John Bel Edwards GOVERNOR



State of Louisiana

Louisiana Department of Health Office of Public Health

TO:

The Honorable John Bel Edwards, Governor

The Honorable Jeff Landry, Attorney General

The Honorable John A. Alario, Jr., President, Senate

The Honorable Fred H. Mills Jr., Chair, Senate The Honorable Eric LaFleur, Chair, Senate Finance

The Honorable Taylor F. Barras, Speaker of the House of Representatives The Honorable Frank A. Hoffmann, Chair, House Health and Welfare

The Honorable Cameron Henry, Chair, House Appropriations

Catherine Brindley, Editor, Louisiana Register

FROM:

Rebekah E. Gee, MD, MPH, Secretary

DATE:

June 27, 2017

RE:

EMERGENCY RULE: Controlled Dangerous Substance

The Department of Health, Office of Public Health (LDH/OPH), pursuant to the rulemaking authority granted to the Secretary of LDH by R.S. 40:962(C) and (H), hereby adopts the following Emergency Rule for the protection of public health. This rule is being promulgated in accordance with the Administrative Procedure Act (R.S. 49:950, et seq.). and shall remain in effect for the maximum period allowed under the Act or until adoption of a final Rule, whichever occurs first.

Based on the criteria, factors, and guidance set forth in R.S. 40:962(C) and 40:963, the Secretary, under this rulemaking, has determined that following substances:

- cyclopropylfentanyl N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide
- deschloroketamine 2-phenyl-2(methylamino)cyclohexanone

have a high potential for abuse and should be scheduled as controlled dangerous substances to avoid an imminent peril to the public health, safety, or welfare. In reaching the decision to designate the below listed substances as controlled dangerous substances under Schedule I, the Secretary has considered the criteria provided under R.S. 40:963 and the specific factors listed under R.S. 40:962(C).

The Secretary has determined that Schedule I is the most appropriate due to her findings that the substances added herein have a high potential for abuse, the substances have no currently accepted medical use for treatment in the United States, and there is a lack of accepted safety for use of the substances under medical supervision.

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These substances are typically referred to as a "research chemical" and labeled with words "not for human consumption" like many other synthetic designer drugs. The drugs have been found in bulk powder form and in small plastic bags similar to the way other street drugs are sold. These substances have no accepted medical use in the United States, and have only recently been encountered by law enforcement officials.

Approved and Effective on the 27th day of June 2017 by:

JUMMY GUDRY, M.D., STATE HEALTH OFFICER AND LDH MEDICAL DIRECTOR REBEKAH E. GEE, SECRETARY DEPARTMENT OF HEALTH

REG:JG:PJ:MLTS:amr-g

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DECLARATION OF EMERGENCY

Department of Health Office of Public Health Added Controlled Dangerous Substances

(LAC 46:LIII.2704)

The Department of Health, Office of Public Health (LDH/OPH), pursuant to the rulemaking authority granted to the Secretary of LDH by R.S. 40:962(C) and (H), hereby adopts the following Emergency Rule for the protection of public health. This rule is being promulgated in accordance with the Administrative Procedure Act (R.S. 49:950, et seq.). and shall remain in effect for the maximum period allowed under the Act or until adoption of a final Rule, whichever occurs first.

Based on the criteria, factors, and guidance set forth in R.S. 40:962(C) and 40:963, the Secretary, under this rulemaking, has determined that the below listed substances have a high potential for abuse and should be scheduled as controlled dangerous substances to avoid an imminent peril to the public health, safety, or welfare. In reaching the decision to designate the below listed substances as controlled dangerous substances under Schedule I, the Secretary has considered the criteria provided under R.S. 40:963 and the specific factors listed under R.S. 40:962(C). The Secretary has determined that Schedule I is the most appropriate due to her findings that the substances added herein have a high potential for abuse, the substances have no currently accepted medical use for treatment in the United States, and there is a lack of accepted safety for use of the substances under medical supervision.

Title 46 PROFESSIONAL AND OCCUPATIONAL STANDARDS Part LIII. Pharmacists

Chapter 27. Controlled Dangerous Substances

Subchapter A. General Provisions

§2704. Added Controlled Dangerous Substances

- A. The following drugs or substances are added to Schedule I of the Louisiana Uniform Controlled Dangerous Substances Law, R.S. 40:961 *et seq*.:
 - 5. cyclopropylfentanyl N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide
 - 6. deschloroketamine 2-phenyl-2(methylamino)cyclohexanone

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:962, R.S. 40:963, and R.S. 49:953(B). HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 42:__

Provider Impact Statement

The proposed Rule should not have any known or foreseeable impact on providers as defined by HCR 170 of the 2014 Regular Legislative Session. In particular, there should be no known or foreseeable effect on the: staffing level requirements or qualifications required to provide the same level of service; total direct and indirect effect on the cost to the providers to provide the same level of service; or overall effect on the ability of the provider to provide the same level of service.

Approved and Effective on the 27th day of June 2017 by:

JIMMY GUIDRY, M.D., STATE HEALTH
OFFICER AND LDH MEDICAL DIRECTOR

REBEKAH E. GEE, SECRETARY
DEPARTMENT OF HEALTH

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information is hereby provided:

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NOTICE OF INTENT

Official publication to the State's Journal scheduled for Wednesday July 5, 2017. Pursuant to the provisions of La. R.S. 40:996.1 *et seq.*, the Secretary of the Louisiana Department of Health ("LDH") hereby gives notice of intention to adopt a rule declaring:

- 1. cyclopropylfentanylN-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide
- 2. deschloroketamine 2-phenyl-2(methylamino)cyclohexanone (hereinafter sometimes referred to as "the substances") as dangerous substances and issuing a dangerous substance stop order prohibiting the sale, distribution, manufacture, or dispensing of the substances. In accordance with La. R.S. 40:996.5(C), the following

(1) An explanation of the basis and rationale for the intended action, a summary of the information, and data supporting the intended action:

The Secretary intends to adopt said rule due to her determination that the substances pose a threat to the health of the residents of the State of Louisiana. Cyclopropylfentanyl N-(1phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide (hereinafter referred to as "Cyclopropylfentanyl") is the latest in a group of ultra-potent synthetic opioids that are being abused and causing fatalities and which have recently been identified in other states across the country according to poison control centers, state crime lab, coroner's and reputable news reports. These substances are typically referred to as a "research chemical" and labeled with words "not for human consumption" like many other synthetic designer drugs. The drugs have been found in bulk powder form, in small plastic bags similar to the way other street drugs are sold, in liquid form and in tablet form mimicking the shape, color and imprint of prescription opioid medications. Cyclopropylfentanyl, like furanylfentanyl and acrylfentanyl, has been shown in scientific literature to have actions similar to morphine. It has a high potential for abuse, has no accepted medical use in the United States, and no safety data for use in humans is available. Cyclopropylfentanyl is available for purchase from multiple internet sites. It is being referred to as a "research chemical" and labeled with words "not for human consumption" we have come to expect on these synthetic designer drugs of abuse. The drug has been found in bulk powder form. Six fatalities have been reported recently in Georgia where an outbreak of over 50 cases of cyclopropylfentanyl overdose were reported in a single week. The Louisiana State Police Crime Lab received counterfeit oxycodone tablets that had cyclopropylfentanyl as the active substance.

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Deschloroketamine is a dissociative anesthetic. This substance belongs to the arylcyclohexylamine chemical class which produces dissociative, anesthetic and hallucinogenic effects. Due to issues related to the abuse of descloroketamine both the United Kingdom and Canada have banned this substance. A lack of human use data, demonstrated abuse and a postulated potential immunosuppressant effect reinforce the need to regulate this substance. It is also sold currently on illicit designer drug websites as a research chemical. This substance has also been identified in samples submitted to the Louisiana State Police Crime Lab in both crystalline and liquid forms.

(2) The time, the location, and the manner in which interested persons may present their views thereon:

Interested persons have until 4:30 p.m. on July 10, 2017 to submit a request for oral argument or presentation concerning the proposed rule, and until 4:30 p.m. on July 12, 2017 to submit data, views, comments, or arguments in writing concerning the proposed rule. Such requests or comments should be addressed to Brian R. Warren, Food and Drug Unit, Sanitarian Services Section, Office of Public Health, Mail Bin # 10, P.O. Box 4489, Baton Rouge, LA 70821-4489, or faxed to (225) 342-7672. If requests or comments are to be shipped or hand-delivered, please address the information as shown above and deliver to the Bienville Building, 628 N. 4th Street - Room 166, Baton Rouge, LA 70802. If a timely request for an opportunity for oral presentation or argument is made as provided herein, then a public hearing will be held on July 19, 2017. Please call (225) 342-9513 to find out if a public hearing is being held.

(3) A statement that the intended action complies with the provisions of R.S. 40:996.1 through 996.7:

The intended action and rule complies with the provisions of R.S. 40:996.1 through 996.7.

(4) The text of the proposed rule:

Rule

Pursuant to the authority granted by La. R.S. 40:996.1 et seq., the Secretary of the Louisiana Department of Health has determined that the following substances constitute an imminent hazard to the public health, safety, and welfare, and, accordingly, is hereby declared to be a "dangerous substances":

- 1. cyclopropylfentanyl N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide
- 2. deschloroketamine 2-phenyl-2(methylamino)cyclohexanone

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A "dangerous substance stop order", as defined in La. R.S. 40:996.2, prohibiting the sale, distribution, manufacture, or dispensing of the above-listed dangerous substances, is hereby issued and declared. The Secretary's finding that the above-listed substances are "dangerous substances", and the issuance herein of a "dangerous substance stop order" concerning said substances, is based upon the following findings and determinations, made after the Secretary's consideration of the factors set forth in La. R.S: 40:996.3(B):

- 1. The substances have a high potential for abuse. Because the substances have no legitimate medicinal use and are highly potent drugs to which severe physical ailments have been attributed, any use thereof constitutes abuse.
- 2. The substances have no current medical use in treatment in the United States. After consulting with the State Health Officer, the Secretary has determined that the substances have no accepted medical use in the United States or any other country.
- 3. There is a lack of accepted safety for use of the substances under medical supervision. The substances have no accepted medical use. Moreover, neither the Secretary nor the State Health Officer is aware of any scientific studies concerning the potency of the substances. Use of the substances even under medical supervision would therefore be unsafe and unacceptable.
- 4. There is an imminent hazard to the health, safety, and welfare of the residents of Louisiana requiring the substances to be declared dangerous substances and the issuance of a dangerous substance stop order as authorized by the provisions of this Section.

The above-listed rule shall, unless a legislative oversight hearing is conducted and the rule is found unacceptable by the legislative oversight committee and the governor does not disapprove of the action taken by the legislative oversight committee, become effective on August 4, 2017, and remain in effect through the sixtieth day after final adjournment of the 2018 regular session of