 2006 at 10:00 a.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 a proposed rule to add rules regarding the reporting, monitoring, and preventive procedures to protect from lead poisoning and to

establish requirements for case management of a child with lead poisoning and delete the reporting and other requirements for blood lead levels from 410 IAC 1-2.3.

This rule is written to comply with the requirements of IC 16-41-39.4.

Copies of these rules are now on file at the Community and Family Health Services Commission at the Indiana State Department of Health, 2 North Meridian Street and Legislative Services Agency, One North Capitol, Suite 325, Indianapolis, Indiana and are open for public inspection.

Sue Uhl
Deputy State Health Commissioner
Indiana State Department of Health