John Bel Edwards GOVERNOR



Louisiana Department of Health Office of the Secretary

November 10, 2021

Via Statutorily Prescribed Email

To:

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

The Honorable Larry Bagley, Chairman, House Health & Welfare Committee

From:

Dr. Courtney N. Phillips

Secretary

Re:

Second Report LAC 51:II.701 - Immunization Schedule

Pursuant to the Louisiana Administrative Procedure Act, the Louisiana Department of Health, Office of Public Health, submits its second report regarding the proposed Immunization Schedule.

A Notice of Intent on the proposed amendments was published in the September 20, 2021 issue of the Louisiana Register (LR 47:1414). No written comments were received and there was no request for a public hearing were received during the notice period. Because there were no requests for a public hearing, one was not held for these proposed amendments. Additionally, no substantive changes were made to the proposed amendments since the report provide for in R.S. 49:968B-C was submitted.

Unless otherwise directed, the Department anticipates adopting the September 20, 2021, Notice of Intent when it is published as a final rule in the December 20, 2021, issue of the Louisiana Register.

Please contact DeAnn Gruber, Ph.D., <u>deann.gruber@la.gov</u>, if you have any questions or require additional information about this matter.

Cc:

Joseph Kanter, MD, MPH, State Health Officer

Kimberly Hood, JD, MPH, OPH Assistant Secretary, LDH

Melissa Mendoza, JD, MPH, OPH Legislative and Regulatory Affairs Director, LDH

Aliya Rubenstein, JD, MPH, OPH Rulemaking Liaison, LDH

Bethany Blackson, Legislative Liaison, LDH

Catherine Brindley, Editor, Louisiana Register, Office of the State Register

Small Business Analysis

In compliance with Act 820 of the 2008 Regular Session of the Louisiana Legislature, the economic-impact of this proposed Rule on small businesses has been considered. It is anticipated that this proposed Rule will have a positive impact on small businesses, as described in R.S. 49:965.2 et seq, as it will allow them to obtain independent review for claims.

Provider Impact Statement

In compliance with House Concurrent Resolution (HCR) 170 of the 2014 Regular Session of the Louisiana Legislature, the provider impact of this proposed Rule has been considered. It is anticipated that this proposed Rule will have no impact on the staffing level requirements or qualifications required to provide the same level of service, no direct or indirect cost to the provider to provide the same level of service, and will have no impact on the provider's ability to provide the same level of service as described in HCR 170.

Public Comments

Interested persons may submit written comments to Patrick Gillies, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821—9030. Mr. Gillies is responsible for responding to inquiries regarding this proposed Rule. The deadline for submitting written comments is at 4:30 p.m. on October 30, 2021.

Public Hearing

Interested persons may submit a written request to conduct a public hearing 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 October 12, 2021. If the criteria set forth in R.S. 49:953(A)(2)(a) are satisfied, LDH-will conduct a public hearing at 9:30-a.m. on October 28, 2021 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 Allen Enger at (225) 342-1342 after October 12, 2021. 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.

> Dr. Courtney N. Phillips Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: Managed Care for Physical and

Behavioral Health Independent Review Process for Provider Claims

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

It-is-anticipated that implementation of this proposed rule will have no programmatic fiscal impact to the state other than the cost of promulgation for FY 21-22. It is anticipated that \$1,296 (\$648-SGF and \$648-FED) will be expended in FY 21-22 for the state's administrative expense for promulgation of this proposed rule and the final rule.

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

It is anticipated that the implementation of this proposed rule will have no effect on revenue collections other than the federal share of the promulgation costs for FY 21-22. It is anticipated that \$648 will be collected in FY 21-22 for the federal share of the expense for promulgation of this proposed rule and the final rule.

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

In compliance with Act 204 of the 2021 Regular Session of the Louisiana Legislature, this proposed rule amends the provisions governing the independent review process for claims filed by managed care providers in order to add provisions that allow mental health rehabilitation providers to seek an independent review of waste and abuse recoupments by managed care organizations (MCOs). This proposed rule will be beneficial to providers of mental health rehabilitation services as it will allow them to obtain independent reviews of adverse determinations by MCOs that result in the recoupment of the payment of claims. The implementation of this proposed rule may result in an impact to the MCOs and mental health rehabilitation providers for FY 21 22, FY 22 23, and FY 23 24; however, any potential impact cannot be determined as there is no way to know if there will be recoupments or payments made as a result of this process.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

This rule has no known effect on competition and employment.

Patrick Gillies
Executive Medicaid Director
2109#052

Alan M. Boxberger Staff Director Legislative Fiscal Office

NOTICE OF INTENT

Department of Health Office of Public Health

Public Health Immunization Requirements (LAC 51:II.701)

Under the authority of R.S. 40:4 and 40:5, and in accordance with R.S. 49:950 et seq., the Administrative Procedure Act, notice is hereby given that the state health officer, acting through the Department of Health, Office of Public Health (LDH/OPH), intends to amend and recodify parts of Chapter 7 of Title 51—Public Health Immunization Requirements.

This proposed Rule will amend §701 of Chapter 7 of Title 51—Public Health Immunization Requirements. The proposed amendments add vaccines for SARS-CoV-2 to the list of required vaccinations for school entry to the extent that such vaccines are approved by the Food and Drug Administration for the individual's age, and also require such vaccines, and all potential boosters, on the same basis for school attendance.

Title 51

PUBLIC HEALTH—SANITARY CODE

Part II. The Control of Diseases

Chapter 7. Public Health Immunization 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;
- 3. 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.
- 7. vaccines for severe acute respiratory syndrome-coronavirus 2 (SARS-CoV-2, the virus which causes Coronavirus Disease 2019, also known as COVID-19), or variants thereof, to the extent that such vaccines have been fully approved by the U.S. Food & Drug Administration (FDA) for the individual's age.

B. - D. ...

E. Notwithstanding anything in this Section or Code to the contrary, and in addition to any other requirements of law, each individual entering or attending any school within the state in-person shall present to such school satisfactory evidence of having received vaccination(s) in accordance with the dosing schedule, including any booster doses recommended by the U.S. Centers for Disease Control and Prevention (CDC), set forth in the applicable Vaccine Information Statement (VIS) for severe acute respiratory syndrome-coronavirus 2 (SARS-CoV-2, the virus which causes COVID-19), or known variants thereof, to the extent that such vaccines have been fully approved by the U.S. Food and Drug Administration (FDA) for the individual's age. Satisfactory evidence that administration of such vaccinations is in progress will satisfy this requirement. Each school in this state shall prohibit in-person attendance of any individual not vaccinated as required by this subsection, unless the individual submits a written statement from a physician stating that such vaccination is contraindicated for medical reasons, or the individual or his parent or guardian submits a written dissent. Each school in this state shall maintain records showing compliance of each attending individual with the requirements of this subsection. As used in this subsection, the term "school" shall include, but is not limited to, elementary and secondary schools, kindergartens, colleges, universities, proprietary schools, vocation schools, and licensed day care centers.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2), R.S. 40:5(A) and R.S. 40:31.15. Also see R.S. 17:170, R.S. 22:1030, 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 45:670 (May 2019), amended LR 46:590 (April 2020), amended by the Department of Health, Office of Public Health, LR 47:

Family Impact Statement

- 1. Will the proposed rule affect the stability of the family? Yes. The stability of the family will be enhanced by having more persons in the home vaccinated against SARS-CoV-2 and by protecting the health of the children.
- 2. Will the proposed rule affect the authority and rights of parents regarding the education and supervision of their children? No, parents will still be able to exempt their children from being vaccinated for religious, medical, or philosophical reasons.
- 3. Will the proposed rule affect the functioning of the family? No.
- 4. Will the proposed rule affect family earnings and family budget? No.
- 5. Will the proposed rule affect the behavior and personal responsibility of children? No.
- 6. Is the family or a local government able to perform the function as contained the proposed rule? Yes.

Poverty Impact Statement

- 1. The effect on household income, assets, and financial security. The intent of this vaccination Rule is to prevent the additional spreading of SARS-CoV-2 disease to other persons; therefore, prevention of additional cases of the disease will help to keep other family members and the community at-large healthy and thus would be expected to help to prevent the depletion of household income, assets, and financial security.
- 2. The effect on early childhood development and preschool through postsecondary education development. Other than attempting to keep school aged children healthy, there will be no effect on childhood development and preschool through postsecondary education development.
- 3. The effect on employment and workforce development. Persons who are able to prevent becoming infected with SARS-CoV-2 would be expected to remain healthy and such healthy persons would improve his or her chances to either remain employed or become employed. Keeping persons healthy would enhance the workforce as a whole.
- 4. The effect on taxes and tax credits. Keeping persons healthy by implementing this proposed Rule should help to maintain taxes at a lower level since the fewer sick persons there are in the SARS-CoV-2 pandemic would be expected to check the total amount of funds necessary to maintain a healthy population. This, in turn, should help to prevent the need for additional taxation.
- 5. The effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance. There will be a positive effect on child and dependent care,

housing, health care, nutrition, transportation, and utilities assistance because less services will be needed.

Small Business Analysis

It is anticipated that the proposed Rule will not have a significant adverse impact on small businesses as defined in the Small Business Protection Act.

Provider Impact Statement

The proposed Rule should not have any known or foreseeable impact on providers as defined by HCR 170 of the 2014 Regular Legislative Session. In particular, there should be no known or foreseeable effect on:

- 1. the staffing level requirements or qualifications required to provide the same level of service;
- 2. the total direct and indirect effect on the cost to the providers to provide the same level of service; or
- 3. the overall effect on the ability of the provider to provide the same level of service.

Public Comments

Interested persons may submit written comments no later than October 28, 2021 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 October 10, 2021. If the criteria set forth in R.S. 49:953(A)(2)(a) are satisfied, LDH will conduct a public hearing at 9 a.m. on Monday, October 28, 2021, in Room 173 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 Allen Enger at (225) 342-1342 after October 11, 2021. 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 the Bienville Building's front security desk.

> Joseph Kanter, MD, MPH State Health Officer and Dr. Courtney N. Phillips Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES RULE TITLE: Public Health Immunization Requirements

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

The Office of Public Health (OPH) will incur \$426 in expenses associated with the publication of this proposed rule change. The expenses will be paid with State General Fund.

There will also be a cost to the Medicaid program associated with reimbursing providers for administering vaccines to Medicaid patients. This total cost to the Medicaid program is dependent on the number of Medicaid patients that receive the vaccine. The Medicaid reimbursement rate is \$37.08 and paid for with 100% federal funds.

This proposed rule amends §701 of Chapter 7 of Title 51—Public Health Immunization Requirements. The proposed amendments add vaccines for SARS-CoV-2 to the list of required vaccinations for school entry to the extent that such vaccines are approved by the Food and Drug Administration for the individual's age. The rule also provides that each school in this state shall prohibit in-person attendance of any individual not vaccinated, unless the individual submits a written statement from a physician stating that such vaccination is contraindicated for medical reasons, or the individual or his/her parent or guardian submits a written dissent.

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

The proposed rule change will not affect revenue collections for state or local governmental units.

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

The proposed rule may have an economic benefit to healthcare providers that administer vaccines and vaccine manufacturers, given that this is likely to be an increase demand for vaccinations. The proposed rule may have an increased cost to health insurance programs, including Medicaid, associated with reimbursing providers for the cost associated with administering the vaccines.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule is not anticipated to have an impact on existing competition or employment among vaccination providers.

Kimberly Hood, JD, MPH Assistant Secretary 2109#033 Alan M. Boxberger Staff Director Legislative Fiscal Office

NOTICE OF INTENT

Department of Insurance
Office of the Commissioner

Regulation 119 Issuance of Consent or a Waiver Pursuant to R.S. 22:1554 (LAC 37:XIII.Chapter 177)

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 promulgate Regulation 119 Issuance of Consent or a Waiver Pursuant to R.S. 22:1554. Regulation 119 (1) establishes the procedure for the issuance of consent or a waiver to an-insurance-producer seeking to employ or to otherwise associate with his business an individual engaged in the business of insurance who has been convicted of a felony in accordance with R.S. 22:1554(A)(18); (2) prescribes the duration and transferability of consent or a waiver-issued-to-an insurance producer; (3) provides-for the applicability of 18 U.S.C. §1033(e)(B)(2); and (4) provides for the penalties imposed for failure to comply with this regulation in accordance with R.S. 22:1554A.