
HOUSE COMMITTEE AMENDMENTS

2025 Regular Session

Substitute for Original House Bill No. 377 by Representative Owen as proposed by the House Committee on Health and Welfare

This document reflects the content of a substitute bill but is not in a bill form; page numbers in this document DO NOT correspond to page numbers in the substitute bill itself.

To enact R.S. 40:5.13, relative to the administration of medical activities under Emergency Use Authorization; to require the surgeon general to promulgate rules for the administration of emergency use authorization-related medical activities; to provide for the applicability of these rules to all members of the healthcare community; to specify that these rules apply during health emergencies and regular operations; to provide for the scope and content of the rules; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 40:5.13 is hereby enacted to read as follows:

§5.13. Rules for administration of medical activities under Emergency Use Authorization

A. The purpose of this Section is to ensure the safe, effective, and uniform administration of medical activities under Emergency Use Authorization (EUA) by all members of the healthcare community in this state, during both health emergencies and regular operations, to protect public health and safety.

B. For the purposes of this Section:

(1) "Emergency Use Authorization" or "EUA" refers to the authority granted under federal law, specifically Section 564 of the Federal Food, Drug, and Cosmetic Act 21 U.S.C. 360bbb-3, to allow the use of unapproved medical products or unapproved uses of approved medical products during a public health emergency.

(2) "Healthcare community" includes but is not limited to hospitals, public and private clinics, pharmacies, nursing homes, and any other entity that participates in healthcare activities where EUA may apply, whether during a health emergency or under the regular order of business for the medical community..

(3) "Health emergency" means a state of emergency declared by the governor or a public health emergency declared by the state health officer under the Louisiana Health Emergency Powers Act, R.S. 29:760 et seq.

C. (1) The surgeon general shall promulgate rules in accordance with the Administrative Procedure Act for the administration of medical activities under Emergency Use Authorization (EUA) by all members of the healthcare community in this state.

(2) Such rules shall apply to all entities within the healthcare community, including but not limited to hospitals, public and private clinics, pharmacies, nursing homes, and any other entity involved in healthcare activities where EUA may apply, whether during a health emergency or under the regular order of business for the medical community.

D. The rules promulgated by the surgeon general shall include but not be limited to the following:

(1) Procedures for the safe and effective administration of EUA-authorized medical products including therapeutics, vaccines, diagnostics, and other interventions.

(2) Guidelines for informed consent, ensuring that patients are fully informed of the risks, benefits, and alternatives associated with EUA-authorized products.

(3) Protocols for monitoring and reporting adverse events related to EUA-authorized products, including mandatory reporting to the Louisiana Department of Health and, where applicable, federal authorities.

(4) Standards for training and education of healthcare providers on the proper use and administration of EUA-authorized products.

(5) Measures to ensure access to EUA-authorized products and protections across all segments of the population, with specific attention to underserved and rural communities.

(6) Provisions for transparency, including public disclosure of EUA-related activities by healthcare entities, to maintain public trust during health emergencies.

(7) Procedures for compliance and enforcement, including penalties for noncompliance by healthcare entities, to ensure uniformity and accountability.

E.(1) The rules promulgated in accordance with this Section shall apply to all EUA-related medical activities conducted by the healthcare community in this state, whether during a health emergency or under the regular order of business for the medical community.

(2) The rules shall not supersede federal regulations governing EUA but shall complement such regulations by providing state-specific guidance to ensure uniformity and safety in administration.

Section 2. The surgeon general shall begin the rulemaking process as required by Section 1 of this Act no later than six months after the effective of this Act.

Section 3. This Act shall become effective upon signature by the governor or, if not signed by the governor, upon expiration of the time for bills to become law without signature by the governor, as provided by Article III, Section 18 of the Constitution of Louisiana. If vetoed by the governor and subsequently approved by the legislature, this Act shall become effective on the day following such approval.

DIGEST

The digest printed below was prepared by House Legislative Services. It constitutes no part of the legislative instrument. The keyword, one-liner, abstract, and digest do not constitute part of the law or proof or indicia of legislative intent. [R.S. 1:13(B) and 24:177(E)]

HB Draft

2025 Regular Session

Abstract: Provides relative to emergency use authorization.

Proposed law provides for the administration of medical activities under Emergency Use Authorization (EUA) as authorized by federal law but does not specify state-level rules for the healthcare community in Louisiana.

Proposed law requires the surgeon general to promulgate rules for the administration of EUA-related medical activities by all members of the healthcare community, including hospitals, public and private clinics, pharmacies, nursing homes, and other entities involved in healthcare activities where EUA may apply.

Proposed law specifies that these rules shall apply during health emergencies and under the regular order of business for the medical community, covering procedures for safe administration, informed consent, adverse event reporting, training, equitable access, transparency, and compliance.

Effective upon signature of the governor or lapse of time for gubernatorial action.

(Adds R.S. 40:5.13)