

Department of Health and Hospitals

April 10, 2019

TO:

The Honorable Fred H. Mills, Jr., Chair, Senate Health & Welfare Committee

The Honorable Frank A. Hoffmann, Chair, House Health & Welfare Committee

FROM:

Rebekah E. Gee MD, MPH, Secretary

RE: Proposed Title 51 Parts II and III Revisions – 2nd Legislative Oversight Committee Report

Pursuant to the Louisiana Administrative Procedure Act, the Louisiana Department of Health, Office of Public Health, submits its second report relative to the agency's proposal to amend Parts II (The Control of Diseases) and III (The Control of Rabies and Other Zoonotic Diseases) of Title 51 of the LAC. A Notice of Intent on the proposed amendments was published in the February 20, 2019, issue of the *Louisiana Register* (LR 45:318).

The public and other interested entities were provided a 20-day opportunity to request a public hearing; however, no person or other interested entity requested a public hearing. Thus, a public hearing was not held.

The public and other interested entities were provided a 37-day opportunity to submit written comments. The comment period ended on Thursday, March 28, 2019 at 4:30 pm. Approximately 167 letters of opposition were received by the Office of Public Health, including letters from members of the public and the Baton Rouge Chapter of the National Association for the Advancement of Colored People (NAACP). All of the letters expressed opposition specifically to the proposed requirement for laboratories to report negative test results for HIV/AIDS, hepatitis C, and syphilis to the Office of Public Health. Particular concerns about the need for the state to maintain a negative test result database, privacy of personal health information, and the possible unintended consequences on minority communities were all addressed in the letters.

In separate letters addressed to each person submitting comments, the Office of Public Health responded to the comments on April 9, 2019. All issues were addressed in a single letter and this letter was mailed by USPS or email, when available, to all individuals who submitted a comment to the Office of Public Health. Accordingly, only one letter is attached. The response letter was also posted to the Louisiana Department of Health website. After considering the comments and the policy behind the proposed amendments, the Office of Public Health decided not to make any substantive changes to the rule because there are clinical and public health reasons for regularly obtaining negative test results and safeguards in place for protecting personal health information. Further, the possible negative effects of collecting this data are outweighed by the benefits that can be derived from having negative test results.

Page 2 of 2 March 29, 2019

Re: Proposed Title 51 Parts II and III Revisions – 2nd Legislative Oversight Committee Report

A technical omission was noticed in the publication of the Notice of Intent that was published on February 20, 2019. The citation did mention amending Chapter 1 of Part II but failed to mention that Chapter 7 of Part II is also proposed to be amended; thus, the Office of Public Health now proposes to make a technical correction to correct this citation in the proposed final rule.

Subject to legislative oversight by either the House or Senate Health and Welfare Committees, the department anticipates adopting the published Notice of Intent (with a proposed technical correction as referenced in the previous paragraph) as a final Rule in the May 20, 2019 issue of the *Louisiana Register*. Enclosed, please find a copy of the NOI (showing the proposed technical correction) with the published summary page of the Fiscal and Economic Impact Statement.

Should you have any questions, please contact Alexander Billioux, MD, DPhil, Assistant Secretary, Office of Public Health, at (225) 342-8093.

cc: Rebekah E. Gee, MD, MPH, Secretary
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M. Beth Scalco, Deputy Assistant Secretary, OPH
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Allen Enger, Rulemaking Officer, OPH
Anita Dupuy, Legislative Liaison, Louisiana Department of Health
Catherine Brindley, Editor, Louisiana Register



State of Louisiana

Louisiana Department of Health
Office of Public Health

April 9, 2019

Re: Response to Opposition to Adoption of Disease Reporting

Requirement Rule Amendments

To whom it may concern:

Thank you for submitting your comments concerning the Office of Public Health's (OPH) proposed amendments to the disease reporting requirements. Specifically, you expressed opposition to the proposed requirement for laboratories to report negative test results for HIV/AIDS, hepatitis C, and syphilis testing to OPH. Your concerns about the need for the state to maintain a negative test result database, privacy of personal health information, and the possible unintended consequences on minority communities have been considered by the leadership of OPH.

The Louisiana Department of Health (LDH) is mandated to promote and protect the health of all individuals and communities in Louisiana, and it is this duty that motivated the changes we have proposed to the Sanitary Code. LDH has proposed requiring laboratories to report all test results for HIV/AIDS, hepatitis C, and syphilis, including negative results, to OPH to enable the Department to more effectively address these challenging epidemics in Louisiana. Clinically, negative test results provide critical information to determine the length and end of periods of infectivity, identify when seroconversion occurs, differentiate between acute/active and treated/inactive cases, and identify false positive cases. In addition, negative test results are critical parts of monitoring response to treatment for all three of these infections. From a public health perspective, negative reporting for these three diseases will allow OPH to identify providers in need of consultation to improve their testing practices to bring them in line with the health standards. Enhanced screening practices throughout Louisiana will improve overall health.

Protection of personal health information is taken very seriously by the LDH. The test result data will be stored on secure systems that have been certified according to guidelines established by the Centers for Disease Control and Prevention. As a covered entity under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the LDH and OPH are required by federal law to safeguard all health data produced and received, including negative test results reported by laboratories within the state. Accordingly, all LDH staff receive required HIPAA training at regular intervals and only

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staff with a need to know will be able to access the information, in keeping with HIPAA's "minimum necessary" requirement.¹

We recognize that requiring disclosure of both positive and negative test results to OPH carries a risk of producing a "chilling effect" on testing, especially in minority communities where these diseases carry a heightened stigma. Certainly, there are many policy considerations involved with reporting negative test results and strong arguments for and against adopting the proposed amendments. Ultimately, OPH believes that the possible negative effects are outweighed by the benefits that can be derived from having negative test results, some of which are listed above. We also consider the risk of inadvertent disclosure to be minimal. Finally, OPH remains committed to regularly reviewing our procedures, data management policies, and regulations, including the Sanitary Code, to ensure they remain responsive to the latest science, best practices, and health needs of our people and communities.

Again, OPH appreciates your comments and the time you took to express your concerns.

Sincerely,

Alexander Billioux, MD, DPhil

Assistant Secretary, Office of Public Health

cc: Senate Health and Welfare Committee House Health and Welfare Committee Rebekah E. Gee MD, MPH, Secretary Jimmy Guidry, MD, State Health Officer

¹ 45 C.F.R. 164.502(b); 164.514(d).

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adopted pursuant to LA R.S. 37:3445(D). Lastly, the proposed rule changes make technical changes.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

The proposed rule changes will not affect revenue collections of state or local governmental units

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

Pursuant to Act 626 of the 2018 Regular Session, the proposed rule changes increase the number of practitioner seats on the board by one, from 3 to 4. Furthermore, the proposed rule changes decrease the number of consumer seats on the board by one, from 2 to 1. As a result, there are more opportunities for practitioners to serve on the board, while there are fewer opportunities for consumers to serve on the board. However, the total number of board seats, five (5), remains unchanged.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule changes will not affect competition or employment.

Stephen W. Glusman General Counsel 1902#024 Evan J. Brasseaux Staff Director Legislative Fiscal Office

NOTICE OF INTENT

Department of Health Office of Public Health

Disease Reporting Requirements; Public Health Immunization Requirements; and Anti-Rabies Vaccination Requirements for Dogs and Cats (LAC 51:II.Chapter 1 and III.Chapter 1)

Notice is hereby given, in accordance with the Administrative Procedure Act, R.S. 49:950 et seq., that the state health officer acting through the Louisiana Department of Health, Office of Public Health (LDH-OPH), pursuant to the authority in R.S. 40:4(A)(2), and R.S. 40:5, intends to amend and revise Title 51 (Public Health—Sanitary Code), Part II (The Control of Diseases).

The proposed amendments to Part II, Chapter 1, are regarding disease reporting requirements. The proposed revisions to these requirements will keep them up to date with current national and state disease surveillance needs. Proposed amendments to Part II, Chapter 7, are regarding the immunization schedule. The proposed revisions to these requirements will update the Louisiana immunization schedule in accordance with the Advisory Committee on Immunization Practice (ACIP) of the United States Public Health Service.

In addition, the state health officer acting through the LDH-OPH, pursuant to the authority in R.S. 40:4(A)(2), R.S. 40:5(A)(1)(2) and R.S. 40:1269.3, also Intends to amend and revise Title 51, Part III (The Control of Rabies and Other Zoonotic Diseases). This proposed amendment relates to the appropriate re-vaccination interval of dogs and cats based upon the particular anti-rabies vaccine being administered to the animal, as well as updating required actions for domestic animals bitten by rabid animals to conform to current national best practices.

The proposed amendments shall be made by effecting substantive changes as outlined below.

Title 51

PUBLIC HEALTH—SANITARY CODE Part II. The Control of Diseases

Chapter 1. Disease Reporting Requirements §101. Definitions

[formerly paragraph 2:001]

A. Unless otherwise specifically provided herein, the following words and terms used in this Part and all other Parts which are adopted or may be adopted, are defined for the purposes thereof as follows.

* * *

Case—a particular instance of disease.

Case of Perinatal Exposure to Human Immunodeficiency Virus (HIV)—any instance of a live birth to a woman in whom HIV infection was present prior to the birth (indicated by maternal or neonatal HIV testing).

Case of Perinatal Exposure to Treponema Pallidum—any instance of a live birth or stillbirth to a woman in whom syphilis infection was present prior to the birth (indicated by maternal or neonatal syphilis testing).

* * *

AUTHORITY NOTE: The first source of authority for promulgation of the sanitary code is in R.S. 36:258(B), with more particular provisions found in Chapters 1 and 4 of Title 40 of the Louisiana Revised Statutes. This Part is promulgated in accordance with the specific provisions of R.S. 40:4(A)(2) and R.S. 40:5(A)(1)(2) and (10).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1212 (June 2002), amended LR 32:1050 (June 2006), LR 34:2173 (October 2008), repromulgated LR 34:2582 (December 2008), LR 36:1014 (May 2010), amended by the Department of Health, Office of Public Health, LR 45:

§105. Reportable Diseases and Conditions [formerly paragraph 2:003]

A. It is hereby made the duty of every physician practicing medicine in the state of Louisiana to report to the state health officer, according to the requirements of this Section and utilizing the appropriate method(s) of reporting required under Subsection E of this Section, any case or suspected case of reportable disease or condition which he or she is attending, or has examined, or for which such physician has prescribed. The report shall be made promptly at the time the physician first visits, examines or prescribes for the patient, and such report shall state the name, age, sex, race, usual residence, place where the patient is to be found, the nature of the disease or condition and the date of onset, and the pregnancy status of the patient (if the pregnancy status is known and if it is clinically relevant to the disease or condition being reported). Reports of occupational disease/injury shall state contact information of the reporting person as well as the patient's name, contact information, age (or date of birth), sex, race/ethnicity, usual residence, occupation, employer information, the nature of the disease or injury, and the date of diagnosis.

B. - D.1.a. ...

- i. Acinetobacter spp., carbapenem-resistant;
- ii. acute flaccid paralysis, including acute flaccid myeltis;

- iii. amoeba (free living) infection (including Acanthamoeba, Naegleria, Balamuthia and others;
 - iv. anthrax;
- v. avian or novel strain influenza A (initial detection);
 - vi. botulism;
 - vii. brucellosis;
- viii. Candida auris, as well as common misidentifications of C. auris (e.g., C. haemulonii, C. duobushaemulonii, C. famata, C. sake, C. lusitaniae, C. parapsilosis, C. catenulata, C. guilliermondii, and Rhodotorula glutinis);
 - ix. cholera;
 - x. Clostridium perfringens food-borne illness;
 - xi. diphtheria;
 - xii. Enterobacterlacea, carbenum-resistant;
- xiii. fish or shellfish poisoning (domoic acid poisoning, neurotoxic shellfish poisoning, ciguatera, paralytic shellfish poisoning, scombroid);
 - xiv. food-borne illness;
 - xv. glanders (Burkholderia mallei);
 - xvi. Haemophilus influenzae (invasive infection);
 - xvii. influenza-associated mortality;
 - xviii. measles (rubeola, imported or indigenous);
 - xix. melioidosis (Burkholderia pseudomallei);
 - xx. Neisseria meningitidis (invasive infection);
 - xxi. outbreaks of any infectious diseases;
 - xxii. pertussis;
 - xxiii. plague (Yersinia pestis);
 - xxiv. poliomyelitis (paralytic and non-paralytic);
- xxv. Pseudomonas aeruginosa, carbapenem-resistant;
 - xxvi. Q fever (Coxiella burnettii);
 - xxvii. rabies (animal and human);
 - xxviii. ricin poisoning;
 - xxix. rubella (congenital syndrome);
 - xxx. rubella (German measles);
- xxxi. severe acute respiratory syndrome-associated coronavirus (SARS-CoV);
- xxxii. Staphylococcus aureus, vancomycin intermediate or resistant (VISA.VRSA);
- xxxiii. staphylococcal enterotoxin B (SEB) pulmonary poisoning;
 - xxxiv. smallpox;
 - xxxv. tularemia (Francisella tularensis);
- xxxvi. viral hemorrhagic fever (Ebola, Lassa, Marburg, Crimean Congo, etc.); and
 - xxxvii. yellow fever.
 - 2. 2.a. ..
 - i. anaplasmosis;
- ii. arthropod-borne viral infections (including West Nile, Dengue, St. Louis, California, Eastern Equine, Western Equine, Chikungunya, Usutu, Zika, and others);
 - iii. aseptic meningitis;
 - iv. babesiosis;
 - v. Chagas disease;
 - vi. chancroid;
 - vii, cryptosporidiosis;
 - viii. cyclosporiasis;
- ix. Escherichia coli, Shiga-toxin producing (STEC), including E. coli O157:H7;
 - x. granuloma inguinale;

- xi. hantavirus (infection or pulmonary syndrome);
- xii. hemolytic-uremic syndrome;
- xiii. hepatitis A (acute illness);
- xiv. hepatitis B (acute illness and carriage in pregnancy);
 - xv. hepatitis B (perinatal infection);
 - xvi. hepatitis C (acute illness);
 - xvii. hepatitis C (perinatal infection);
 - xviii, hepatitis E;
 - xix. herpes (neonatal);
- xx. human immunodeficiency virus [(HIV), infection in pregnancy]^{2,6};
- xxi. human immunodeficiency virus [(HIV), perinatal exposure]^{2,6};
 - xxii. legionellosis;
 - xxiii. listeriosis;
 - xxiv. malaria;
 - xxv. mumps;
 - xxvi. salmonellosis
 - xxvii. shigellosis;
 - xxviii. syphilis1
- xxix. syphilis [(Treponema pallidum), infection in pregnancy]^{1,6}
- xxx. syphilis [(Treponema pallidum), perinatal exposure]^{1,6};
 - xxxi. tetanus;
- xxxii. tuberculosis³ due to Mycobacterium tuberculosis, bovis or africanum;
 - xxxiii. typhoid fever;
 - xxxiv. Vibrio infections (other than cholera); and
 - xxxv. Zika virus-associated birth defects.
- 3. Class C Diseases or Conditions which Shall Require Reporting within Five Business Days
 - a. a.i.
 - ii. aspergillosis;
 - iii. vii.
- viii. ehrlichiosis (human granulocytic, humar monocytic, Ehrlichia chaffeensis and ewingii);
- ix. Enterococcus, vancomycin resistant [(VRE), invasive disease];
 - x. giardiasis;
- xi. gonorrhea¹ (genital, oral, ophthalmic, pelvic inflammatory disease, rectal);
 - xii. Guillain-Barré syndrome;
 - xiii. Hansen's disease (leprosy):
- xiv. hepatitis C (infection, other than as in Class $B)^2$;
 - xv. histoplasmosis;
- xvi. human immunodeficiency virus [(HIV) infection, other than as in class B]²;
- xvii. human T lymphocyte virus (HTLV I and II) infection;
 - xviii. leptospirosis;
 - xix. Lyme disease;
 - xx. lymphogranuloma venereum¹;
- xxi. meningitis, eosinophilic (including those due to Angiostrongylus infection);
 - xxii. Nipah virus infection;
 - xxiii. non-gonococcal urethritis;
 - xxiv. nontuberculous mycobacteria;
 - xxv. ophthalmia neonatorum;
 - xxvi. psittacosis;

xxvii. spotted fever rickettsioses [Rickettsia species including Rocky Mountain spotted fever (RMSF)];

xxviii. staphylococcal toxic shock syndrome;

xxix. Staphylococcus aureus, methicillin/oxacillin-resistant [(MRSA), invasive infection];

xxx. streptococcal disease, group A (invasive disease);

xxxi. streptococcal disease, group B (invasive disease);

xxxii. streptococcal toxic shock syndrome;

xxxiii. Streptococcus pneumoniae invasive disease;

xxxiv. transmissible spongiform encephalopathies (Creutzfeldt-Jakob disease and variants);

xxxv. trichinosis;

xxxvi. varicella (chickenpox); and;

xxxvii. yersiniosis.

4. Class D Special Reportable Diseases or Conditions Shall Require Reporting within Five Business Days

a. - a.i.

ii. carbon monoxide exposure and/or poisoning⁵;

iii. - vii,

viii. lead exposure and/or poisoning (all ages)⁵;

ix. pesticide-related illness or injury (all ages)⁵;

х. ..

xi. pneumoconiosis (asbestosis, berylliosis, silicosis, byssinosis, etc.)⁵;

xii. radiation exposure, over normal limits⁵;

xiii. - xviii. ...

- 5. Class E Reportable Occupational Diseases or Conditions Shall Require Reporting within 10 Business Days⁵
- a. Class E diseases or conditions shall include any occupationally-related diseases or conditions of significant public health concern. This includes cases where the work environment is suspected to be the cause of an illness or injury or cases where the work environment is thought to be the cause of an illness exacerbation. Class E diseases or conditions shall be reported to the Office of Public Health, Section of Environmental Epidemiology and Toxicology, Occupational Health and Injury Surveillance Program, within 10 business days after existence of the case, suspected case, or positive test result is known.

E. - E.1. ...

- 2. ²Report to the Louisiana STD/HIV Program. Visit www.hiv.dhh.louisiana.gov or call (504) 568-7474 for regional contact information.
 - 3. 4. ...
- 5. ⁵Report to the Section of Environmental Epidemiology and Toxicology, Occupational Health and Injury Surveillance Program, www.seet.dhh.louisiana.gov or call (504) 568-8150, toll free at (888) 293-7020, or by fax at (504) 568-8149.
- 6. ⁶Report to the Louisiana STD/HIV Program on HIV/Syphilis during Pregnancy Reporting Form. Visit www.hiv.ldh.louisiana.gov or by phone at (504) 568-7474.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2) and R.S. 40:5(A)(1)(2)(10)(11).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1212 (June 2002), amended LR 32:1050 (June 2006), LR 34:2173 (October 2008), repromulgated LR 34:2582 (December 2008), LR 36:1014 (May 2010), repromulgated LR 36:1253 (June 2010), amended LR

39:1053 (April 2013), LR 41:2653 (December 2015), amended by the Department of Health, Office of Public Health, LR 45:

§107. Laboratory and Healthcare Facility Reporting Requirements (formerly §113)

A. The director of every laboratory and the director of an applicable healthcare facility whether public, private, hospital or other, within or out of the state shall report to the state health officer the results of all tests that are in any way clinically relevant, suggestive or indicative of an individual having active disease, past or present exposure to, past or present contact with and/or past or present association with any of the disease/conditions listed in LAC 51 (Public Health-Sanitary Code), Part II, Chapter 1, §105. The results of the tests to be reported to the state health officer do not have to be conducted for diagnostic reasons, nor do the results have to be diagnostic or confirmatory. The report shall be received in a timely manner consistent with the requirements of the diseases/conditions by class for the diseases/conditions described in §105 of this Chapter and shall state the name, date of birth, sex, race, usual residence. pregnancy status of the individual (if the pregnancy status is known and if it is clinically relevant to the disease or condition being reported), specimen identification code/ID and test results of the tested individual as well as the name of the physician or person submitting the specimen. Contact information for the laboratory or an applicable healthcare facility performing the test(s) shall be provided, Laboratories or an applicable healthcare facility shall not defer their public health reporting responsibilities to any other authorities within the institutions they serve. In addition, laboratories or an applicable healthcare facility performing tests on specimens received from other laboratories or an applicable healthcare facility shall report to the state health officer all results as prescribed above plus the contact information for the facility/laboratory or an applicable healthcare facility where the specimen originated. Moreover, no considerations, evaluations or concerns, regarding any test technology or test result by institutions and/or organizations whether federal, state or otherwise (e.g., FDA, CMS-CLIA, etc.) which may be overseeing, approving, evaluating or licensing laboratory testing, shall represent an a priori rationale for withholding laboratory reports from the state health officer.

B. - B.4. ...

5. hepatitis C (past or present infection), including genotype where available;

6. - 9. ...

- C. A reference culture or culture-independent diagnostic test (CIDT) specimen is required to be sent to the Office of Public Health laboratory, or a specialized laboratory as indicated below, for the following microorganisms within five business days of the final identification of the microorganism:
- 1. Acinetobacter spp., pan-resistant; consult with the OPH's Infectious Disease Epidemiology for submission to the CDC's Antibiotic Resistance Laboratory Network (ARLN);
 - 2. Bacillus anthracis (confirmed or suspected);
 - 3. Bordetella pertussis;
 - 4. Brucella spp.

- Burkholderia mallei;
- Burkholderia pseudomallei;
- Campylobacter spp.;
- Candida auris submitted to the CDC's ARLN; consult with the OPH's Infectious Disease Epidemiology for common misidentifications of C. auris (e.g., C. haemulonii, C. duobushaemulonii, C. famata, C. sake, C. lusitaniae, C. parapsilosis, C. catenulata, C. guilliermondii, Rhodotorula glutinis);
 - 9. Corynebacterium diphtheriae;
 - 10. E. coli O157:H7 or E. coli Shiga toxin producing;
- 11. Enterobacteriaceae, carbapenem-resistant (excluding Klebsiella pneumoniae, K. oxytoca, E. coli, and Enterobacter spp.); consult with OPH's Infectious Disease Epidemiology for submission to the CDC ARLN;
 - 12. Francisella spp.;
- 13. Klebsiella pneumoniae, K. oxytoca. E. coli, and Enterobacter spp., carbapenum-resistant;
 - 14. Listeria spp.;
 - 15. Mycobacterium tuberculosis, bovis or africanum;
 - 16. Plesiomonas spp;
 - 17. Pseudomonas aeruginosa, carbapenum-resistant;
 - 18. Salmonella spp.;
 - 19. Shigella spp.;
 - 20. Vibrio spp.;
 - 21. Yersinia enterocolitica; and
 - 22. Yersinia pestis.
- D. A reference culture or culture-independent diagnostic test (CIDT) specimen is required to be sent to the Office of Public Health laboratory for the following microorganisms if the original culture was from a sterile site (e.g., blood, spinal fluid, other internal fluid, tissue, etc.). Such reference culture shall be sent to the Office of Public Health laboratory within five business days of the final identification of the microorganism:
 - D.1. E.
- F. Electronic reporting by a laboratory/facility shall include any results, negative or positive, for all components of testing indicative of the following conditions:
 - 1. hepatitis C virus;
- 2. human immunodeficiency virus (HIV), including nucleotide sequences; and
 - 3. syphilis.
- G. Laboratories and applicable healthcare facilities are encouraged to report results electronically using Health Level Seven (HL7)-compliant message structure and appropriate standard Logical Observation Identifiers Names and Codes (LOINC) terminology designating the test(s) performed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2) and R.S. 40:5(A)(2)(10)(11).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1214 (June 2002), amended LR 32:1052 (June 2006), LR 39:1054 (April 2013), LR 41:2655 (December 2015), amended by Department of Health, Office of Public Health, LR:45:

Public Health Immunization Chapter 7. Requirements

§701. Immunization Schedule [formerly paragraph 2:025]

A. The Office of Public Health (OPH) will determine the

Louisiana immunization schedule, with appropriate immunizations for age using the current immunization schedule from the Advisory Committee for Immunization Practice (ACIP) of the United States Public Health Service (USPHS). Compliance for school and day care center entry will be based on the individual having received an appropriate number of immunizations for his/her age of the following types:

- 1. vaccines which contain tetanus and diphtheria toxoids, including Diphtheria and Tetanus (DT), Diphtheria/Tetanus/Acellular Pertussis (DTaP), Tetanus and Diphtheria (Tdap), Tetanus Toxoid (TT) or combinations which include these components;
- 2. polio vaccine, including Inactivated Polio Vaccine (IPV), or combinations which include this component;
- vaccines which contain measles antigen, including Measles, Mumps, and Rubella (MMR) and combinations which include these components;
- 4. vaccines which contain hepatitis antigen, including Hepatitis B (HepB), Hepatitis A (HepA), and combinations which include these components;
- 5. vaccines which contain varicella antigen, including varicella and combinations which include this component.
- 6. vaccines which contain meningococcal antigen and combinations which include this component.
- B. A one-month period will be allowed from the time the immunization is due until it is considered overdue. Medical, religious, and philosophic exemptions will be allowed for compliance with regulations concerning day care attendees and school enterers. Only medical and religious exemptions will be allowed for compliance with regulations concerning public assistance recipients. A copy of the current Office of Public Health immunization schedule can be obtained by writing to the Immunization Program, Office of Public Health, 1450 Poydras Street, Suite 1938, New Orleans, LA 70112 or by telephone (504)568-2600.
- C. [formerly paragraph 2:025-1] Any child 18 years or under, admitted to any elementary and secondary school, kindergarten, college, university, proprietary school, vocational school, licensed day care center or residential facility shall have verification that the child has had all appropriate immunizations for age of the child according to the Louisiana immunization schedule unless presenting a written statement from a physician stating that the procedure is contraindicated for medical reasons, or a written dissent from parents. The operator of any elementary and secondary school, kindergarten, college, university, proprietary school, vocational school, licensed day care center or residential facility shall report to the state health officer through the health unit of the parish or municipality where such facility is located any case or suspected case of reportable disease. Health records, including immunization records, shall be made available during normal operating hours for inspection when requested by the state health officer. When an outbreak of a communicable disease occurs in an elementary and secondary school, kindergarten, college, university, proprietary school, vocational school, licensed day care center or residential facility, the operator of said facility shall comply with outbreak control procedures as directed by the state health officer.
- D. [formerly paragraph 2:025-2] On or before October 1 of each year, the operator of each elementary and secondary school, kindergarten, college, university, proprietary school, vocational school, licensed day care center or residential

facility enrolling or housing any child 18 years or under, inclusive but not limited to these listed facilities shall submit a preliminary immunization status report of all children enrolled or housed as of that date. This compliance report shall be submitted utilizing the official Louisiana immunization information registry system (frequently referred to as LINKS) for reporting and shall include identifying information for each child, and for each dose of vaccine received by the child since birth. Any child exempt from the immunization requirement shall also be identified, and the reason for exemption given on the report. After review of the report(s) by the state health officer or his or her the elementary and secondary kindergarten, college, university, proprietary school. vocational school, licensed day care center or residential facility operator shall notify, on or before December 31 of each year, the parent or guardian of all enrolled or housed children, who are not compliant, with the immunization requirement of \$701.A and C of this Part.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2) and R.S. 40:5. Also see R.S. 17:170, R.S. 22:1030, R.S. 40:31.15 and R.S. 44:17.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1221 (June 2002), amended LR 38:1252 (May 2012) amended by the Department of Health, Office of Public Health, LR 45:

Part III. The Control of Rabies and Other Zoonotic Diseases

Chapter 1. Anti-Rabies Vaccination Requirements for Dogs and Cats

§103. Mandatory Vaccinations of Dogs, Cats, and Ferrets

[formerly paragraph 3:002]

A. No person shall own, keep or have in his custody a dog, cat, or ferret over 3 months of age that has not been vaccinated against rabies by a licensed veterinarian. Every owner of a dog, cat, or ferret shall cause said animal to be vaccinated initially with a series of two vaccinations, the first to be administered at 3 months of age, the second to be administered one year after the initial vaccination, Dogs, cats, or ferrets initially vaccinated later than 3 months of age shall also be administered a series of two vaccines, the second vaccine to be given one year after the initial vaccination. Thereafter, the interval between revaccinations shall conform to the Compendium of Animal Rabies Prevention and Control, 2016 Edition, Part II, Section B and Appendix 1: Rabies Vaccines Licensed and Marketed in the United States, 2016, which is published by the National Association of State Public Health Veterinarians, Inc. Vaccine licensing and labeling, including duration of immunity, is authorized by the Center for Veterinary Biologics at the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS) and those decisions are based on testing conducted by the vaccine manufacturer. The results of testing are presented to USDA during the registration process.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2)(a), R.S. 40:5(A) (2)(10)(11) and R.S. 40:1269.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1223 (June 2002), amended LR 33:650 (April 2007), LR 41:2657 (December 2015), amended by the Department of Health, Office of Public Health, LR:45:

§105. Human Exposure to Domestic Animal Bites [formerly paragraph 3:003]

A. When any dog, cat, or ferret bites a human being, said animal shall be confined (as described in §111) for a minimum of 10 days following the bite, or said animal shall be killed and the head submitted immediately to a laboratory of the Louisiana Department of Health for examination for rabies. During the observation period a rabies vaccine should not be administered to the animal to avoid confusing signs of rabies with possible side effects of vaccine administration. Any dog, cat, or ferret that develops any signs during the 10 day observation period shall be reported immediately to the local health authority and, provided such signs are compatible with rabies as determined by a licensed veterinarian or the official state public health veterinarian, the animal shall be killed and the head submitted to a laboratory of the Louisiana Department of Health for examination.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4A(2)(a), and R.S. 40:1269.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1223 (June 2002), amended LR 33:650 (April 2007), amended by the Department of Health, Office of Public Health, LR:45:

§107. Domestic Animals Bitten by Rabid Animals [formerly paragraph 3:004]

A. When bitten by a rabid animal, unvaccinated dogs, cats, or ferrets shall be destroyed immediately unless the owner is unwilling to have this done, in which case, the unvaccinated animal shall be confined (as described in §111) for four months for dogs and cats and six months for ferrets being released. A rabies vaccine shall be administered at the time of entry into quarantine (confinement) to bring the animal up to current rabies vaccination status. Administration of the vaccine shall be done as soon as possible. It is recommended that the period from exposure to vaccination not exceed 96 hours. If vaccination is delayed the official state public health veterinarian may consider increasing the quarantine period for dogs and cats from four to six months. Dogs, cats, or ferrets that are currently vaccinated shall be re-vaccinated immediately and confined (as described in §111) for 45 days.

- 1. Overdue dogs and cats. Dogs and cats that are overdue for a booster vaccination and that have appropriate documentation of having received a USDA-licensed rabies vaccine at least once previously shall immediately receive a booster vaccination and shall—be kept under the owner's control and observed for 45 days. Dogs and cats that are overdue for a booster and without appropriate documentation of having received a USDA-licensed rabies vaccine at least once previously shall be:
- a. treated as unvaccinated, immediately given a booster vaccination and placed in strict quarantine; or
- b. the official state public health veterinarian may consider use of prospective serological monitoring (PSM) of the animal to document prior vaccination by providing evidence of an anamnestic response to booster vaccination. If the official state public health veterinarian authorizes PSM, the animal shall be strictly quarantined while PSM is performed. If the official state public health veterinarian confirms that PSM provides evidence of an anamnestic response, the period of strict quarantine may be ended, and the animal may be kept under the owner's control and

observed for 45 days. If there is inadequate evidence of an anamnestic response, the animal is considered to have never been vaccinated and shall be placed in strict quarantine for 4 to 6 months.

Overdue ferrets. Ferrets that are overdue for a booster shall be considered unvaccinated and shall be immediately vaccinated for rabies and strictly quarantined for 6 months.

B.-D. ...

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2)(a), and R.S. 40:1269.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1223 (June 2002), amended LR 33:651 (April 2007), amended by the Department of Health, Office of Public Health, LR:45:

§111. Confinement or Quarantine of Animals [formerly paragraph 3:007]

A. ...

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4A(2)(a), and R.S. 40:1269.3.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1224 (June 2002), amended LR 33:651 (April 2007), amended by the Department of Health, Office of Public Health, LR:45:

Family Impact Statement

- (1) The effect on the stability of the family. There is no anticipated effect on the stability of the family.
- (2) The effect on the authority and rights of parents regarding the education and supervision of their children. There is no anticipated effect on the authority and rights of parents regarding the education and supervision of their children
- (3) The effect on the functioning of the family. There is no anticipated effect on the functioning of the family.
- (4) The effect on the family earnings and family budget. There is no anticipated effect on the family earnings and family budget.
- (5) The effect on the behavior and personal responsibility of children. There is no anticipated effect on the behavior and personal responsibility of children.
- (6) The ability of the family or local government to perform the function as contained in the proposed rule. There is no anticipated effect on the ability of the family or local government to perform the function as contained in the proposed rule.

Poverty Impact Statement

- (1.) The effect on household income, assets, and financial security. There is no anticipated effect on household income, assets, and financial security.
- (2.) The effect on early childhood development and preschool through postsecondary education development. There is no anticipated effect on early childhood development and preschool through postsecondary education development.
- (3.) The effect on employment and workforce development. There is no anticipated effect on employment and workforce development.
- (4.) The effect on taxes and tax credits. There is no anticipated effect on taxes and tax credits.

(5.) The effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance. There is no anticipated effect on child and dependent care, housing, health care, nutrition, transportation and utilities assistance.

Small Business Impact Statement

The impact of the proposed Rule on small businesses as defined in the Regulatory Flexibility Act has been considered. It is anticipated that the proposed rule will not have a significant adverse impact on small businesses as defined in the Regulatory Flexibility Act. The agency, consistent with health, safety, environmental, and economic factors has considered, and, where applicable, utilized regulatory methods in drafting the proposed rule to accomplish the objectives of the applicable statutes while minimizing any anticipated adverse impact on small businesses.

Provider Impact Statement

The proposed Rule should have minimal impact on providers as defined by HCR 170 of 2014 Regular Legislative Session.

Public Comments

Interested persons may submit written comments on the proposed Rule. Such comments must be received no later than Thursday, March 28, 2019 at COB, 4:30 pm, and should be addressed to DeAnn Gruber, Bureau Director, Bureau of Infectious Diseases, Office of Public Health, 1450 Poydras St., Ste. 2136, New Orleans, LA, 70112 or faxed to (504) 568-7044.

Public Hearing

Interested persons may submit a written request to conduct a public hearing either by U.S. mail to the Office of the Secretary ATTN: LDH Rulemaking Coordinator. Post Office Box 629, Baton Rouge, LA 70821-0629; however, such request must be received no later than 4:30 p.m. on March 11, 2019. If the criteria set forth in R.S. 49:953(A)(2)(a) are satisfied, LDH will conduct a public hearing at 10 am on Wednesday, March 27, 2019, in Room 118 of the Bienville Building, which is located at 628 North Fourth Street, Baton Rouge, LA. To confirm whether or not a public hearing will be held, interested persons should first call Stanley Bordelon at (225) 219-3454 after March 11, 2019. If a public hearing is to be held, all interested persons are invited to attend and present data, views, comments, or arguments, orally or in writing. In the event of a hearing, parking is available to the public in the Galvez Parking Garage which is located between North Sixth and North Fifth/North and Main Streets (cater-corner from the Bienville Building). Validated parking for the Galvez Garage may be available to public hearing attendees when the parking ticket is presented to LDH staff at the hearing.

> Jimmy Guidry, MD State Health Officer and Rebekah E. Gee, MD, MPH Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES RULE TITLE: Public Health—Sanitary Code

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

The proposed rule change is anticipated to increase expenditures for the Office of Public Health (OPH) by approximately \$2,630 in FY 19 for the publication of the proposed rule. It is not anticipated that any other state or local governmental units will incur costs or savings as a result of this rule change.

The proposed rule updates the reporting criteria for several infectious diseases in order to bring Louisiana's reporting requirements in line with recommendations from the Council of State and Territorial Epidemiologists (CSTE) and the Centers for Disease Control and Prevention (CDC). The proposed rule also updates the guidelines for rabies vaccination intervals for dogs and cats and updates required actions for domestic animals bitten by rabid animals to conform to current national best practices. Additionally, the proposed rule updates the Louisiana Immunization schedule in accordance with the Advisory Committee on Immunization Practice (ACIP) of the United States Public Health Service.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

There is no estimated effect on revenue collections of state or local governmental units.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

The estimated costs to directly affected persons or nongovernmental groups is expected to be negligible. Hospitals, clinics, laboratories, and other facilities that report infectious diseases may be affected by the proposed rule. Due to the addition of diseases to the list of reportable conditions, there may be a slight increase in workload to support these reporting requirements. Most of the added conditions are uncommon and will not result in a substantial increase in reporting effort. Additionally, some diseases will now only be reportable by laboratories, rather than all healthcare facilities, reducing some of the overall burden of reporting.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule has no known effect on competition and employment.

Alexander Billioux, MD, DPhil Assistant Secretary 1902#025 Evan Brasseaux Staff Director Legislative Fiscal Office

NOTICE OF INTENT

Department of Insurance Office of the Commissioner

Regulation 89—Suitability in Annuity Transactions (LAC 37:XIII.Chapter 117)

The Department of Insurance, pursuant to the authority of the Louisiana Insurance Code, R.S. 22:1 et seq., and in accordance with the Administrative Procedure Act, R.S. 49:950 et seq., hereby gives notice of its intent to amend Regulation 89—Suitability in Annuity Transactions.

The purpose of the amendments to Regulation 89 is to adopt changes made to date to the National Association of Insurance Commissioners' Suitability in Annuity Transactions Model Regulation and to makes those changes consistent with the Louisiana Insurance Code.

Title 37 INSURANCE

Part XIII. Regulations

Chapter 117. Regulation Number 89—Suitability in Annuity Transactions

§11701. Purpose

A. The purpose of this regulation is to require insurers to establish a system to supervise recommendations and to set forth standards and procedures for recommendations to consumers that result in transactions involving annuity products so that the insurance needs and financial objectives of consumers at the time of the transaction are appropriately addressed.

В. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11 and the Administrative Procedure Act, R.S. 49:950 et seq.

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 32:2268 (December 2006), amended LR 45:

§11703. Scope

A. This regulation shall apply to any recommendation to purchase, exchange, or replace an annuity made to a consumer by an insurance producer, or an insurer where no producer is involved, that results in the recommended purchase, exchange, or replacement.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11 and the Administrative Procedure Act, R.S. 49:950 et seq.

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 32:2268 (December 2006), amended LR 45:

§11705. Authority

A. This regulation is promulgated under the authority of R.S. 22:11 and the auspices of R.S. 22:1961 et seq., referred to as "Unfair Trade Practices."

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11 and the Administrative Procedure Act, R.S. 49:950 et seq.

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 32:2268 (December 2006), amended LR 45:

§11707. Exemptions

A. Unless otherwise specifically included, this regulation shall not apply to transactions involving:

1. - 2.f. ..

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11 and the Administrative Procedure Act, R.S. 49:950 et seq.

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 32:2268 (December 2006), amended LR 45:

§11709. Definitions

Annuity—an annuity that is an insurance product under State law that is individually solicited, whether the product is classified as an individual or group annuity.

FINRA—the Financial Industry Regulatory Authority or a succeeding agency.

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