

Rebekah E. Gee MD, MPH

State of Louisiana

Louisiana Department of Health Office of the Secretary

December 9, 2019

Via Statutorily Required Email

To: The Honorable John Alario, President, Louisiana Senate

The Honorable Taylor Barras, Speaker, Louisiana House of Representatives

The Honorable Fred H. Mills, Jr., Chairman, Sanata Harlet, & W. 16.

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

The Honorable Frank A. Hoffmann, Chairman, House Health & Welfare

Committee

From:

Rebekah E. Gee, MD, MPH

Secretary

Re: First Report. Proposed Amendments to LAC 51.VII.2707

Under the authority of the laws of the State of Louisiana and in accordance with the provisions of Chapter 6 of Title 36 of the Louisiana Revised Statutes of 1950, and with the Administrative Procedure Act, La. R.S. 49:950 et seq., the secretary hereby gives notice that rulemaking procedures have been initiated to promulgate amendments to the rules governing the Emergency Preparedness Activities – LAC 48:I.Chapter 6.

I. Copy of the rule as it is proposed after amendment, with new proposed language indicated by the underscored text.

See attachment.

II. A Statement of the proposed action.

The department proposes to enact rules to authorize hospitals and healthcare providers to use protected health information for the sole purpose of participating in emergency preparedness training, which includes testing the functionality of the AtRisk Registry. The AtRisk Registry assists providers with the safe evacuation of at-risk patients, by keeping track of at-risk patients in any emergency event. The AtRisk Registry is able to integrate with the military systems used to plan and execute evacuations. In order to ensure proper use of the Louisiana AtRisk Registry during public health emergencies, it is critical that health care providers engage in exercises that simulate the actual process prior to an emergency event. Training of proper use of the system, which involves using protected health information, helps to ensure

patient health and safety and timely evacuation in the event of a true public health emergency.

III. Specific citation of law authorizing promulgation of the rule.

R.S. 40:4 and 40:5.

Circumstances which require the amendment of the rule.

Existing sampling requirements place an undue and onerous burden on small businesses in the state of Louisiana while not providing additional protections for public health.

IV. Statement of Fiscal and Economic Impact.

See attachment.

Please contact Henry Yenni at <u>Henry Yenni@la.gov</u> or (225) 342-0428, if you have any questions or require additional information about this matter.

Attachments (2)

cc: Jimmy Guidry, MD, State Health Officer
Alexander Billioux, MD, DPhil, Assistant Secretary, Office of Public Health
Henty Yenni, Louisiana Department of Health
Anita Dupuy, Legislative Liaison, Louisiana Department of Health
Rhea Davis, Rulemaking Liaison, Office of Public Health
Allen Enger, Rulemaking Coordinator, Louisiana Department of Health
Catherine Brindley, Editor, Louisiana Register, Office of State Register

NOTICE OF INTENT

Department of Health

Office of Public Health

Emergency Preparedness Activities

Notice is hereby given, in accordance with the Louisiana 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 proposes to promulgate LAC 48:I.Chapter 6, Uses and Disclosures of Information for Public Health Emergency Preparedness Activities. R.S. 40:4 and R.S. 40:5 authorize the State Health Officer acting through the Office of Public Health of the Louisiana Department of Health to prepare, promulgate, and enforce rules and regulations related to public health in the State of Louisiana. R.S. 29:766(E) authorizes the Governor's Office of Homeland Security and Emergency Preparedness, in consultation with the Secretary of the Louisiana Department of Health, to coordinate all matters pertaining to the public health emergency response of the state. 45 CFR §\$164.512(b) and (j) authorize the use and disclosure of protected health information for public health activities and to avert serious threats to health or safety.

This Chapter is enacted to authorize hospitals and other health care providers to use protected health information for the sole purpose of participating in emergency preparedness training, which includes testing the functionality of the AtRisk Registry.

The AtRisk Registry assists providers with the safe evacuation of at-risk patients, by keeping track of at-risk patients in any emergency event. The AtRisk Registry is able to integrate with the military systems used to plan and execute evacuations. In order to ensure proper use of the Louisiana AtRisk Registry during public health emergencies, it is critical that health care providers engage in exercises that simulate the actual process prior to an emergency event. Training of proper use of the system, which involves using protected health information, helps to ensure patient health and safety and timely evacuation in the event of a true public health emergency.

Title 48

PUBLIC HEALTH - GENERAL

Part I. General Administration

Subpart 1. General

Chapter 6. Uses and Disclosures of Information for Public Health Emergency Preparedness Activities

\$601. Purpose and Scope

A. The purpose of this rule is to authorize health care providers operating in the state of Louisiana to use and disclose protected health information (PHI) to the Louisiana AtRisk Registry, or any other reporting database or registry employed by the Louisiana Emergency Support Function (ESF) 8, for the sole purpose of participating in emergency preparedness

training activities, which includes exercises to test the AtRisk Registry.

B. The scope of this rule covers all hospitals, home health agencies, hospice agencies, and other health care providers who are enrolled in the Louisiana AtRisk Registry. The rule authorizes health care providers to use and disclose PHI to the Louisiana AtRisk Registry, or any other reporting database or registry employed by ESF 8, for the purpose of participating in public health emergency preparedness activities, unless prohibited by other state or federal law or regulation. This Chapter does not authorize unlawful disclosure of patient PHI.

\$603. Definitions

Unless otherwise specifically provided herein, the following words and terms used in this Part are defined for the purposes thereof as follows:

AtRisk Registry - a database used by Louisiana Emergency
Support Function (ESF) 8 to manage patient information related
to the Medical Institution Evacuation Plan.

Disclosure — has the same meaning as set forth in 45 C.F.R. \$160.103.

Emergency preparedness - has the same meaning as set forth
in R.S. 29:723.

Health Care Provider- has the same meaning as set forth in 45 C.F.R. §160.103.

Home Health Agency - has the same meaning as set forth in LAC 48:I.9101.

Hospice - has the same meaning as set forth in LAC 48:I.8201.

Hospital - has the same meaning as set forth in LAC 48:I.9303.

Protected Health Information (PHI) - has the same meaning as set forth in 45 C.F.R. §160.103.

Public Health Authority - has the same meaning as set forth in 45 C.F.R. §160.501.

Use - has the same meaning as set forth in 45 C.F.R. \$160.103.

§605. Permitted Uses and Disclosures for Public Health Emergency Preparedness Activities

- A. Protected health information (PHI) of patients of home health agencies and hospice agencies may be used and disclosed for emergency preparedness training activities and for an actual event when:
- 1. The patient of the home health agency or hospice agency or the patient's legal representative has signed a Health Insurance Portability and Accountability Act (HIPAA)-compliant authorization for use and disclosure of PHI; and

- 2. The home health agency or hospice agency certifies on a weekly basis that the patient meets at least one of the following criteria:
- a. The patient lives alone, without a caregiver and is unable to evacuate himself;
- b. The patient has a caregiver, but the caregiver is physically or mentally incapable of complying with an evacuation order;
- c. The patient does not have the financial means to comply with an evacuation order; or
- d. The patient refuses to evacuate.
- B. A hospital may use and disclose PHI without the patient's consent or knowledge for the purpose of its participation in public health emergency preparedness activities, including, but not limited to, training, assessment, and program development, if the provider's use of the PHI meets the requirements of Paragraph 1 below, or if the provider's disclosure of the PHI meets the requirements of Paragraphs 1 and 2 below:
- 1. The use or disclosure is necessary for the treatment of the individual or for public health activities authorized by law, including public health emergency preparedness activities.
- 2. The disclosure is made to a public health authority, its agent, or to another hospital or other health care provider involved in the public health emergency preparedness activities.

§607. Treatment of Protected Health Information

- A. For both emergency preparedness training activities and actual public health emergency events, the health care provider shall upload patient protected health information (PHI) to the Louisiana AtRisk Registry.
- The Louisiana AtRisk Registry shall maintain PHI on a secure File Transfer Protocol (FTP) server.
- 2. After an event or training, all data uploaded to the Louisiana AtRisk Registry FTP server shall be deleted and be non-recoverable.
- B. Access to PHI on the Louisiana AtRisk Registry shall be limited to the following entities:
- 1. Department of Health (LDH) shall have access to all patient PHI in the Louisiana AtRisk Registry throughout the state.
- 2. The Regional Disaster Recovery Center (DRC) shall have access to PHI for patients within its region.
- 3. Enrolled hospitals shall have access only to its patient's PHI. If a patient is transferred to another hospital, both the sending and receiving hospitals have access to the patient's PHI.
- 4. Enrolled hospice and home health agencies shall have access only to its patient's PHI.

5. The Louisiana-Mississippi Hospice and Palliative Care
Organization (LMHPCO) shall have access to PHI of patients of
all enrolled hospice and home health agencies.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4, 40:5 and 29:766(E).

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 45: (May 2019).

Family Impact Statement

- I. The proposed regulation should have no measurable impact upon the stability of the family.
- II. The proposed regulation should have no impact upon the rights and authority of parents regarding the education and supervision of their children.
- III. The proposed regulation should have no direct impact upon the functioning of the family.
- IV. The proposed regulation should have no direct impact upon family earnings and budget.
- V. The proposed regulation should have no impact upon the behavior and personal responsibility of children.
- VI. The proposed regulation should have no impact upon the ability of the family or a local governmental unit to perform the function as contained in the rule.

Poverty Impact Statement

- I. The proposed regulation should have no effect on household income assets and financial security.
- II. The proposed regulation should have no effect on early childhood development and preschool through postsecondary education development.
- III. The proposed regulation should have no effect on employment and workforce development.
- IV. The proposed regulation should have no effect on taxes and tax credits.
- V. The proposed regulation may have an undeterminable impact on child and dependent care, housing, healthcare, nutrition, transportation, and utilities assistance.

Small Business Analysis

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

- The proposed regulation should have no measurable adverse impact upon small businesses.
- II. The proposed regulation should have no measureable adverse impact on projected reporting, record keeping, and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record.
- III. The proposed regulation should have no measureable adverse impact upon small businesses.
- IV. The proposed regulation should have no measurable adverse impact upon small businesses; therefore, there are no less intrusive or less costly alternatives to the implementation of the proposed regulation.

Provider Impact Statement

- I. The proposed regulation should have no effect on the staffing level requirements or qualifications required to provide the same level of service.
- II. The proposed regulation should have no effect, either directly or indirectly, on the cost to the provider to provide the same level of service.
- III. The proposed regulation should not have an effect on the overall ability of the provider to provide the same level of service.

Public Comments

Interested persons may submit written comments on the proposed rule. Such comments must be received no later than Tuesday, January 28, 2020, at COB, 4:30 pm, and should be addressed to Henry Yennie, Office of Public Health, P.O. Box 629, Baton Rouge, LA 70821-0629.

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 January 10, 2020. If the criteria set forth in R.S. 49:953(A)(2)(a) are satisfied, LDH will conduct a public hearing at 9:00 a.m. on Tuesday, January 28, 2020, 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 January 10, 2020. 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

100 MONING INCHISE ENGLIS				
Person				
Preparing Statement:	Allen Enger	Dept.:	Louisiana Department of Health	
Phone:	225-342-9037	Office:	Office of Public Health	
Return				
Address:	628 N. 4th St.,			
	Baton Rouge, LA 70802	Rule Tit	le: Use and Disclosure of Information for	
			ealth Emergency Preparedness Activities	
		Date Rule Tal	kes Effect:: <u>Upon Promulgation</u>	
SUMMARY				
(Use complete sentences)				
fiscal and eco FOLLOWING	nomic impact statement on STATEMENTS SUMMARIZ	the rule proposed E ATTACHED WO	vised Statutes, there is hereby submitted a for adoption, repeal or amendment. THE DRKSHEETS, I THROUGH IV AND WILL PROPOSED AGENCY RULE.	
I. STIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS (Summary)				
The pr (OPH) anticip	The proposed rule change is anticipated to increase expenditures for the Office of Public Health (OPH) by approximately \$693 in FY 2019 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 provides for the use and disclosure of protected health information (PHI) by health care providers for emergency preparedness activities. Specifically, the rule permits home health agencies, hospice agencies, and hospitals to use and disclose certain PHI without a patient's consent for the purpose of participating in emergency preparedness activities, such as training, assessments, and program development. The rule provides that the health care provider shall upload the PHI into the Louisiana AtRisk Registry and that all PHI uploaded to the registry will be deleted after the emergency preparedness activity is complete. The rule also provides a list of entities that will have access to the PHI in the registry.				
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. ESTIM OR NO	ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS (Summary)			
Health care providers that choose to participate in the Louisiana AtRisk Registry may experience a slight decrease in workload as a result of the provisions of the proposed rule. Health care providers will be able to directly upload patients' protected health information into the registry without having to complete paperwork or to create mock patient information.				
IV. ESTIM	ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)			
The proposed rule has no known effect on competition and employment.				
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Signature of As	gency Head or Designee		Legislative Fiscal Officer or Designee	
Alexander Billioux, MD, DPhil				
Assistant Secretary, Office of Public Health Typed Name & Title of Agency Head or Designee				
[2/7]	115		12-16/2016	

Date of Signature

Date of Signature