

Emergency Rules

DECLARATION OF EMERGENCY

Department of Agriculture and Forestry Office of the Commissioner

Chloramphenicol in Crabs and Crabmeat Testing and Sale
(LAC 7:XXXV.143 and 145)

The Commissioner of Agriculture and Forestry hereby adopts the following Emergency Rule governing the testing and sale of crab or crabmeat in Louisiana. This Rule is being adopted in accordance with R.S. 3:2(A), 3:3(B), R.S. 3:4608 and the Emergency Rule provisions of R.S. 49:953(B) of the Administrative Procedure Act.

The commissioner has promulgated these rules and regulations to implement standards relating to Chloramphenicol in crab or crabmeat that are consistent with standards adopted by the FDA regarding chloramphenicol in foods. All crab or crabmeat sold in Louisiana must meet the standards adopted by the commissioner, herein, prior to distribution and sale.

Chloramphenicol is a broad-spectrum antibiotic that has been restricted by the FDA for use in humans only in those cases where other antibiotics have not been successful. The FDA has set a zero tolerance level for Chloramphenicol in food and has prohibited the extra label use of Chloramphenicol in the United States in food producing animals, (21 CFR 530.41).

Chloramphenicol is known to cause aplastic anemia, which adversely affects the ability of a person's bone marrow to produce red blood cells. Aplastic anemia can be fatal. In addition, according to the National Institute on Environmental and Health Sciences, Chloramphenicol can reasonably be anticipated to be a human carcinogen. In widely accepted references such as "Drugs in Pregnancy and Lactation," the use of Chloramphenicol is strongly dissuaded during pregnancy, especially late pregnancy. Chloramphenicol can be transmitted to an unborn child through the placenta and to an infant through the mother's milk. The dosage transmitted to an unborn child is essentially the same dosage as is taken in by the mother. However, the unborn child is unable to metabolize Chloramphenicol as efficiently, thereby causing the risk of an increasing toxicity level in the unborn child. Although the effect on an infant as a result of nursing from a mother who has taken Chloramphenicol is unknown, it is known that such an infant will run the risk of bone marrow depression.

Recently, FDA, the states of Alabama and Louisiana have found chloramphenicol in crab or crabmeat imported from other countries. The department has found chloramphenicol in crab or crabmeat imported from Vietnam, Thailand and China. The possibility exists that other countries may export chloramphenicol-contaminated crab or crabmeat to the U.S.A.

The sale of such imported crab or crabmeat in Louisiana will expose Louisiana's citizens, including unborn children and nursing infants, to Chloramphenicol, a known health

hazard. The sale, in Louisiana, of crab or crabmeat containing Chloramphenicol presents an imminent peril to the public's health, safety and welfare. This peril can cause consumers to quit buying crab or crabmeat from any source, including Louisiana. If consumers cease to buy, or substantially reduce, their purchases of Louisiana crab or crabmeat then Louisiana's crab industry will be faced with substantial economic losses. Any economic losses suffered by Louisiana's crab industry will be especially severe in light of the current economic situation, thereby causing an imminent threat to the public welfare.

The Commissioner of Agriculture and Forestry has, therefore, determined that these emergency rules are necessary to immediately implement testing of crab or crabmeat for Chloramphenicol, to provide for the sale of crab or crabmeat and any products containing crab or crabmeat that are not contaminated with Chloramphenicol. This Rule becomes effective upon signature, May 21, 2004, and will remain in effect 120 days, unless renewed by the Commissioner or until a permanent Rule is promulgated.

Title 7

AGRICULTURE AND ANIMALS

Part XXXV. Agro-Consumer Services

Chapter 1. Weights and Measures

§143. Chloramphenicol in crab and crabmeat prohibited; testing and sale of

A. Definitions

Food Producing Animals Both animals that are produced or used for food and animals, such as seafood, that produce material used as food.

Geographic Area A country, province, state, or territory or definable geographic region.

Packaged Crab Any crab or crabmeat, as defined herein, that is in a package, can, or other container, and which is intended to eventually be sold to the ultimate retail purchaser in the package, can or container.

Crab Any such animals, whether whole, portioned, processed, shelled, and any product containing any crab or crabmeat.

B. No crab or crabmeat may be held, offered or exposed for sale, or sold in Louisiana if such crab or crabmeat contains Chloramphenicol.

C. No crab or crabmeat that is harvested from or produced, processed or packed in a geographic area, that the Commissioner declares to be a location where Chloramphenicol is being used on or found in food producing animals or in products from such animals, may be held, offered or exposed for sale, or sold in Louisiana without first meeting the requirements of Subsection E. No crab or crabmeat from any such geographic area may be used, as an ingredient in any food held, offered or exposed for sale, or sold in Louisiana without first meeting the requirements of Subsection E.

D. The commissioner may declare a geographic area to be a location where Chloramphenicol is being used on or found in food producing animals or in products from such animals, based upon information that would lead a

reasonable person to believe that Chloramphenicol is being used on or found in food producing animals, or in products from such animals, in that geographic area.

1. Any such declaration shall be subject to promulgation in accordance with the provisions of the Administrative Procedure Act.

2. The commissioner may release any such geographic area from a previous declaration that Chloramphenicol is being used on food producing animals in that location. Any such release shall be subject to promulgation in accordance with the Administrative Procedure Act.

E. Crab or crabmeat that comes from a geographic area declared by the commissioner to be a location where Chloramphenicol is being used on, or is found in food producing animals or in products from such animals, must meet the following requirements for sampling, identification, sample preparation, testing and analysis before being held, offered or exposed for sale, or sold in Louisiana.

1. Sampling:

a. The numbers of samples that shall be taken are as follows:

i. two samples are to be taken of crab or crabmeat that are in lots of fifty pounds or less.

ii. four samples are to be taken of crab or crabmeat that are in lots of fifty-one to one hundred pounds.

iii. twelve samples are to be taken of crab or crabmeat that are in lots of one hundred and one pounds up to fifty tons.

iv. twelve samples for each fifty tons are to be taken of crab or crabmeat that are in lots of over fifty tons.

b. For packaged crab or crabmeat, each sample shall be at least six ounces, (170.1 grams), in size and shall be taken at random throughout each lot of crab or crabmeat. For all other crab or crabmeat, obtain approximately one pound, (454 grams), of crab or crabmeat per sample from randomly selected areas.

c. If the crab or crabmeat to be sampled consists of packages of crab or crabmeat grouped together, but labeled under two or more trade or brand names, then the crab or crabmeat packaged under each trade or brand name shall be sampled separately. If the crab or crabmeat to be sampled are not packaged, but are segregated in such a way as to constitute separate groupings, then each separate grouping shall be sampled separately.

d. A composite of the samples shall not be made. Each sample shall be tested individually. Each sample shall be clearly identifiable as belonging to a specific group of crab or crabmeat. All samples shall be kept frozen and delivered to the lab.

2. Each sample shall be identified as follows:

a. any package label;

b. any lot or batch numbers;

c. the country, province and city of origin;

d. the name and address of the importing company;

e. unique sample number identifying the group or batch sample and subsample extension number for each subsample.

3. Sample Preparation. For small packages of crab or crabmeat up to and including one pound, use the entire sample. Shell the crabs, exercising care to exclude all shells

from sample. Grind sample with food processor type blender while semi-frozen or with dry ice. Divide the sample in half. Use half of the sample for the original analysis portion and retain the other half of the sample in a freezer as a reserve.

4. Sample Analysis

a. Immunoassay test kits may be used if the manufacturer's published detection limit is one part per billion, (1 ppb) or less. Acceptable test kits include r-iopharm Ridascreen Chloramphenicol enzyme immunoassay kit and the Charm II Chloramphenicol kit. The commissioner may authorize other immunoassay kits with appropriate detection limits of 1 ppb or below to be used. Each sample must be run using the manufacturer's test method. The manufacturer's specified calibration curve must be run with each set. All results 1 ppb or above must be assumed to be Chloramphenicol unless further testing by approved GC/LC method indicates the result to be an artifact.

b. HPLC-MS, GC-ECD, GC-MS methods currently approved by FDA, the United States Department of Agriculture or the Canadian Food Inspection Agency with detection limits of 1 ppb or below may also be used.

c. Other methods for sampling, identification, sample preparation, testing and analysis may be used if expressly approved in writing by the commissioner.

5. Any qualified laboratory may perform the testing and analysis of the samples unless the laboratory is located in any geographic area that the commissioner has declared to be a location where Chloramphenicol is being used on or found in food producing animals, or in products from such animals. The commissioner shall resolve any questions about whether a laboratory is qualified to perform the testing and analysis.

6. The laboratory that tests and analyzes a sample or samples for Chloramphenicol shall certify the test results in writing.

7. A copy of the certified test results along with the written documentation necessary to show the methodology used for the sampling, identification, sample preparation, testing and analysis of each sample shall be sent to and actually received by the department prior to the crab or crabmeat being held for sale, offered or exposed for sale, or sold in Louisiana.

a. The test results and accompanying documentation must contain a test reference number.

b. The certified test results and the accompanying documentation must be in English and contain the name and address of the laboratory and the name and address of a person who may be contacted at the laboratory regarding the testing of the crab or crabmeat.

8. Upon actual receipt by the department of a copy of the certified test results and written documentation required to accompany the certified test results then the crab or crabmeat may be held, offered or exposed for sale, or sold in Louisiana, unless a written stop-sale, hold or removal order is issued by the commissioner.

9. A copy of the test results, including the test reference number, shall either accompany every shipment and be attached to the documentation submitted with every shipment of such crab or crabmeat sent to each location in Louisiana or shall be immediately accessible to the department, upon request, from any such location.

H. Any person who is seeking to bring crab or crabmeat that is required to be sampled and tested under this Section, into Louisiana, or who holds, offers or exposes for sale, or sells such crab or crabmeat in Louisiana shall be responsible for having such crab or crabmeat sampled and tested in accordance with Subsection E. Any such person must, at all times, be in full and complete compliance with all the provisions of this Section.

I. The commissioner may reject the test results for any crab or crabmeat if the commissioner determines that the methodology used in sampling, identifying, sample preparation, testing or analyzing any sample is scientifically deficient so as to render the certified test results unreliable, or if such methodology was not utilized in accordance with, or does not otherwise meet the requirements of this Section.

J. In the event that any certified test results are rejected by the commissioner then any person shipping or holding the crab or crabmeat will be notified immediately of such rejection and issued a stop-sale, hold or removal order by the commissioner. Thereafter, it will be the duty of any such person to abide by such order until the commissioner lifts the order in writing. Any such person may have the crab or crabmeat retested in accordance with this Section and apply for a lifting of the commissioner's order upon a showing that the provisions of this Section have been complied with and that the crab or crabmeat are certified as being free of Chloramphenicol.

K. The department may inspect, and take samples for testing, any crab or crabmeat, of whatever origin, being held, offered or exposed for sale, or sold in Louisiana.

L. A stop-sale, hold or removal order, including a prohibition on disposal, may be placed on any crab or crabmeat that does not meet the requirements of this Section. Any such order shall remain in place until lifted in writing by the commissioner.

M. The department may take physical possession and control of any crab or crabmeat that violate the requirements of this Section if the commissioner finds that the crab or crabmeat presents an imminent peril to the public health, safety and welfare and that issuance of a stop-sale, hold or removal order will not adequately protect the public health, safety and welfare.

N. The commissioner declares that he has information that would lead a reasonable person to believe that Chloramphenicol is being used on or found in food producing animals, or in products from such animals, in the following geographic area(s).

1. The geographic area or areas are:

a. the countries of Vietnam, Thailand, Mexico, Malaysia and China.

2. All crab and crabmeat harvested from or produced, processed or packed in any of the above listed geographic areas are hereby declared to be subject to all the provisions of this Section, including sampling and testing provisions.

O. All records and information regarding the distribution, purchase and sale of crabs or crabmeat or any food containing crab or crabmeat shall be maintained for two years and shall be open to inspection by the department.

P. Penalties for any violation of this Section shall be the same as and assessed in accordance with R. S. 3:4624.

Q. The effective date of this Section is March 14, 2003.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:2, 3:3, and 3:4608.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of the Commissioner, LR 30:

§145. Labeling of foreign crab and crabmeat by country of origin

A. Definitions.

Foreign Crab or Crabmeat Any crab or crabmeat, as defined herein that is harvested from or produced, processed or packed in a country other than the United States.

Crab or Crabmeat Any crab or crabmeat, whether whole, portioned, processed or shelled and any product containing any crab or crabmeat.

B. All foreign crab or crabmeat, imported, shipped or brought into Louisiana shall indicate the country of origin, except as otherwise provided in this Section.

C. Every package or container that contains foreign crab or crabmeat, shall be marked or labeled in a conspicuous place as legibly, indelibly, and permanently as the nature of the package or container will permit so as to indicate to the ultimate retail purchaser of the crab or crabmeat with the English name of the country of origin.

1. Legibility must be such that the ultimate retail purchaser in the United States is able to find the marking or label easily and read it without strain.

2. Indelibility must be such that the wording will not fade, wash off or otherwise be obliterated by moisture, cold or other adverse factors that such crab or crabmeat are normally subjected to in storage and transportation.

3. Permanency must be such that, in any reasonably foreseeable circumstance, the marking or label shall remain on the container until it reaches the ultimate retail purchaser unless it is deliberately removed. The marking or label must be capable of surviving normal distribution and storing.

D. When foreign crab or crabmeat are combined with domestic crab or crabmeat, or products made from or containing domestic crab or crabmeat, the marking or label on the container or package or the sign included with any display shall clearly show the country of origin of the foreign crab or crabmeat.

E. In any case in which the words "United States," or "American," the letters "U.S.A.," any variation of such words or letters, or the name of any state, city or location in the United States, appear on any container or package containing foreign crab or crabmeat, or any sign advertising such foreign crab or crabmeat for sale, and those words, letters or names may mislead or deceive the ultimate retail purchaser as to the actual country of origin of the crab or crabmeat, then the name of the country of origin preceded by "made in," "product of," or other words of similar meaning shall appear on the marking, label or sign. The wording indicating that the crab or crabmeat is from a country other than the United States shall be placed in close proximity to the words, letters or name that indicates the crab or crabmeat is a product of the United States in a legible, indelible and permanent manner. No provision of this Section is intended to or is to be construed as authorizing the use of the words "United States," "American," or the letters "U.S.A.," or any variation of such words or letters, or the name of any state, city or location in the United States, if such use is deceptive, misleading or prohibited by other federal or state law.

F. Foreign crab or crabmeat shall not have to be marked or labeled with the country of origin if such crab or crabmeat is included as components in a product manufactured in the

United States and the crab or crabmeat is substantially transformed in the manufacturing of the final product. But in no event shall thawing, freezing, packing, packaging, re-packing, re-packaging, adding water, portioning, shelling, processing, peeling, partially cooking or combining with domestic crab or crabmeat shall not be considered to be a substantial transformation.

G. The commissioner shall have all the powers granted to him by law, or in accordance with any cooperative endeavor with any other public agency, to enforce this Section, including the issuance of stop-sale, hold or removal orders and the seizing of crab or crabmeat mislabeled or misbranded as to the country of origin.

H. Penalties for any violation of this Section shall be the same as and assessed in accordance with R.S. 3:4624.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:2, 3:3, and 3:4608.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of the Commissioner, LR 30:

Bob Odom
Commissioner

0406#017

DECLARATION OF EMERGENCY

Department of Agriculture and Forestry Office of the Commissioner

Chloramphenicol in Honey Testing and Sale (LAC 7:XXXV.141)

The Commissioner of Agriculture and Forestry hereby adopts the following Emergency Rule governing the testing and sale of honey in Louisiana. This Rule is being adopted in accordance with R.S. 3:2(A), 3:3(B), R.S. 3:4608 and the Emergency Rule provisions of R.S. 49:953(B) of the Administrative Procedure Act.

The commissioner has promulgated these rules and regulations to implement standards relating to Chloramphenicol in honey that are consistent with standards adopted by the FDA regarding chloramphenicol in foods. All honey sold in Louisiana must meet the standards adopted by the commissioner, herein, prior to distribution and sale.

Chloramphenicol is a broad-spectrum antibiotic that has been restricted by the FDA for use in humans only in those cases where other antibiotics have not been successful. The FDA has set a zero tolerance level for Chloramphenicol in food and has prohibited the extra label use of Chloramphenicol in the United States in food producing animals, including bees (21 CFR 530.41).

Chloramphenicol is known to cause aplastic anemia, which adversely affects the ability of a person's bone marrow to produce red blood cells. Aplastic anemia can be fatal. In addition, according to the National Institute on Environmental and Health Sciences, Chloramphenicol can reasonably be anticipated to be a human carcinogen. In widely accepted references such as "Drugs in Pregnancy and Lactation," the use of Chloramphenicol is strongly dissuaded during pregnancy, especially late pregnancy. Chloramphenicol can be transmitted to an unborn child through the placenta and to an infant through the mother's milk. The dosage transmitted to an unborn child is

essentially the same dosage as is taken in by the mother. However, the unborn child is unable to metabolize Chloramphenicol as efficiently, thereby causing the risk of an increasing toxicity level in the unborn child. Although the effect on an infant as a result of nursing from a mother who has taken Chloramphenicol is unknown, it is known that such an infant will run the risk of bone marrow depression.

Recently, Canada, the United Kingdom, the European Union, and Japan have found chloramphenicol in honey imported from China. The department has found chloramphenicol in honey imported from Thailand. Preliminary test results from Canada indicate about 80 percent of the samples are positive for chloramphenicol. The possibility exists that other countries may export chloramphenicol-contaminated honey to the U.S.A., either by diversion of Chinese honey or their own use of chloramphenicol.

The sale of such honey in Louisiana will expose Louisiana's citizens, including unborn children and nursing infants, to Chloramphenicol, a known health hazard. The sale, in Louisiana, of honey containing Chloramphenicol presents an imminent peril to the public's health, safety and welfare. This peril can cause consumers to quit buying honey from any source, including Louisiana honey. If consumers cease to buy, or substantially reduce, their purchases of Louisiana honey then Louisiana honey producers will be faced with substantial economic losses. Any economic losses suffered by Louisiana's honey producers will be especially severe in light of the current economic situation, thereby causing an imminent threat to the public welfare.

The Commissioner of Agriculture and Forestry has, therefore, determined that this Emergency Rule is necessary to immediately implement testing of honey for Chloramphenicol, to provide for the sale of honey and products containing honey that are not contaminated with Chloramphenicol. This Rule becomes effective upon signature, May 21, 2004, and will remain in effect 120 days, unless renewed by the commissioner or until a permanent Rule is promulgated.

Title 7

AGRICULTURE AND ANIMALS

Part XXXV. Agro-Consumer Services

Chapter 1. Weights and Measures

§141. Chloramphenicol in Honey Prohibited; Testing and Sale of

A. Definitions

Food Producing Animals Both animals that are produced or used for food and animals, including bees, which produce material used as food.

Geographic Area A country, province, state, or territory or definable geographic region.

Honey Any honey, whether raw or processed.

B. No honey or food containing honey may be held, offered or exposed for sale, or sold in Louisiana if such honey or food containing honey contains Chloramphenicol.

C. No honey that is harvested from or produced, processed or packed in a geographic area, that the commissioner declares to be a location where Chloramphenicol is being used on or found in food producing animals, including bees, or in products from such animals, may be held, offered or exposed for sale, or sold in

Louisiana without first meeting the requirements of Subsection E. No honey from any such geographic area may be used, as an ingredient in any food held, offered or exposed for sale, or sold in Louisiana without first meeting the requirements of Subsection E.

D. The commissioner may declare a geographic area to be a location where Chloramphenicol is being used on or found in food producing animals, including bees or in products from such animals, based upon information that would lead a reasonable person to believe that Chloramphenicol is being used on or found in food producing animals, or in products from such animals, in that geographic area.

1. Any such declaration shall be subject to promulgation in accordance with the provisions of the Administrative Procedure Act.

2. The commissioner may release any such geographic area from a previous declaration that Chloramphenicol is being used on food producing animals, including bees, in that location. Any such release shall be subject to promulgation in accordance with the Administrative Procedure Act.

E. Honey that comes from a geographic area declared by the commissioner to be a location where Chloramphenicol is being used on, or is found in food producing animals, including bees, or in products from such animals, must meet the following requirements for sampling, identification, sample preparation, testing and analysis before being held, offered or exposed for sale, or sold in Louisiana:

1. Sampling

a. The numbers of samples that shall be taken are as follows:

i. two samples are to be taken of honey that is in lots of fifty pounds or less.

ii. four samples are to be taken of honey that is in lots of fifty-one to one hundred pounds.

iii. twelve samples are to be taken of honey that is in lots of one hundred and one pounds up to fifty tons.

b. For honey in bulk wholesale containers, each sample shall be at least one pound or twelve fluid ounces and must be pulled at random throughout each lot.

c. For packaged honey, each sample shall be at least eight ounces in size and shall be taken at random throughout each lot.

d. If the honey to be sampled consists of packages of honey grouped together, but labeled under two or more trade or brand names, then the honey packaged under each trade or brand name shall be sampled separately. If the honey to be sampled are not packaged, but are segregated in such a way as to constitute separate groupings, then each separate grouping shall be sampled separately.

e. A composite of the samples shall not be made. All samples shall be delivered to the lab. Each sample shall be clearly identifiable as belonging to a specific group of honey and shall be tested individually.

2. Each sample shall be identified as follows:

- a. any package label;
- b. any lot or batch numbers;
- c. the country, province and city of origin;
- d. the name and address of the importing company;

e. unique sample number identifying the group or batch sample and subsample extension number for each subsample.

3. Sample Preparation. For small packages of honey up to and including eight ounces, use the entire sample. If honey sample includes more than one container, they shall be blended together. Divide the sample in half. Use half of the sample for the original analysis portion and retain the other half of the sample as a reserve.

4. Sample Analysis

a. Immunoassay test kits may be used if the manufacturer's published detection limit is one part per billion, (1 ppb) or less. Acceptable test kits include r-iopharm Ridascreen Chloramphenicol enzyme immunoassay kit and the Charm II Chloramphenicol kit. The commissioner may authorize other immunoassay kits with appropriate detection limits of 1 ppb or below to be used. Each sample must be run using the manufacturer's test method. The Manufacturer's specified calibration curve must be run with each set. All results above 1 ppb must be assumed to be Chloramphenicol unless further testing by approved GC/LC method indicates the result to be an artifact.

b. HPLC-MS, GC-ECD, GC-MS methods currently approved by FDA, the United States Department of Agriculture or the Canadian Food Inspection Agency with detection limits of 1 ppb or below may also be used.

c. Other methods for sampling, identification, sample preparation, testing and analysis may be used if expressly approved in writing by the commissioner.

5. Any qualified laboratory may perform the testing and analysis of the samples unless it is located in a geographic area that the commissioner has declared to be a location where Chloramphenicol is being used on or found in food producing animals including bees, or in products from such animals. The commissioner shall resolve any questions about whether a laboratory is qualified to perform the testing and analysis.

6. The laboratory that tests and analyzes a sample or samples for Chloramphenicol shall certify the test results in writing.

7. A copy of the certified test results along with the written documentation necessary to show the methodology used for the sampling, identification, sample preparation, testing and analysis of each sample shall be sent to and actually received by the department prior to the honey or food containing honey being held for sale, offered or exposed for sale, or sold in Louisiana.

a. The test results and accompanying documentation must contain a test reference number.

b. The certified test results and the accompanying documentation must be in English and contain the name and address of the laboratory and the name and address of a person who may be contacted at the laboratory regarding the testing of the honey.

8. Upon the department's actual receipt of a copy of the certified test results and written documentation required to accompany the certified test results, the honey or food containing honey may be held, offered or exposed for sale, or sold in Louisiana, unless a written stop-sale, hold or removal order is issued by the commissioner.

9. A copy of the test results, including the test reference number, shall either accompany every shipment of such honey or food containing honey, and be attached to the documentation submitted with every shipment sent to each location in Louisiana, or shall be immediately accessible to the department, upon request, from any such location.

F. Any person who is seeking to bring honey, or any food containing honey, that is required to be sampled and tested under this Section, into Louisiana, or who holds, offers or exposes for sale, or sells such honey or food containing honey in Louisiana shall be responsible for having the honey, sampled and tested in accordance with Subsection E. Any such person must, at all times, be in full and complete compliance with all the provisions of this Section.

G. The commissioner may reject the test results for any honey if the commissioner determines that the methodology used in sampling, identifying, sample preparation, testing or analyzing any sample is scientifically deficient so as to render the certified test results unreliable, or if such methodology was not utilized in accordance with, or does not otherwise meet the requirements of this Section.

H. If any certified test results are rejected by the commissioner then any person shipping or holding the honey or food containing honey will be notified immediately of such rejection and issued a stop-sale, hold or removal order by the commissioner. Thereafter, any such person shall abide by such order until the commissioner lifts the order in writing. Any such person may have the honey retested in accordance with this Section and apply for a lifting of the commissioner's order upon a showing that the provisions of this Section have been complied with and that the honey is certified as being free of Chloramphenicol.

I. The department may inspect any honey and any food containing honey, found in Louisiana, and take samples for testing.

J. A stop-sale, hold or removal order, including a prohibition on disposal, may be placed on any honey or any food containing honey that does not meet the requirements of this Section. Any such order shall remain in place until lifted, in writing, by the commissioner.

K. The department may take physical possession and control of any honey or any food containing honey that violate the requirements of this Section if the commissioner finds that the honey or food containing honey presents an imminent peril to the public health, safety and welfare and that issuance of a stop-sale, hold or removal order will not adequately protect the public health, safety and welfare.

L. The commissioner declares that he has information that would lead a reasonable person to believe that Chloramphenicol is being used on or found in food producing animals including bees, or in products from such animals, in certain geographic area(s):

1. The geographic area or areas are:
 - a. the country of the People's Republic of China.
 - b. the country of Thailand.

2. All honey harvested from or produced, processed or packed in any of the above listed geographic areas are hereby declared to be subject to all the provisions of this Section, including sampling and testing provisions.

M. All records and information regarding the distribution, purchase and sale of honey or any food

containing honey shall be maintained for two years and shall be open to inspection by the department.

N. Penalties for any violation of this Section shall be the same as and assessed in accordance with R. S. 3:4624.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:2, 3:3, and 3:4608.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of the Commissioner, LR 30:

Bob Odom
Commissioner

0406#016

DECLARATION OF EMERGENCY

Department of Agriculture and Forestry Office of the Commissioner

Chloramphenicol in Shrimp and Crawfish Testing and Sale
(LAC 7:XXXV.137 and 139)

The Commissioner of Agriculture and Forestry hereby adopts the following Emergency Rule governing the testing and sale of shrimp and crawfish in Louisiana and the labeling of foreign shrimp and crawfish. This Rule is being adopted in accordance with R.S. 3:2(A), 3:3(B), R.S. 3:4608 and the Emergency Rule provisions of R.S. 49:953(B) of the Administrative Procedure Act.

The Louisiana Legislature, by SCR 13 of the 2002 Regular Session, has urged and requested that the Commissioner of Agriculture and Forestry require all shrimp and crawfish, prior to sale in Louisiana, meet standards relating to Chloramphenicol that are consistent with those standards promulgated by the United States Food and Drug Administration, (FDA). The legislature has also urged and requested the commissioner to promulgate rules and regulations necessary to implement the standards relating to Chloramphenicol in shrimp and crawfish that are consistent with those standards promulgated by the FDA, and which rules and regulations require all shrimp and crawfish sold in Louisiana to meet the standards adopted by the commissioner, prior to sale.

Chloramphenicol is an antibiotic the FDA has restricted for use in humans only in those cases where other antibiotics or medicines have not been successful. The FDA has banned the use of Chloramphenicol in animals raised for food production. See, 21 CFR 522.390(3). The FDA has set a zero tolerance level for Chloramphenicol in food.

Chloramphenicol is known to cause aplastic anemia, which adversely affects the ability of a person's bone marrow to produce red blood cells. Aplastic anemia can be fatal. In addition, according to the National Institute on Environmental and Health Sciences, Chloramphenicol can reasonably be anticipated to be a human carcinogen. In widely accepted references such as "Drugs in Pregnancy and Lactation," the use of Chloramphenicol is strongly dissuaded during pregnancy, especially late pregnancy. Chloramphenicol can be transmitted to an unborn child through the placenta and to an infant through the mother's milk. The dosage transmitted to an unborn child is essentially the same dosage as is taken in by the mother. However, the unborn child is unable to metabolize Chloramphenicol as efficiently, thereby causing the risk of

an increasing toxicity level in the unborn child. Although the effect on an infant as a result of nursing from a mother who has taken Chloramphenicol is unknown, it is known that such an infant will run the risk of bone marrow depression.

Recently, European Union inspectors found chloramphenicol residues in shrimp and crawfish harvested from and produced in China. The inspectors also found "serious deficiencies of the Chinese residue control system and problems related to the use of banned substances in the veterinary field," which may contribute to Chloramphenicol residues in Chinese shrimp and crawfish. The Chinese are known to use antibiotics, such as Chloramphenicol, in farm-raised shrimp. They are also known to process crawfish and shrimp harvested in the wild in the same plants used to process farm-raised shrimp.

The European Union, in January of this year, banned the import of shrimp and crawfish from China because Chloramphenicol has been found in shrimp and crawfish imported from China. Canada has, this year, banned the import of shrimp and crawfish that contain levels of chloramphenicol above the level established by Canada. Between 1999 and 2000 imports of Chinese Shrimp to the United States doubled, from 19,502,000 pounds to 40,130,000 pounds. With the recent bans imposed by the European Union and Canada there is an imminent danger that the shrimp and crawfish that China would normally export to the European Union and Canada will be dumped and sold in the United States, including Louisiana.

The sale of such shrimp and crawfish in Louisiana will expose Louisiana's citizens, including unborn children and nursing infants, to Chloramphenicol, a known health hazard. The sale, in Louisiana, of shrimp and crawfish containing Chloramphenicol presents an imminent peril to the public's health, safety and welfare.

This peril can cause consumers to quit buying shrimp and crawfish from any source, including Louisiana shrimp and crawfish. If consumers cease to buy, or substantially reduce, their purchases of Louisiana shrimp and seafood, Louisiana aquaculture and fisheries will be faced with substantial economic losses. Any economic losses suffered by Louisiana's aquaculture and fisheries will be especially severe in light of the current economic situation, thereby causing an imminent threat to the public welfare.

Consumers of shrimp and crawfish cannot make an informed decision as to what shrimp or crawfish to purchase and the commissioner cannot adequately enforce the regulations regarding the sampling and testing of shrimp and crawfish unless shrimp and crawfish produced in foreign countries are properly labeled as to the country of origin.

The Commissioner of Agriculture and Forestry has, therefore, determined that these emergency rules are necessary to immediately implement testing of shrimp and crawfish for Chloramphenicol, to provide for the sale of shrimp and crawfish that are not contaminated with Chloramphenicol and to provide for the labeling of shrimp and crawfish harvested from or produced, processed or packed in countries other than the United States. This Rule becomes effective upon signature, May 21, 2004, and will remain in effect 120 days, unless renewed by the commissioner or until a permanent Rule is promulgated.

Title 7

AGRICULTURE AND ANIMALS

Part XXXV. Agro-Consumer Services

Chapter 1. Weights and Measures

§137. Chloramphenicol in shrimp and crawfish prohibited; testing and sale of

A. Definitions

Food Producing Animals Both animals that are produced or used for food and animals, such as dairy cows, that produce material used as food.

Geographic Area A country, province, state, or territory or definable geographic region.

Packaged Shrimp or Crawfish Any shrimp or crawfish, as defined herein, that is in a package, can, or other container, and which is intended to eventually be sold to the ultimate retail purchaser in the package, can or container.

Shrimp or Crawfish Any such animals, whether whole, de-headed, de-veined or peeled, and any product containing any shrimp or crawfish.

B. No shrimp or crawfish may be held, offered or exposed for sale, or sold in Louisiana if such shrimp or crawfish contain Chloramphenicol.

C. No shrimp or crawfish may be held, offered or exposed for sale, or sold in Louisiana without being accompanied by the following records and information, written in English:

1. The records and information required are:

a. The quantity and species of shrimp and crawfish acquired or sold;

b. The date the shrimp or crawfish was acquired or sold;

c. The name and license number of the wholesale/retail seafood dealer or the out-of-state seller from whom the shrimp or crawfish was acquired or sold;

d. The geographic area where the shrimp or crawfish was harvested;

e. The geographic area where the shrimp or crawfish was produced processed or packed;

f. The trade or brand name under which the shrimp or crawfish is held, offered or exposed for sale or sold; and

g. The size of the packaging of the packaged shrimp or crawfish.

2. Any person maintaining records and information as required to be kept by the Louisiana Department of Wildlife and Fisheries in accordance with R.S. 56:306.5, may submit a copy of those records, along with any additional information requested herein, with the shrimp or crawfish.

3. Any shrimp or crawfish not accompanied by all of this information shall be subject to the issuance of a stop-sale, hold or removal order until the shrimp or crawfish is tested for and shown to be clear of Chloramphenicol, or the commissioner determines that the shrimp or crawfish does not come from a geographic area where Chloramphenicol is being used on or found in food producing animals, or in products from such animals.

D. No shrimp or crawfish that is harvested from or produced, processed or packed in a geographic area, that the Commissioner declares to be a location where Chloramphenicol is being used on or found in food producing animals, or in products from such animals, may

be held, offered or exposed for sale, or sold in Louisiana without first meeting the requirements of Subsection F.

E. The commissioner may declare a geographic area to be a location where Chloramphenicol is being used on or found in food producing animals, or in products from such animals, based upon information that would lead a reasonable person to believe that Chloramphenicol is being used on or found in food producing animals, or in products from such animals, in that geographic area.

1. Any such declaration shall be subject to promulgation in accordance with the provisions of the Administrative Procedure Act.

2. The commissioner may release any such geographic area from a previous declaration that Chloramphenicol is being used on food producing animals in that location. Any such release shall be subject to promulgation in accordance with the Administrative Procedure Act.

F. Shrimp or crawfish, that comes from a geographic area declared by the commissioner to be a location where Chloramphenicol is being used on, or is found in food producing animals, or in products from such animals, must meet the following requirements for sampling, identification, sample preparation, testing and analysis before being held, offered or exposed for sale, or sold in Louisiana:

1. Sampling

a. The numbers of samples that shall be taken are as follows:

- i. two samples are to be taken of shrimp or crawfish that are in lots of fifty pounds or less;
- ii. four samples are to be taken of shrimp or crawfish that are in lots of fifty-one to one hundred pounds;
- iii. twelve samples are to be taken of shrimp or crawfish that are in lots of one hundred and one pounds up to fifty tons;
- iv. twelve samples for each fifty tons are to be taken of shrimp or crawfish that are in lots of over fifty tons.

b. For packaged shrimp or crawfish, each sample shall be at least eight ounces, (226.79 grams), in size and shall be taken at random throughout each lot of shrimp or crawfish. For all other shrimp or crawfish, obtain approximately one pound, (454 grams), of shrimp or crawfish per sample from randomly selected areas.

c. If the shrimp or crawfish to be sampled consists of packages of shrimp or crawfish grouped together, but labeled under two or more trade or brand names, then the shrimp or crawfish packaged under each trade or brand name shall be sampled separately. If the shrimp or crawfish to be sampled are not packaged, but are segregated in such a way as to constitute separate groupings, then each separate grouping shall be sampled separately.

d. A composite of the samples shall not be made. Each sample shall be tested individually. Each sample shall be clearly identifiable as belonging to a specific group of shrimp or crawfish. All samples shall be kept frozen and delivered to the lab.

2. Each sample shall be identified as follows:

- a. any package label;
- b. any lot or batch numbers;
- c. the country, province and city of origin;
- d. the name and address of the importing company;

e. unique sample number identifying the group or batch sample and subsample extension number for each subsample.

3. Sample Preparation. For small packages of shrimp or crawfish up to and including one pound, use the entire sample. Shell the shrimp or crawfish, exercising care to exclude all shells from sample. Grind sample with food processor type blender while semi-frozen or with dry ice. Divide the sample in half. Use half of the sample for the original analysis portion and retain the other half of the sample in a freezer as a reserve.

4. Sample Analysis

a. Immunoassay test kits may be used if the manufacturer's published detection limit is one part per billion, (1 ppb) or less. Acceptable test kits include r-iopharm Ridascreen Chloramphenicol enzyme immunoassay kit and the Charm II Chloramphenicol kit. The Commissioner may authorize other immunoassay kits with appropriate detection limits of 1 ppb or below to be used. Each sample must be run using the manufacturer's test method. The Manufacturer's specified calibration curve must be run with each set. All results 1 ppb or above must be assumed to be Chloramphenicol unless further testing by approved GC/LC method indicates the result to be an artifact.

b. HPLC-MS, GC-ECD, GC-MS methods currently approved by FDA, the United States Department of Agriculture or the Canadian Food Inspection Agency with detection limits of 1 ppb or below may also be used.

c. Other methods for sampling, identification, sample preparation, testing and analysis may be used if expressly approved in writing by the Commissioner.

5. Any qualified laboratory may perform the testing and analysis of the samples unless the laboratory is located in any geographic area that the commissioner has declared to be a location where Chloramphenicol is being used on or found in food producing animals, or in products from such animals. The commissioner shall resolve any questions about whether a laboratory is qualified to perform the testing and analysis.

6. The laboratory that tests and analyzes a sample or samples for Chloramphenicol shall certify the test results in writing.

7. A copy of the certified test results along with the written documentation necessary to show the methodology used for the sampling, identification, sample preparation, testing and analysis of each sample shall be sent to and actually received by the department prior to the shrimp or crawfish being held for sale, offered or exposed for sale, or sold in Louisiana.

a. The test results and accompanying documentation must contain a test reference number.

b. The certified test results and the accompanying documentation must be in English and contain the name and address of the laboratory and the name and address of a person who may be contacted at the laboratory regarding the testing of the shrimp or crawfish.

8. Upon actual receipt by the Department of a copy of the certified test results and written documentation required to accompany the certified test results then the shrimp or crawfish may be held, offered or exposed for sale, or sold in

Louisiana, unless a written stop-sale, hold or removal order is issued by the commissioner.

9. A copy of the test results, including the test reference number, shall either accompany every shipment and be attached to the documentation submitted with every shipment of such shrimp or crawfish sent to each location in Louisiana or shall be immediately accessible to the department, upon request, from any such location.

G. Any person who is seeking to bring shrimp or crawfish that is required to be sampled and tested under this Section, into Louisiana, or who holds, offers or exposes for sale, or sells such shrimp or crawfish in Louisiana shall be responsible for having such shrimp or crawfish sampled and tested in accordance with Subsection F. Any such person must, at all times, be in full and complete compliance with all the provisions of this Section.

H. The commissioner may reject the test results for any shrimp or crawfish if the commissioner determines that the methodology used in sampling, identifying, sample preparation, testing or analyzing any sample is scientifically deficient so as to render the certified test results unreliable, or if such methodology was not utilized in accordance with, or does not otherwise meet the requirements of this Section.

I. In the event that any certified test results are rejected by the commissioner then any person shipping or holding the shrimp or crawfish will be notified immediately of such rejection and issued a stop-sale, hold or removal order by the commissioner. Thereafter, it will be the duty of any such person to abide by such order until the commissioner lifts the order in writing. Any such person may have the shrimp or crawfish retested in accordance with this Section and apply for a lifting of the Commissioner's order upon a showing that the provisions of this Section have been complied with and that the shrimp or crawfish are certified as being free of Chloramphenicol.

J. The department may inspect, and take samples for testing, any shrimp or crawfish, of whatever origin, being held, offered or exposed for sale, or sold in Louisiana.

K. A stop-sale, hold or removal order, including a prohibition on disposal, may be placed on any shrimp or crawfish that does not meet the requirements of this Section. Any such order shall remain in place until lifted in writing by the commissioner.

L. The department may take physical possession and control of any shrimp or crawfish that violate the requirements of this Section if the commissioner finds that the shrimp or crawfish presents an imminent peril to the public health, safety and welfare and that issuance of a stop-sale, hold or removal order will not adequately protect the public health, safety and welfare.

M. The commissioner declares that he has information that would lead a reasonable person to believe that Chloramphenicol is being used on or found in food producing animals, or in products from such animals, in the following geographic area(s).

1. The geographic area or areas are:
 - a. the country of the People's Republic of China.
2. All shrimp and crawfish harvested from or produced, processed or packed in any of the above listed geographic areas are hereby declared to be subject to all the provisions of this Section, including sampling and testing provisions.

N. The records and information required under this Section shall be maintained for two years and shall be open to inspection by the department.

O. Penalties for any violation of this Section shall be the same as and assessed in accordance with R. S. 3:4624.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:2, 3:3, and 3:4608.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of the Commissioner, LR 30:

§139. Labeling of Foreign Shrimp and Crawfish by Country of Origin

A. Definitions.

Foreign Shrimp or Crawfish Any shrimp or crawfish, as defined herein that is harvested from or produced, processed or packed in a country other than the United States.

Shrimp or Crawfish Any shrimp or crawfish, whether whole, de-headed, de-veined or peeled, and any product containing any shrimp or crawfish.

B. All foreign shrimp or crawfish, imported, shipped or brought into Louisiana shall indicate the country of origin, except as otherwise provided in this Section.

C. Every package or container that contains foreign shrimp or crawfish, shall be marked or labeled in a conspicuous place as legibly, indelibly, and permanently as the nature of the package or container will permit so as to indicate to the ultimate retail purchaser of the shrimp or crawfish the English name of the country of origin.

1. Legibility must be such that the ultimate retail purchaser in the United States is able to find the marking or label easily and read it without strain.

2. Indelibility must be such that the wording will not fade, wash off or otherwise be obliterated by moisture, cold or other adverse factors that such shrimp or crawfish are normally subjected to in storage and transportation.

3. Permanency must be such that, in any reasonably foreseeable circumstance, the marking or label shall remain on the container until it reaches the ultimate retail purchaser unless it is deliberately removed. The marking or label must be capable of surviving normal distribution and storing.

D. When foreign shrimp or crawfish are combined with domestic shrimp or crawfish, or products made from or containing domestic shrimp or crawfish, the marking or label on the container or package or the sign included with any display shall clearly show the country of origin of the foreign shrimp or crawfish.

E. In any case in which the words "United States," or "American," the letters "U.S.A.," any variation of such words or letters, or the name of any state, city or location in the United States, appear on any container or package containing foreign shrimp or crawfish, or any sign advertising such foreign shrimp or crawfish for sale, and those words, letters or names may mislead or deceive the ultimate retail purchaser as to the actual country of origin of the shrimp or crawfish, then the name of the country of origin preceded by "made in," "product of," or other words of similar meaning shall appear on the marking, label or sign. The wording indicating that the shrimp or crawfish is from a country other than the United States shall be placed in close proximity to the words, letters or name that indicates the shrimp or crawfish is a product of the United States in a legible, indelible and permanent manner. No provision of

this Section is intended to or is to be construed as authorizing the use of the words "United States," or "American," the letters "U.S.A.," any variation of such words or letters, or the name of any state, city or location in the United States, if such use is deceptive, misleading or prohibited by other federal or state law.

F. Foreign shrimp or crawfish shall not have to be marked or labeled with the country of origin if such shrimp or crawfish are included as components in a product manufactured in the United States and the shrimp or crawfish is substantially transformed in the manufacturing of the final product. But in no event shall thawing, freezing, packing, packaging, re-packing, re-packaging, adding water, de-heading, de-veining, peeling, partially cooking or combining with domestic shrimp or crawfish shall not be considered to be a substantial transformation.

G. The commissioner shall have all the powers granted to him by law, or in accordance with any cooperative endeavor with any other public agency, to enforce this Section, including the issuance of stop-sale, hold or removal orders and the seizing of shrimp or crawfish mislabeled or misbranded as to the country of origin.

H. Penalties for any violation of this Section shall be the same as and assessed in accordance with R. S. 3:4624.

AUTHORITY NOTE: Promulgated in accordance with R.S. 3:2, 3:3, and 3:4608.

HISTORICAL NOTE: Promulgated by the Department of Agriculture and Forestry, Office of the Commissioner, LR 30:

Bob Odom
Commissioner

0406#015

DECLARATION OF EMERGENCY

Office of Student Financial Assistance Tuition Trust Authority

Student Tuition and Revenue Trust (START Saving)
Program Allocation of Earnings Enhancements
(LAC 28:VI.307)

The Louisiana Tuition Trust Authority (LATTA) is exercising the emergency provisions of the Administrative Procedure Act [R.S. 49:953(B)] to amend rules of the Student Tuition Assistance and Revenue Trust (START Saving) Program (R.S. 17:3091 et seq.).

This Emergency Rule is necessary to allow the Louisiana Office of Student Financial Assistance and educational institutions to effectively administer these programs. A delay in promulgating a Rule would have an adverse impact on the financial welfare of the eligible students and the financial condition of their families. LATTA has determined that this Emergency Rule is necessary in order to prevent imminent financial peril to the welfare of the affected students.

This declaration of emergency is effective May 23, 2004, and shall remain in effect for the maximum period allowed under the Administrative Procedure Act.

Title 28 EDUCATION

Part VI. Student Financial Assistance Higher Education Savings

Chapter 3. Education Savings Account

§307. Allocation of Earnings Enhancements

A. - G.2. ...

H. Frequency of Allocation of Earnings Enhancements to Education Savings Accounts. Earnings enhancements will be allocated annually, posted to the accounts as of December 31 of the year earned and reported to account owners before March 31 following the allocation.

I. - J.3. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 17:3091-3099.2.

HISTORICAL NOTE: Promulgated by the Office of Student Financial Assistance, Tuition Trust Authority LR 23:715 (June 1997), amended LR 24:1271 (July 1998), LR 25:1794 (October 1999), LR 26:1263 (June 2000), LR 26:2263 (October 2000), LR 27:37 (January 2001), LR 27:1880 (November 2001), LR 28:779 (April 2002), LR 30:

George Badge Eldredge
General Counsel

0406#018

DECLARATION OF EMERGENCY

Department of Health and Hospitals Office of the Secretary Bureau of Health Services Financing

Disproportionate Share Hospital Payment Methodologies
(LAC 50:V.Chapter 3)

The Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing promulgates the following Emergency Rule in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This Emergency Rule is promulgated in accordance with the Administrative Procedure Act, R.S. 49:953(B)(1) et seq., and shall be in effect for the maximum period allowed under the Act or until adoption of the final Rule, whichever occurs first.

The Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing promulgated a Rule to adopt the provisions governing the disproportionate share payment methodologies for hospitals in May of 1999 (*Louisiana Register*, Volume 25, Number 5). The May 20, 1999 Rule was later amended to change the criteria used to define rural hospitals and to clarify the policy governing final payments and adjustments (*Louisiana Register*, Volume 29, Number 1).

The Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 made provisions for public hospitals to receive disproportionate share hospital adjustment payments up to 175 percent of their allowable uncompensated care cost. Act 1024 of the 2001 Regular Session directed the Department of Health and Hospitals, as the federally designated Medicaid state agency, to specify in

the Medicaid State Plan how uncompensated care is defined and calculated and to determine what facilities qualify for uncompensated care payments and the amount of the payments. In determining payments, the department shall prioritize local access to primary health care for the medically indigent and uninsured, and shall not include unreimbursed costs resulting from excess inpatient hospital capacity. For the period July 1, 2003 through June 30, 2005, the state's Medicaid uncompensated care payments shall be distributed in proportion to the amount and type of uncompensated care reported by all qualified facilities as required by Senate Bill No. 883 of the 2001 Regular Session. Nothing shall be construed to impede or preclude the Department of Health and Hospitals from implementing the provisions in the Rural Hospital Preservation Act. Further, Senate Concurrent Resolution 94 of the 2001 Regular Session and Senate Concurrent Resolution 27 of the 2002 Regular Session of the Louisiana Legislature requested the Department of Health and Hospitals, the Louisiana State University Health Sciences Center-Health Services Division, and the Louisiana State University Health Sciences Center-Shreveport to study and recommend common acute hospital payment methodologies for state and non-state hospitals participating in the Medicaid Program and the Medicaid Disproportionate Share Program. In accordance with the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 and the findings and recommendations contained in the final reports of the study committees, the department repealed and replaced all provisions governing disproportionate share hospital payments (*Louisiana Register*, Volume 29, Number 6). Acts 14, 526 and 1148 of the 2003 Regular Session of the Louisiana Legislature directed the department to amend the qualifying criteria and the payment methodology for disproportionate share payments to small rural hospitals. In compliance with Acts 14, 526 and 1148, the bureau amended the July 1, 2003 Emergency Rule (*Louisiana Register*, Volume 29, Number 9). This Emergency Rule is being promulgated to continue provisions contained in the July 1, 2003 rule. This action is being taken to enhance federal revenue.

Effective June 28, 2004 the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing hereby repeals and replaces all rules governing disproportionate share hospital payment methodologies.

Title 50

PUBLIC HEALTH MEDICAL ASSISTANCE

Part V. Medical Assistance Program Hospital Services

Subpart 1. Inpatient Hospitals

Chapter 3. Disproportionate Share Hospital Payment Methodologies

§301. General Provisions

A. The reimbursement methodology for inpatient hospital services incorporates a provision for an additional payment adjustment for hospitals serving a disproportionate share of low income patients.

B. The following provisions govern the disproportionate share hospital (DSH) payment methodologies for qualifying hospitals.

1. Total cumulative disproportionate share payments under any and all disproportionate share hospital payment methodologies shall not exceed the federal disproportionate

share state allotment for Louisiana for each federal fiscal year or the state appropriation for disproportionate share payments for each state fiscal year. The Department shall make necessary downward adjustments to hospital's disproportionate share payments to remain within the federal disproportionate share allotment and the state disproportionate share appropriated amount.

2. Appropriate action including, but not limited to, deductions from DSH, Medicaid payments and cost report settlements shall be taken to recover any overpayments resulting from the use of erroneous data, or if it is determined upon audit that a hospital did not qualify.

3. DSH payments to a hospital determined under any of the methodologies described in this Chapter 3 shall not exceed the hospital's net uncompensated cost as defined in §305-313 or the disproportionate share limits as defined in Section 1923(g)(1)(A) of the Social Security Act for the state fiscal year to which the payment is applicable. Any Medicaid profit shall be used to offset the cost of treating the uninsured in determining the hospital specific DHH limits. High Medicaid hospitals can also qualify as other uninsured hospitals. Public hospitals included in §313 shall receive DSH payments up to 175 percent of the hospital's net uncompensated costs.

4. Qualification is based on the hospital's latest filed cost report as of March 31 of the current state fiscal year and related uncompensated cost data as required by the Department. Qualification for small rural hospitals is based on the latest filed cost report. Hospitals must file cost reports in accordance with Medicare deadlines, including extensions. Hospitals that fail to timely file Medicare cost reports and related uncompensated cost data will be assumed to be ineligible for disproportionate share payments. Only hospitals that return timely disproportionate share qualification documentation will be considered for disproportionate share payments. After the final payment during the state fiscal year has been issued, no adjustment will be given on DSH payments with the exception of public state-operated hospitals, even if subsequently submitted documentation demonstrates an increase in uncompensated care costs for the qualifying hospital. For hospitals with distinct part psychiatric units, qualification is based on the entire hospital's utilization.

5. Hospitals shall be notified by letter at least 60 days in advance of calculation of DSH payment to submit documentation required to establish DSH qualification. Only hospitals that timely return DSH qualification documentation will be considered for DSH payments. The required documents are:

- a. obstetrical qualification criteria;
- b. low income utilization revenue calculation;
- c. Medicaid cost report; and
- d. uncompensated cost calculation.

6. Hospitals and/or units which close or withdraw from the Medicaid Program shall become ineligible for further DSH pool payments for the remainder of the current DSH pool payment cycle and thereafter.

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, Office of the Secretary, Bureau of Health Services Financing, LR 30:

§303. Disproportionate Share Hospital Qualifications

A. In order to qualify as a disproportionate share hospital, a hospital must:

1. have at least two obstetricians who have staff privileges and who have agreed to provide obstetric services to individuals who are Medicaid eligible. In the case of a hospital located in a rural area (i.e., an area outside of a metropolitan statistical area), the term *obstetrician* includes any physician who has staff privileges at the hospital to perform nonemergency obstetric procedures; or

2. treat inpatients who are predominantly individuals under 18 years of age; or

3. be a hospital which did not offer nonemergency obstetric services to the general population as of December 22, 1987; and

4. have a utilization rate in excess of one or more of the following specified minimum utilization rates:

a. Medicaid utilization rate is a fraction (expressed as a percentage). The numerator is the hospital's number of Medicaid (Title XIX) inpatient days. The denominator is the total number of the hospital's inpatient days for a cost reporting period. Inpatient days include newborn and psychiatric days and exclude swing bed and skilled nursing days. Hospitals shall be deemed disproportionate share providers if their Medicaid utilization rates are in excess of the mean, plus one standard deviation of the Medicaid utilization rates for all hospitals in the state receiving payments; or

b. hospitals shall be deemed disproportionate share providers if their low-income utilization rates are in excess of 25 percent. Low-income utilization rate is the sum of:

i. the fraction (expressed as a percentage). The numerator is the sum (for the period) of the total Medicaid patient revenues plus the amount of the cash subsidies for patient services received directly from state and local governments. The denominator is the total amount of revenues of the hospital for patient services (including the amount of such cash subsidies) in the cost reporting period from the financial statements; and

ii. the fraction (expressed as a percentage). The numerator is the total amount of the hospital's charges for inpatient services which are attributable to charity (free) care in a period, less the portion of any cash subsidies as described in §303.A.4.b.i in the period which are reasonably attributable to inpatient hospital services. The denominator is the total amount of the hospital's charges for inpatient hospital services in the period. For public providers furnishing inpatient services free of charge or at a nominal charge, this percentage shall not be less than zero. This numerator shall not include contractual allowances and discounts (other than for indigent patients ineligible for Medicaid), i.e., reductions in charges given to other third-party payers, such as HMOs, Medicare, or Blue Cross; nor charges attributable to Hill-Burton obligations. A hospital providing "free care" must submit its criteria and procedures for identifying patients who qualify for free care to the Bureau of Health Services Financing for approval. The policy for free care must be posted prominently and all patients must be advised of the availability of free care and the procedures for applying. Hospitals not in compliance with free care criteria will be subject to recoupment of DSH and Medicaid payments; or

c. hospitals shall be deemed disproportionate share providers eligible for reimbursement for inpatient services if their inpatient uninsured utilization rates are in excess of 3 percent.

i. Inpatient uninsured utilization rate is a fraction (expressed as a percentage). The numerator is the total amount of the hospital's charges for inpatient services furnished to uninsured persons for the period. The denominator is the total amount of the hospital's charges for inpatient services furnished to all persons for the period; or

d. hospitals shall be deemed disproportionate share providers eligible for reimbursement for outpatient services if their outpatient uninsured utilization rates are in excess of 3 percent.

i. Outpatient uninsured utilization rate is a fraction (expressed as a percentage). The numerator is the total amount of the hospital's charges for outpatient services furnished to uninsured persons for the period. The denominator is the total amount of the hospital's charges for outpatient services furnished to all persons for the period; or

5. effective November 3, 1997, be a small rural hospital as defined in §311.A.1.a-h; and

6. in addition to the qualification criteria outlined in §303.A.1-5, effective July 1, 1994, must also have a Medicaid inpatient utilization rate of at least 1 percent.

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, Office of the Secretary, Bureau of Health Services Financing, LR 30:

§305. High Uninsured Hospitals

A. Definitions

High Uninsured Utilization Rate Hospital—a hospital that has an uninsured utilization rate in excess of the mean, plus one standard deviation of the uninsured utilization rates for all hospitals.

Net Uncompensated Cost—the cost of furnishing inpatient and outpatient hospital services to uninsured persons, supported by patient-specific data, net of any payments received from such patients.

B. DSH payments to individual high uninsured hospitals shall be calculated as follows:

1. Inpatient High Uninsured. Payments shall be equal to 100 percent of the hospital's cost of furnishing inpatient hospital services to uninsured persons, supported by patient-specific data, net of any payments received from such patients. DSH payments calculated under this payment methodology shall be subject to the adjustment provision below in Subsection E.; and/or

2. Outpatient High Uninsured. Payments shall be equal to 100 percent of the hospital's cost of furnishing outpatient hospital services to uninsured persons, supported by patient-specific data, net of any payments received from such patients. DSH payments calculated under this payment methodology shall be subject to the adjustment provision below in Subsection E.

C. It is mandatory that hospitals seek all third party payments including Medicare, Medicaid and other third party carriers and payments from patients. Hospitals must certify that excluded from net uncompensated cost are any costs for the care of persons eligible for Medicaid at the time of registration. Hospitals must maintain a log documenting the provision of uninsured care as directed by the

department. Hospitals must adjust uninsured charges to reflect retroactive Medicaid eligibility determination. Patient specific data is required after July 1, 2003. Hospitals shall annually submit:

1. an annual attestation that patients whose care is included in the hospitals' net uncompensated cost are not Medicaid eligible at the time of registration; and

2. supporting patient-specific demographic data that does not identify individuals, but is sufficient for audit of the hospitals' compliance with the Medicaid ineligibility requirement as required by the Department, including:

- a. patient age;
- b. family size;
- c. number of dependent children; and
- d. household income.

D. DSH payments to individual high uninsured hospitals shall be equal to 100 percent of the hospital's net uncompensated costs and subject to the adjustment provision in §301.B.

E. In the event that it is necessary to reduce the amount of disproportionate share payments to remain within the federal disproportionate share allotment or the state DSH-appropriated amount, the department shall calculate a pro rata decrease for each high uninsured hospital based on the ratio determined by:

1. dividing that hospital's uncompensated cost by the total uncompensated cost for all qualifying high uninsured hospitals during the state fiscal year; and then

2. multiplying by the amount of disproportionate share payments calculated in excess of the federal disproportionate allotment or state DSH-appropriated amount.

F. A hospital receiving DSH payments shall furnish emergency and nonemergency services to uninsured persons with family incomes less than or equal to 100 percent of the federal poverty level on an equal basis to insured patients.

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, Office of the Secretary, Bureau of Health Services Financing, LR 30:

§307. Other Uninsured Hospitals

A. Definitions

Net Uncompensated Cost The cost of furnishing inpatient and outpatient hospital services to uninsured persons, supported by patient-specific data, net of any payments received from such patients.

Other Uninsured Utilization Rate Hospital A qualifying hospital that is not included in §305, §311, §313 or §315.

B. DSH payments to an individual other uninsured hospital shall be calculated as follows:

1. Inpatient Other Uninsured. All qualifying hospitals shall be arrayed from lowest to highest rate according to their inpatient uninsured utilization rate. DSH payments to hospitals in the first quintile of the distribution shall be equal to 25 percent of the hospital's cost of furnishing inpatient hospital services to uninsured persons, supported by patient-specific data, net of payments received from such patients and subject to the adjustment provision below. DSH payments to hospitals in the second through the fifth quintiles of the distribution shall be equal to 40, 55, 70 and 85 percent of the hospital's cost of furnishing inpatient

hospital services to uninsured persons, supported by patient-specific data, net of payments received from such patients, respectively and subject to the adjustment provision below in Subsection E.

2. Outpatient Other Uninsured. All qualifying hospitals shall be arrayed from lowest to highest rate according to their outpatient uninsured utilization rate. DSH payments to hospitals in the first quintile of the distribution shall be equal to 25 percent of the hospital's cost of furnishing inpatient hospital services to uninsured persons, supported by patient-specific data, net of payments received from such patients and subject to the adjustment provision below. DSH payments to hospitals in the second through the fifth quintiles of the distribution shall be equal to 40, 55, 70 and 85 percent of the hospital's cost of furnishing inpatient hospital services to uninsured persons, supported by patient-specific data, net of payments received from such patients, respectively and subject to the adjustment provision below in Subsection E.

C. It is mandatory that hospitals seek all third party payments including Medicare, Medicaid and other third party carriers and payments from patients. Hospitals must certify that excluded from net uncompensated cost are any costs for the care of persons eligible for Medicaid at the time of registration. Hospitals must maintain a log documenting the provision of uninsured care as directed by the Department. Hospitals must adjust uninsured charges to reflect retroactive Medicaid eligibility determination. Patient specific data is required after July 1, 2003. Hospitals shall annually submit:

1. an attestation that patients whose care is included in the hospitals' net uncompensated cost are not Medicaid eligible at the time of registration; and

2. supporting patient-specific demographic data that does not identify individuals, but is sufficient for audit of the hospitals' compliance with the Medicaid ineligibility requirement as required by the Department, including:

- a. patient age;
- b. family size;
- c. number of dependent children; and
- d. household income.

D. DSH payments to an individual other uninsured hospital shall be based on the hospital's uninsured utilization rate and the distribution of all other uninsured hospitals uninsured utilization rates. DSH payments to hospitals in the first quintile of the distribution shall be equal to 25 percent of the hospital's net uncompensated costs and subject to the adjustment provision in §301.B. DSH payments to hospitals in the second through the fifth quintiles of the distribution shall be equal to 40, 55, 70 and 85 percent of the hospital's net uncompensated cost, respectively.

E. In the event it is necessary to reduce the amount of disproportionate share payments to remain within the federal disproportionate share allotment or the state DSH-appropriated amount, the Department shall calculate a pro rata decrease for each other uninsured hospital based on the ratio determined by:

1. dividing that hospital's uncompensated cost by the total uncompensated cost for all qualifying other uninsured hospitals during the state fiscal year; and then

2. multiplying by the amount of disproportionate share payments calculated in excess of the federal

disproportionate allotment or state DSH-appropriated amount.

F. A hospital receiving DSH payments shall furnish emergency and nonemergency services to uninsured persons with family incomes less than or equal to 100 percent of the federal poverty level on an equal basis to insured patients.

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, Office of the Secretary, Bureau of Health Services Financing, LR 30:

§309. High Medicaid Hospitals

A. Definition. *High Medicaid Utilization Rate Hospital*—A hospital that has a Medicaid utilization rate in excess of the mean, plus one standard deviation of the Medicaid utilization rates for all hospitals in the state receiving payments and that is not included in §305.

1. Medicaid utilization rate is a fraction (expressed as a percentage). The numerator is the hospital's number of Medicaid (Title XIX) inpatient days. The denominator is the total number of the hospital's inpatient days for a cost-reporting period.

B. DSH payments to individual high Medicaid hospitals shall be based on actual paid Medicaid days for a six-month period ending on the last day of the last month of that period, but reported at least 30 days preceding the date of payment. Annualization of days for the purposes of the Medicaid days pool is not permitted. The amount will be obtained by DHH from a report of paid Medicaid days by service date.

C. Disproportionate share payments for individual high Medicaid hospitals shall be calculated based on the product of the ratio determined by:

1. dividing each qualifying high Medicaid hospital's actual paid Medicaid inpatient days for a six-month period ending on the last day of the month preceding the date of payment (which will be obtained by DHH from a report of paid Medicaid days by service date) by the total Medicaid inpatient days obtained from the same report of all qualified high Medicaid hospitals. Total Medicaid inpatient days include Medicaid nursery days but do not include skilled nursing facility or swing-bed days; and

2. multiplying by an amount of funds for high Medicaid hospitals to be determined by the director of the Bureau of Health Services Financing.

D. A pro rata decrease necessitated by conditions specified in §301.B. for high Medicaid hospitals will be calculated based on the ratio determined by:

1. dividing the hospitals' Medicaid days by the Medicaid days for all qualifying high Medicaid hospitals; then

2. multiplying by the amount of disproportionate share payments calculated in excess of the federal disproportionate share allotment or the state disproportionate share appropriated amount.

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, Office of the Secretary, Bureau of Health Services Financing, LR 30:

§311. Small Rural Hospitals

A. Definitions

Net Uncompensated Cost—The cost of furnishing inpatient and outpatient hospital services, net of Medicare costs, Medicaid payments (excluding disproportionate share payments), costs associated with patients who have insurance for services provided, private payer payments, and all other inpatient and outpatient payments received from patients. Any uncompensated costs of providing health care services in a rural health clinic licensed as part of a small rural hospital as defined below shall be considered outpatient hospital services in the calculation of uncompensated costs.

Small Rural Hospital—A hospital (excluding a long-term care hospital, rehabilitation hospital, or freestanding psychiatric hospital but including distinct part psychiatric units) that meets the following criteria:

a. had no more than 60 hospital beds as of July 1, 1994, and is located in a parish with a population of less than 50,000 or in a municipality with a population of less than 20,000; or

b. meets the qualifications of a sole community hospital under 42 CFR §412.92(a); or

c. had no more than 60 hospital beds as of July 1, 1999 and is located in a parish with a population of less than 17,000 as measured by the 1990 census; or

d. had no more than 60 hospital beds as of July 1, 1997 and is a publicly-owned and operated hospital that is located in either a parish with a population of less than 50,000 or a municipality with a population of less than 20,000; or

e. had no more than 60 hospital beds as of June 30, 2000 and is located in a municipality with a population, as measured by the 1990 census, of less than 20,000; or

f. had no more than 60 beds as of July 1, 1997 and is located in a parish with a population, as measured by the 1990 and 2000 census, of less than 50,000; or

g. was a hospital facility licensed by the Department that had no more than 60 hospital beds as of July 1, 1994, which hospital facility:

i. has been in continuous operation since July 1, 1994;

ii. is currently operating under a license issued by the Department; and

iii. is located in a parish with a population, as measured by the 1990 census, of less than 50,000; or

h. has no more than 60 hospital beds or has notified the Department as of March 7, 2002 of its intent to reduce its number of hospital beds to no more than 60, and is located in a municipality with a population of less than 13,000 and in a parish with a population of less than 32,000 as measured by the 2000 census; or

i. has no more than 60 hospital beds or has notified DHH as of December 31, 2003, of its intent to reduce its number of hospital beds to no more than 60; and

i. is located, as measured by the 2000 census, in a municipality with a population of less than 7,000;

ii. is located, as measured by the 2000 census, in a parish with a population of less than 53,000; and

iii. is located within 10 miles of a United States military base; or

j. has no more than 60 hospital beds as of September 26, 2002; and

i. is located, as measured by the 2000 census, in a municipality with a population of less than 10,000; and

ii. is located, as measured by the 2000 census, in a parish with a population of less than 33,000; or

k. has no more than 60 hospital beds as of January 1, 2003; and

i. is located, as measured by the 2000 census, in a municipality with a population of less than 11,000; and

ii. is located, as measured by the 2000 census, in a parish with a population of less than 90,000.

B. Payment based on uncompensated cost for qualifying small rural hospitals shall be in accordance with the following three pools:

1. *Public (Nonstate) Small Rural Hospitals*—small rural hospitals as defined in §311.A.1, which are owned by a local government.

2. *Private Small Rural Hospitals*—small rural hospitals as defined in §311.A.1, that are privately owned.

3. *Small Rural Hospitals*—small rural hospitals as defined in §311.A.1.i - §311.A.1.k.

C. Payment to hospitals included in §311.B.1, §311.B.2, and §311.B.3 is equal to each qualifying rural hospital's pro rata share of uncompensated cost for all hospitals meeting these criteria for the latest filed cost report multiplied by the amount set for each pool. If the cost reporting period is not a full period (12 months), actual uncompensated cost data from the previous cost reporting period may be used on a pro rata basis to equate a full year.

D. Pro Rata Decrease

1. A pro rata decrease necessitated by conditions specified in §301.B. for rural hospitals described in this §311 will be calculated using the ratio determined by:

a. dividing the qualifying rural hospital's uncompensated costs by the uncompensated costs for all rural hospitals in §311; then

b. multiplying by the amount of disproportionate share payments calculated in excess of the federal DSH allotment or the state DSH appropriated amount.

2. No additional payments shall be made after the final payment for the state fiscal year is disbursed by the Department. Recoupment shall be initiated upon completion of an audit if it is determined that the actual uncompensated care costs for the state fiscal year for which the payment is applicable is less than the actual amount paid.

E. Qualifying hospitals must meet the definition for a small rural hospital contained in §311.A.1. Qualifying hospitals must maintain a log documenting the provision of uninsured care as directed by the Department.

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, Office of the Secretary, Bureau of Health Services Financing, LR 30:

§313. Public State-Operated Hospitals

A. Definitions

Net Uncompensated Cost—the cost of furnishing inpatient and outpatient hospital services, net of Medicare costs, Medicaid payments (excluding disproportionate share

payments), costs associated with patients who have insurance for services provided, private payer payments, and all other inpatient and outpatient payments received from patients.

Public State-Operated Hospital—a hospital that is owned or operated by the State of Louisiana.

B. DSH payments to individual public state-owned or operated hospitals shall be up to 175 percent of the hospital's net uncompensated costs. Final payment will be based on the uncompensated cost data per the audited cost report for the period(s) covering the state fiscal year.

C. In the event that it is necessary to reduce the amount of disproportionate share payments to remain within the federal disproportionate share allotment or the state DSH-appropriated amount, the Department shall calculate a pro rata decrease for each public state-owned or operated hospital based on the ratio determined by:

1. dividing that hospital's uncompensated cost by the total uncompensated cost for all qualifying public state-owned or operated hospitals during the state fiscal year; and then

2. multiplying by the amount of disproportionate share payments calculated in excess of the federal disproportionate allotment or state DSH-appropriated amount.

D. It is mandatory that hospitals seek all third party payments including Medicare, Medicaid and other third party carriers and payments from patients. Hospitals must certify that excluded from net uncompensated cost are any costs for the care of persons eligible for Medicaid at the time of registration. Acute hospitals must maintain a log documenting the provision of uninsured care as directed by the Department. Hospitals must adjust uninsured charges to reflect retroactive Medicaid eligibility determination. Patient specific data is required after July 1, 2003. Hospitals shall annually submit:

1. an attestation that patients whose care is included in the hospitals' net uncompensated cost are not Medicaid eligible at the time of registration; and

2. supporting patient-specific demographic data that does not identify individuals, but is sufficient for audit of the hospitals' compliance with the Medicaid ineligibility requirement as required by the Department, including:

- a. patient age;
- b. family size;
- c. number of dependent children; and
- d. household income.

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, Office of the Secretary, Bureau of Health Services Financing, LR 30:

§315. Psychiatric Hospitals

A. Definitions

Net Uncompensated Cost—the cost of furnishing inpatient and outpatient hospital services, net of Medicare costs, Medicaid payments (excluding disproportionate share payments), costs associated with patients who have insurance for services provided, private payer payments, and all other inpatient and outpatient payments received from patients.

Psychiatric Hospital—a free standing psychiatric hospital that is not included in §313.

B. DSH payments to individual free standing psychiatric hospitals shall be based on actual paid Medicaid days for a six-month period ending on the last day of the last month of that period, but reported at least 30 days preceding the date of payment. Annualization of days for the purposes of the Medicaid days pool is not permitted. The amount will be obtained by DHH from a report of paid Medicaid days by service date.

C. Disproportionate share payments for individual free standing psychiatric hospitals shall be calculated based on the product of the ratio determined by:

1. dividing each qualifying free standing psychiatric hospital's actual paid Medicaid inpatient days for a six-month period ending on the last day of the month preceding the date of payment (which will be obtained by DHH from a report of paid Medicaid days by service date) by the total Medicaid inpatient days obtained from the same report of all qualified free standing psychiatric hospitals. Total Medicaid inpatient days include Medicaid nursery days but do not include skilled nursing facility or swing-bed days; and

2. multiplying by an amount of funds for free standing psychiatric to be determined by the director of the Bureau of Health Services Financing

D. A pro rata decrease necessitated by conditions specified in §301.B. for hospitals in §315 will be calculated based on the ratio determined by:

1. dividing the hospitals' Medicaid days by the Medicaid days for all qualifying hospitals in §315; then

2. multiplying by the amount of disproportionate share payments calculated in excess of the federal disproportionate share allotment or the state disproportionate share appropriated amount.

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, Office of the Secretary, Bureau of Health Services Financing, LR 30:

Implementation of the provisions of this rule shall be contingent upon the approval of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services.

Interested persons may submit written comments to Ben A. Bearden at the following address: Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. He is responsible for responding to all inquiries regarding this Emergency Rule. A copy of this Emergency Rule is available for review by interested parties at parish Medicaid offices.

Frederick P. Cerise, M.D., M.P.H.
Secretary

0406#065

DECLARATION OF EMERGENCY

Department of Health and Hospitals Office of the Secretary Bureau of Health Services Financing

Experimental or Investigational
Medical Procedures or Devices

The Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing promulgates the following Emergency Rule in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This Emergency Rule is promulgated in accordance with the Administrative Procedure Act, R.S. 49:953(B)(1) et seq., and shall be in effect for the maximum period allowed under the Act or until adoption of the final Rule, whichever occurs first.

The Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing adopted a Rule on September 20, 1996 governing the coverage of experimental or investigational medical procedures. Coverage was provided only for non-experimental or non-investigational procedures as identified by the American Medical Association, the Federal Drug Administration or recognized experts in the practice of medicine who could lend guidance or judgment regarding the development of new procedures (*Louisiana Register*, Volume 22, Number 9). The bureau has promulgated a rule to amend the September 20, 1996 Rule to revise the criteria governing the coverage of experimental or investigational medical procedures and devices. (*Louisiana Register*, Volume 30, Number 3). This Emergency Rule is being promulgated to continue the provisions contained in the March 2, 2004 Rule. This action is being taken to protect the health and welfare of Medicaid recipients.

Emergency Rule

Effective for dates of service on or after July 1, 2004, the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing amends the September 20, 1996 Rule governing the coverage of experimental or investigational medical procedures and devices.

Louisiana Medicaid does not cover any Federal Drug Administration (FDA) designated experimental or investigational medical procedures or devices until those procedures or devices have received final FDA approval or when a procedure or device is specifically approved for coverage by the Medicaid Director.

Interested persons may submit written comments to Ben A. Bearden at the Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. He is responsible for responding to all inquiries regarding this Emergency

Rule. A copy of this Emergency Rule is available for review by interested parties at parish Medicaid offices.

Frederick P. Cerise, M.D., M.P.H.
Secretary

0406#063

DECLARATION OF EMERGENCY

Department of Health and Hospitals Office of the Secretary Bureau of Health Services Financing

Facility Need Review
Additional Beds for Certain ICF-MRs
(LAC 48:I.12503)

The Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, amends LAC 48:I.12503, Determination of Bed Need, as authorized by R.S. 40:2116. This Emergency Rule is adopted in accordance with the Administrative Procedure Act, R.S. 49:953(B) and shall be in effect for the maximum period allowed under the Act or until adoption of the Rule, whichever occurs first.

The Department of Health and Hospitals adopted a Rule governing Facility Need Review in August 1995 (*Louisiana Register*, Volume 21, Number 8). The August 1995 Rule was amended in July 1999 to adopt new provisions governing the relocation of nursing facility beds (*Louisiana Register*, Volume 25, Number 7). It was further amended in October 2002 to adopt new provisions creating the Emergency Community Home Bed Pool for nonstate-operated community homes (*Louisiana Register*, Volume 28, Number 10).

Act 900 of the 2003 Regular Session of the Louisiana Legislature enacted R.S. 40:2116(G) which grants an exemption from the usual requirements of the Facility Need Review process as set forth in R.S. 40:2116 and in the department's rules and regulations. Any intermediate care facility for the mentally retarded which serves children or adults suffering from mental retardation, autism, or behavioral problems, with no less than 150 and no more than 180 beds, is eligible for the exemption which is granted for a maximum of 50 additional beds. The Legislature did not appropriate any funds to the department to cover the increased expenses it will incur for Medicaid payments for the residents who will occupy the additional beds. The department promulgated an Emergency Rule amending the August 1995 Rule governing the Facility Need Review Process in order to implement the provisions of Act 900 (*Louisiana Register*, Volume 29, Number 11). The department subsequently promulgated another emergency rule to amend the December 1, 2003 Emergency Rule to waive the deadline for enrolling the additional beds after approval. This action is being taken to promote the health and welfare of Louisiana citizens by assuring that adequate community home beds are available for Medicaid recipients (*Louisiana Register*, Volume 30, Number 2). This emergency rule is being promulgated to continue the provisions contained in the February 20, 2004 rule.

Effective June 20, 2004, the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services

Financing, amends the December 1, 2003 Emergency Rule on Facility Need Review.

Title 48

PUBLIC HEALTH GENERAL

Part I. General Administration

Subpart 5. Health Planning

Chapter 125. Facility Need Review

§12503. Determination of Bed Need

A. - A.7.h. ...

8. Exception for Additional Beds for Certain ICF-MRs. Any ICF-MR which serves children or adults suffering from mental retardation, autism, or behavioral problems, and which had no less than 150 and no more than 180 approved beds as of August 15, 2003, shall, upon application to the Department, be granted approval for up to 50 additional beds without being required to meet the standards set forth in Paragraphs A.1-6 above, §12501.F.2 or §12505.

B. - B.11 ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2116.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 21:808 (August 1995), amended LR 28:2190 (October 2002), LR 30:

Interested persons may submit written comments to Ben A. Bearden, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. He is responsible for responding to all inquiries regarding this Emergency Rule. A copy of this Emergency Rule is available at the parish Medicaid office for review by interested parties.

Frederick P. Cerise, M.D., M.P.H.
Secretary

0406#064

DECLARATION OF EMERGENCY

Department of Health and Hospitals Office of the Secretary Bureau of Health Services Financing

Inpatient Psychiatric Services
Public State-Owned or Operated Hospitals
Reimbursement Increase

The Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing promulgates the following Emergency Rule in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This Emergency Rule is promulgated in accordance with the Administrative Procedure Act, R.S. 49:953(B)(1) et seq. and shall be in effect for the maximum period allowed under the Act or until adoption of the Rule, whichever occurs first.

The Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing adopted a Rule which established the prospective reimbursement methodology for inpatient psychiatric hospital services provided in either a free-standing psychiatric hospital or distinct part psychiatric unit of an acute care general hospital (*Louisiana Register*, Volume 19, Number 6). This Rule was subsequently amended to discontinue the practice of automatically applying an inflation adjustment to the

reimbursement rates for inpatient psychiatric services in those years when the rates are not rebased (*Louisiana Register*, Volume 25, Number 5).

The bureau rebased the reimbursement rates paid to public state owned or operated hospitals for inpatient psychiatric hospital services to the 50th percentile of costs per day for services based on cost reports ending in state fiscal year 2002 (*Louisiana Register*, Volume 29, Number 10). This Emergency Rule is being promulgated to continue the provisions of the October 20, 2003 Emergency Rule. This action is being taken to protect the health and welfare of Medicaid recipients by encouraging the continued participation of hospitals that furnish psychiatric services in the Medicaid Program.

Emergency Rule

Effective for dates of service June 18, 2004, the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing increases the reimbursement for inpatient psychiatric hospital services provided in a state owned or operated free-standing psychiatric hospital or distinct part psychiatric unit to a per diem rate based on the 50th percentile facility for costs as reported on the cost report for the year ending between July 1, 2001 and June 30, 2002. The costs utilized to determine the 50th percentile facility will include all free-standing psychiatric hospitals and distinct part psychiatric units providing services to Medicaid recipients in the state. Costs will be trended to the midpoint of the rate year using the Medicare PPS Market Basket Index. The application of inflationary adjustments in subsequent years shall be contingent on the appropriation of funds by the Legislature.

Implementation of the provisions of this Rule shall be contingent upon the approval of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services.

Interested persons may submit written comments to the Ben A. Bearden at the Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. He is responsible for responding to all inquiries regarding this Emergency Rule. A copy of this Emergency Rule is available for review by interested parties at parish Medicaid offices.

Frederick P. Cerise, M.D., M.P.H.
Secretary

0406#004

DECLARATION OF EMERGENCY

**Department of Health and Hospitals
Office of the Secretary
Bureau of Health Services Financing**

**Private Hospitals Inpatient Services
Reimbursement Reduction**

The Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing promulgates the following Emergency Rule under the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act and as directed by the 2003-2004 General Appropriation Act, which states, **A**he secretary shall implement reductions in the Medicaid program as necessary to control expenditures to the level

approved in this schedule. The secretary is hereby directed to utilize various cost containment measures to accomplish these reductions, including but not limited to pre-certification, pre-admission screening, and utilization review, and other measures as allowed by federal law." This Emergency Rule is promulgated in accordance with the Administrative Procedure Act, R.S. 49:953.B(1) et seq., and shall be in effect for the maximum period allowed under the Administrative Procedure Act or until adoption of the final Rule, whichever occurs first.

The Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing adopted a Rule in June of 1994 which established the prospective reimbursement methodology for inpatient services provided in private (nonstate) acute care general hospitals (*Louisiana Register*, Volume 20, Number 6). The June 20, 1994 Rule was subsequently amended to establish a weighted average per diem for each hospital peer group (*Louisiana Register*, Volume 22, Number 1). This Rule was later amended to discontinue the practice of automatically applying an inflation adjustment to the reimbursement rates in those years when the rates are not rebased (*Louisiana Register*, Volume 25, Number 5).

Section 11B of Act 14 of the 2003 Regular Session of the Louisiana Legislature directed the Commissioner of Administration to reduce discretionary state general fund (direct) appropriations contained in the Act by .8 percent across-the-board, or so much thereof more or less as may be necessary, to effect savings of \$17,300,000. Subsequently, the commissioner directed the department to reduce its discretionary expenditures by .8 percent for state fiscal year 2003-2004. In response to the budgetary shortfall, the bureau reduced the reimbursement paid to private (non-state) hospitals for inpatient services to 99.2 percent (a .8 percent reduction) of the per diem rates in effect on September 30, 2003. However, in order to generate the amount of savings necessary to comply with the directives of Act 14, the reimbursement paid in state fiscal year 2003-2004 to private (non-state) hospitals for inpatient services shall be 98.75 percent (a 1.25 percent reduction) of the per diem rates in effect on September 30, 2003. Small rural hospitals as defined by the Rural Hospital Preservation Act (R.S. 40:1300.143) are excluded from this reimbursement reduction. Also, inpatient services provided to fragile newborns or critically ill children in either a Level III Regional Neonatal Intensive Care Unit or a Level I Pediatric Intensive Care Unit, which units have been recognized by the department on or before January 1, 2003, shall be excluded from this reimbursement reduction (*Louisiana Register*, Volume 29, Number 9). This Emergency Rule is being promulgated to continue the provisions of the October 1, 2003 Emergency Rule. This action is being taken in order to avoid a budget deficit in the medical assistance programs. Taking the reduction in per diem rates in state fiscal year 2003-2004 into consideration, the department has carefully reviewed the proposed rates and is satisfied that they are consistent with efficiency, economy and quality of care and are sufficient to enlist enough providers so that private (nonstate) inpatient hospital services under the state plan are available at least to the extent that they are available to the general population in the state.

Emergency Rule

Effective for dates of service May 30, 2004, the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing reduces the reimbursement paid for inpatient services rendered in private (nonstate) acute hospitals, including long term hospitals. The reimbursement paid for inpatient services to private (non-state) hospitals with a Medicaid inpatient days utilization rate of less than 25 percent shall be as follows: in state fiscal year 2003-2004 only, 98.75 percent (a 1.25 percent reduction) of the per diem rates in effect on September 30, 2003 and for subsequent years, a 99.2 percent (a .8 percent reduction) of the per diem rates in effect on September 30, 2003 for private hospitals.

The Medicaid inpatient days utilization rate shall be calculated based on the filed cost report for the period ending in state fiscal year 2002 and received by the Department prior to April 30, 2003. Only Medicaid covered days for inpatient hospital services, which include newborn days and distinct part psychiatric units, are included in this calculation. Inpatient stays covered by Medicare Part A can not be included in the determination of the Medicaid inpatient days utilization rate. Small rural hospitals as defined by the Rural Hospital Preservation Act (R.S. 40:1300.143) shall be excluded from this reimbursement reduction. Also, inpatient services provided to fragile newborns or critically ill children in either a Level III Regional Neonatal Intensive Care Unit or a Level I Pediatric Intensive Care Unit, which units have been recognized by the department on or before January 1, 2003, shall be excluded from this reimbursement reduction.

Implementation of the provisions of this Rule shall be contingent upon the approval of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services.

Interested persons may submit written comments to Ben A. Bearden at the Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. He is responsible for responding to inquiries regarding this Emergency Rule. A copy of this Emergency Rule is available for review by interested parties at parish Medicaid offices.

Frederick P. Cerise, M.D., M.P.H.
Secretary

0406#003

DECLARATION OF EMERGENCY

Department of Public Safety and Corrections Gaming Control Board

Self-Exclusion (LAC 42:III.304)

In accordance with the Administrative Procedure Act, R.S. 49:953(B), and R.S. 27:15 and 24, the Gaming Control Board finds that this emergency amendment to the rules regulating casino licensees, the casino manager and casino operator regarding self-excluded persons is necessary to prevent imminent peril to the public health, safety and welfare.

R.S. 27:27.1 D.4 mandates that the board's rules provide that the list of self-excluded persons not be open to public inspection and that the Board, Division, any licensee, permittee or casino gaming operator or any employee or agent thereof shall not be liable for damages for disclosure of the identity of any self-excluded person other than a willful unlawful disclosure. LAC 42:III.304 D.6. prohibits disclosure of the name or any information concerning a self-excluded person. Certain administrative actions are pending regarding casino licensees and involving self-excluded persons, which may result in administrative hearings.

It is necessary therefore that this amendment be adopted on an emergency basis in order to protect the identity of self-excluded persons by requiring that administrative hearings involving self-excluded persons be closed to the public and that the administrative record created and evidence introduced in conjunction with such hearings be maintained confidential and not open to public inspection.

This Rule change is hereby adopted (May 17, 2004) and shall remain in effect for 120 days.

Title 42

LOUISIANA GAMING

Part III. Gaming Control Board

Chapter 3. Compulsive and Problem Gambling

§304. Self-Exclusion

A. - C.5. ...

D. Self-Exclusion List

1. - 5. ...

6a. Neither the Casino Operator, Casino Manager, nor any casino gaming licensee or any employee or agent thereof shall disclose the self-exclusion list or the name of, or any information about, any person who has requested self-exclusion to anyone other than employees and agents of the Casino Operator or Casino Manager or casino gaming licensee whose duties and functions require access to such information. Notwithstanding the foregoing, the Casino Operator or Casino Manager and each casino licensee may disclose the name of and information about a self-excluded person to appropriate employees of other casino licensees in Louisiana for the purpose of alerting other casinos that a self-excluded person has tried to gamble or obtain gaming related privileges or benefits in a casino gaming establishment. Nothing herein shall be construed to prohibit the licensee from disclosing the identity of self-excluded persons to affiliated entities in Louisiana and other gaming jurisdictions for the limited purpose of assisting in the proper administration of compulsive and problem gaming programs operated by such affiliated entities.

b. Administrative hearings regarding or related to self-excluded persons shall be closed to the public and any record created or evidence introduced in conjunction with such hearings shall be maintained confidential and not made available for public inspection.

E. - G.3. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 27:15 and 24.

HISTORICAL NOTE: Promulgated by the Department of Public Safety and Corrections, Gaming Control Board, LR 28:1990 (September 2002), LR 30:

H. Charles Gaudin
Chairman

0406#002

DECLARATION OF EMERGENCY

**Department of Wildlife and Fisheries
Office of Fisheries**

Iatt Lake Fishing Closure

In accordance with the emergency provisions of R.S. 49:953(B) and R.S. 49:967(D) of the Administrative Procedure Act, and under the authority of R.S. 56:317, the Secretary of the Department of Wildlife and Fisheries hereby declares:

Iatt Lake will be closed to all fishing beginning on July 5, 2004 and continue until the department officially announces the reopening of the lake to fishing, sometime after October 31, 2004 when the lake reaches pool stage (83 feet MSL). Effective with the closure, no person shall take or possess or attempt to take any species of fish while on the waters of Iatt Lake or take or possess or attempt to take any fish from the waters of Iatt Lake. No person shall possess while on the waters of Iatt Lake any fishing gear capable of taking fish.

The reasons for the promulgation of this Declaration of Emergency are as follows: the Aquatic Plant Section of the Department of Wildlife and Fisheries conducts annual vegetative samples on water bodies in late summer, when aquatic vegetation infestations are most severe. Management plans, if necessary, are then written, approved by the department and presented to local citizens. This year's management plan for Iatt Lake in Grant Parish calls for an eight-foot drawdown. This will reduce the surface acreage of Iatt Lake by 80 percent and increase the vulnerability of fish to anglers. The department feels it in the best interest of the resource to prohibit fishing while the lake is drawn down to prevent the over-harvest of fish. Poor fish populations in subsequent years would negatively impact the welfare of businesses catering to Iatt Lake fishermen, some individuals living on the lake and the fishermen using the lake. Because it is necessary to conduct vegetation sampling in late summer, and the lakes which are candidates for drawdowns cannot be determined until after sampling has been completed, there is insufficient time to file a Notice of Intent.

Dwight Landreneau
Secretary

0406#020

DECLARATION OF EMERGENCY

**Department of Wildlife and Fisheries
Office of Fisheries**

Saline Lake Fishing Closure

In accordance with the emergency provisions of R.S. 49:953(B) and R.S. 49:967(D) of the Administrative Procedure Act, and under the authority of R.S. 56:317, the Secretary of the Department of Wildlife and Fisheries hereby declares:

Saline Lake (Winn and Natchitoches Parishes) will be closed to all fishing beginning on July 5, 2004 and continue until the department officially announces the reopening of the lake to fishing, sometime after October 31, 2004 when the lake reaches pool stage (103 feet MSL). Effective with the closure, no person shall take or possess or attempt to take any species of fish while on the waters of Saline Lake or take or possess or attempt to take any fish from the waters of Saline Lake. No person shall possess while on the waters of Saline Lake any fishing gear capable of taking fish.

The reasons for the promulgation of this Declaration of Emergency are as follows: the Aquatic Plant Section of the Department of Wildlife and Fisheries conducts annual vegetative samples on water bodies in late summer, when aquatic vegetation infestations are most severe. Management plans, if necessary, are then written, approved by the department and presented to local citizens. This year's management plan for Saline Lake in Winn and Natchitoches Parishes calls for a six-foot drawdown. This will reduce the surface acreage of Saline Lake by 50 percent and increase the vulnerability of fish to anglers. The department feels it in the best interest of the resource to prohibit fishing while the lake is drawn down to prevent the over-harvest of fish. Poor fish populations in subsequent years would negatively impact the welfare of businesses catering to Saline Lake fishermen, some individuals living on the lake and the fishermen using the lake. Because it is necessary to conduct vegetation sampling in late summer, and the lakes which are candidates for drawdowns cannot be determined until after sampling has been completed, there is insufficient time to file a Notice of Intent.

Dwight Landreneau
Secretary

0406#021

DECLARATION OF EMERGENCY

Department of Wildlife and Fisheries Wildlife and Fisheries Commission

Spotted Seatrout

In accordance with the emergency provisions of R.S. 49:953(B), the Administrative Procedure Act, R.S. 49:967 which allows the Wildlife and Fisheries Commission to use emergency procedures to set finfish seasons and all Rules and regulations pursuant thereto, R.S. 56:326.3 which provides that the Wildlife and Fisheries Commission may set size limits for saltwater finfish, and R.S. 56:325.1(A)2 and B; the Wildlife and Fisheries Commission hereby adds the following Declaration of Emergency for the recreational harvest of spotted seatrout to be effective June 20, 2004:

A final Rule modifying the spotted seatrout Rule establishing a maximum number of fish that can be

harvested recreationally greater than 25 inches to 2 for the Calcasieu Lake, Sabine Lake, and surrounding areas was ratified by the Wildlife and Fisheries Commission at its June 8, 2004 meeting. The Declaration of Emergency regarding "Spotted Seatrout Regulations - Recreational Size and Bag Limit-Calcasieu Lake, Sabine Lake and Surrounding Areas" promulgated by this commission April 1, 2004, shall be rescinded upon the publication of this Final Rule on June 20, 2004. All other applicable rules regarding the harvest of spotted seatrout, established by the commission shall be in effect.

Bill A. Busbice, Jr.
Chairman

0406#044