

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:1252 (June 2010), amended LR 36:2282 (October 2010).

Bruce D. Greenstein  
Secretary

1010#035

## RULE

### Department of Health and Hospitals Office of Public Health

#### Food Processing Plans, Food Recall Plans and Positive Test Result Reporting (LAC 51:VI.101, 125, 127, and 129)

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 and Hospitals, Office of Public Health (DHH-OPH), amends Part VI (Manufacturing, Processing, Packing, and Holding of Food, Drugs, and Cosmetics) of the Louisiana State Sanitary Code (LAC 51). This Rule implements the requirements of Act 341 of the 2009 Regular Session. The major impetus behind this Rule is to require food processing plants to maintain written food processing plans and food recall plans and to mandate notification of the department if laboratory testing reveals contamination of manufactured foods or finished ingredients.

#### Title 51

#### PUBLIC HEALTH—SANITARY CODE

#### Part VI. Manufacturing, Processing, Packing, and Holding of Food, Drugs, and Cosmetics

#### Chapter 1. General Regulations, Definitions, Permits, Registration, Machinery, Equipment and Utensils, Premises and Buildings, Temperature Control

#### §101. Definitions [formerly paragraph 6:001]

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

\* \* \*

*CCP*—see *Critical Control Point*.

*Confirmed Positive Test Result*—any result obtained from a laboratory test of an ingredient, equipment, container, or finished product that indicates the presence of an adulterant, as defined by R.S. 40:607 et seq., in excess of any tolerance specified in state or federal law or regulations.

*Control*—to manage the conditions of an operation to maintain compliance with established criteria, *control* also means that correct procedures are being followed and criteria are being met.

*Control Measure*—any action or activity that can be used to prevent, eliminate, or reduce a significant *hazard* that is managed as a *critical control point*.

*Control Point*—any step at which biological, chemical or physical factors can be controlled.

*Corrective Action*—procedures followed when a *deviation* occurs.

\* \* \*

*Critical Control Point (CCP)*—a step at which *control* can be applied and is essential to prevent or eliminate a *food*, *drug*, or *cosmetic safety hazard* or reduce it to an acceptable level.

*Critical Limit*—the value(s) to which a biological, chemical or physical parameter must be controlled at a *CCP* to prevent, eliminate or reduce to an acceptable level the occurrence of a *food*, *drug*, or *cosmetic safety hazard*.

*Deviation*—a failure to meet a *critical limit*.

\* \* \*

*Food Processing Plant*—a commercial operation that manufactures *food* for human consumption and does not provide *food* directly to a consumer from that location. Such term shall not include a commercial operation that produces raw agricultural commodities and whose end product remains a raw agricultural product.

*GMP*—see *good manufacturing practices*.

*Good Manufacturing Practices*—practices, methods, and controls used in the manufacturing, processing, packing or holding of *foods*, *drugs* or *cosmetics* that comply with the requirements in this Part and for *foods*, with 21 CFR 110.10, 110.19, 110.20, 110.35, 110.37, 110.40, 110.80, and 110.93, to assure that *foods*, *drugs* or *cosmetics* for human consumption or use are safe and have been prepared, packed and held under sanitary conditions.

*HACCP*—see *hazard analysis critical control point*.

*HACCP Plan*—the written document which is based upon the principles of *HACCP* and which delineates the procedures to be followed.

*HACCP System*—the implemented *HACCP plan* and *pre-requisite programs* including any other applicable requirements.

*Hazard*—a biological, chemical, radiological or physical agent that is reasonably likely to cause illness or injury in the absence of its *control*.

*Hazard Analysis Critical Control Point (HAACP)*—a systematic approach to the identification, evaluation and control of significant *food*, *drug*, or *cosmetic safety hazards*.

\* \* \*

*Monitor*—to conduct a planned sequence of observations or measurements to assess whether a *CCP* is under control or to assess the conditions and practices of all required *Pre-Requisite Programs (PPs)* and to produce an accurate record for future use in *verification*.

\* \* \*

*PP*—see *Pre-Requisite Program*.

*Pre-Requisite Program (PP)*—procedures, including *good manufacturing practices*, that address operational conditions providing the foundation for the *HACCP system*.

\* \* \*

*State Health Officer*—the legally appointed or acting State Health Officer of the Department of Health and Hospitals having jurisdiction over the entire state of Louisiana, and includes his/her duly authorized representative in accordance with R.S. 40:4 and 40:5.

*Validation*—the element of *verification* focused on collecting and evaluating scientific and technical information to determine whether the *HACCP plan*, when properly implemented, will effectively control the *hazards*.

*Verification*—those activities, other than *monitoring*, that determine the validity of the *HACCP plan* and that the system is operating according to the plan.

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 R.S. 40:4(A)(1)(a) and R.S. 40:5(2)(3)(5)(8)(15)(17)(19)(21). Also see R.S. 40:601 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1230 (June 2002), amended LR 36:2283 (October 2010).

#### **§125. Food Processing Plan**

A. This Section shall become effective on January 1, 2011.

B. All food processing plants operating within the state of Louisiana shall maintain on-site a written food processing plan that shall be available for review upon request by the State Health Officer.

C. The food processing plan shall include, at a minimum, the following information:

1. a list of processing steps used to manufacture products, including potential biological, chemical, radiological or physical hazards that may be inherent to or introduced to the product at each step;
2. a description of preventative controls used in each step to control listed hazards;
3. a description of monitoring methods used to verify efficacy of preventative controls;
4. records of any corrective actions taken as a result of such monitoring; and
5. records of any amendments to the plan as a result of corrective actions.

D. Any food processing plant that currently holds and maintains a HACCP plan meeting the requirements of United States Department of Agriculture or Food and Drug Administration regulations shall be considered to be in compliance with this Section.

E. Any person or firm operating a food processing plant that violates the provisions of this Section shall be subject to a civil fine of not more than \$500.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(1)(a), R.S. 40:5(2)(3)(5)(8)(15)(17)(19)(21) and R.S. 40:652.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 36:2284 (October 2010).

#### **§127. Food Recall Plan**

A. This Section shall become effective on January 1, 2011.

B. General. All food processing plants operating within the state of Louisiana shall maintain a written food recall plan that shall be available for review upon request by the state health officer. The owners and operators shall amend their written food recall plan with any recommendations deemed necessary by the state health officer to make such plan effective for food safety concerns.

C. Notification. The food recall plan shall include, at a minimum, the provision for notification of representatives of the Food and Drug Unit of the Office of Public Health of the Department of Health and Hospitals. In addition, for any products subject to recall that may have been involved in interstate commerce, the food recall plan shall have additional provisions to notify the Food and Drug

Administration. Notification shall include, at a minimum, the following information:

1. the identity of the product(s) under recall, including name and lot number or batch code;
2. the reason for the recall;
3. the date and means of discovery of the reason for the recall;
4. total amount of product and amount estimated to be in distribution;
5. list of consignees that have or may have received affected product;
6. contact information for a responsible person at the firm who will oversee the recall; and
7. proposed strategy for conducting the recall.

D. Suppliers and Consignees. The food processing plant shall maintain a current list of suppliers and consignees for all ingredients and finished goods used in the manufacturing or distribution of the firm's products. Such list(s) shall be available for review by the state health officer.

E. Communication with the Public. The food recall plan shall include the proposed mode(s) of public communication including, as necessary, telephone, letter, website, and media outlet (newspaper, television, radio, and/or other sources) notifications.

F. Level(s) of Recall. The food recall plan shall include a method or procedure for evaluating whether the recall needs to be conducted at the wholesale, retail, or consumer levels, or if some combination is appropriate.

G. Effectiveness Checks. The food recall plan shall include provisions for conducting effectiveness checks, at the appropriate level(s) as determined necessary in Subsection F of this Section, by means of telephone interviews, site visits, or other effective means of communication.

H. Post Recall Evaluation. The food recall plan shall require a re-evaluation of all elements of the recall plan after a recall has been conducted to correct deficiencies or enhance overall effectiveness.

I. Nothing in this Section shall prevent the state health officer from exercising his authority to protect the public from adulterated or misbranded products by seizure and/or destruction of defective products in accordance with R.S. 40:632 and §105.D of this Chapter.

J. Any person or firm operating a food processing plant that violates the provisions of this Section shall be subject to a civil fine of not more than \$500.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:4(A)(1)(a), R.S. 40:5(2)(3)(5)(8)(15)(17)(19)(21) and R.S. 40:653.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 36:2284 (October 2010).

#### **§129. Laboratory Test Reporting Requirements and Additional Test Mandate**

A. When a person or firm operating a food processing plant in the state of Louisiana receives information from an in-house or external laboratory analyzing samples or specimens of finished foods or finished ingredients which indicates a confirmed positive test result signifying that the food or ingredient may be adulterated (in accordance with the definitions provided in R.S. 40:607, et seq.) or may otherwise constitute an imminent health hazard, the person or firm shall report this confirmed positive test result to

representatives of the Food and Drug Unit of the Office of Public Health of the Department of Health and Hospitals within 24 hours of obtaining such information.

B. The state health officer may, based upon a demonstration of probable cause by the Department of Health and Hospitals indicating that a food processing plant is producing food which may be adulterated (in accordance with the definitions provided in R.S. 40:607 et seq.) or in such a manner as to cause an imminent health hazard, order the food processing plant to submit samples to a laboratory specified by the department for testing at the food processing facility's expense. A copy of the written or electronic results of such testing, including a reference to test methods used, shall be furnished by the food processing plant or by the laboratory to the department as soon as a confirmed test result (either positive or negative) is available but no later than 24 hours of obtaining such information.

C. Any person or firm operating a food processing plant that violates the provisions of this Section shall be subject to a civil fine of not more than \$1,000.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40: 4(A)(1)(a), R.S. 40:5(2)(3)(5)(8)(15)(17)(19)(21) and R.S. 40: 654.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 36:2284 (October 2010).

Alan Levine  
Secretary

1010#080

## RULE

### Office of the Governor Division of Administration Office of Group Benefits

PPO Plan of Benefits—Continued Coverage:  
Michelle's Law (LAC 32:III.103)

In accordance with the applicable provisions of R.S. 49:950 et seq., the Administrative Procedure Act, and pursuant to the authority granted by R.S. 42:801(C) and 802(B)(2), as amended and reenacted by Act 1178 of 2001, vesting the Office of Group Benefits (OGB) with the responsibility for administration of the programs of benefits authorized and provided pursuant to Chapter 12 of Title 42 of the Louisiana Revised Statutes, and granting the power to adopt and promulgate rules with respect thereto, OGB finds that it is necessary to revise and amend the eligibility provisions of its Plan Document to provide availability of continued coverage for students enrolled in post-secondary educational institutions who would otherwise lose eligibility due to a medically necessary leave of absence, as required by "Michelle's Law" (Public Law 110-381). Accordingly, OGB hereby adopts the following Rule to become effective upon promulgation.

## Title 32

### EMPLOYEE BENEFITS

#### Part III. Preferred Provider (PPO) Plan of Benefits

##### Chapter 1. Eligibility

##### §103. Continued Coverage

A. - E.2.b. ...

F.1. Coverage may continue for an employee's never-married dependent child under the age of 24 years of age if, while enrolled as a full-time student in a post-secondary institution, the student ceases to meet the institution's full-time student criteria due to a medically necessary leave of absence. Coverage may continue until the earlier of:

a. one year from the start of the medically necessary leave of absence (COBRA rights would apply after the one year period has expired); or

b. the day the student's coverage would have otherwise ended under the terms of the plan.

2. For purposes of this provision, a "medically necessary leave of absence" includes an actual leave of absence from the post-secondary educational institution, or any other change in enrollment at the institution that:

a. begins while the student is suffering from a serious illness or injury;

b. is medically necessary; and

c. causes the loss of student status under the terms of the plan.

4. Written certification must be provided by a treating physician certifying that the student is suffering from a serious illness or injury that requires the medically necessary leave of absence.

AUTHORITY NOTE: Promulgated in accordance with R.S. 42:801(C) and 802(B)(1).

HISTORICAL NOTE: Promulgated by the Office of the Governor, Board of Trustees of the State Employees Group Benefits Program, LR 25:1827 (October 1999), amended by the Office of the Governor, Division of Administration, Office of Group Benefits, LR 30:1191 (June 2004), LR 32:1884 (October 2006), LR 36:2285 (October 2010).

Tommy D. Teague  
Chief Executive Officer

1010#055

## RULE

### Office of the Governor Division of Administration Office of Group Benefits

PPO Plan of Benefits—Mental Health and  
Substance Abuse Benefits (LAC 32:III.703)

In accordance with the applicable provisions of R.S. 49:950, et seq., the Administrative Procedure Act, and pursuant to the authority granted by R.S. 42:801(C) and 802(B)(2), as amended and reenacted by Act 1178 of 2001, vesting the Office of Group Benefits (OGB) with the responsibility for administration of the programs of benefits authorized and provided pursuant to Chapter 12 of Title 42 of the Louisiana Revised Statutes, and granting the power to adopt and promulgate rules with respect thereto, OGB finds that it is necessary to revise and amend the eligibility provisions of its Plan Document pertaining to mental health and substance abuse benefits to more closely align those benefits with the requirements of the Wellstone-Domenici Mental Health Parity and Addiction Equity Act of 2008 (parts of Public Law 110-343). Accordingly, OGB hereby adopts the following Rule to become effective upon promulgation.