

2025 Regular Session

# ACT No. 396

HOUSE BILL NO. 690 (Substitute for House Bill No. 377 by Representative Owen)

BY REPRESENTATIVES OWEN, AMEDEE, BERAULT, BILLINGS, BUTLER,  
CREWS, EGAN, FIRMENT, HORTON, SCHAMERHORN, SPELL, AND  
WILDER

## AN ACT

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; to provide for certain agencies or organizations to coordinate with the surgeon general on the development 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 by all members of the healthcare community in this state, during both health emergencies and regular operations, to protect public health and safety.

1                    B. For the purposes of this Section:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

20                  F. The surgeon general shall coordinate with the following agencies or  
21                  organizations during the development of his rules:

22                   (1) The office of the attorney general.

23                   (2) The Louisiana State Law Institute.

24                   (3) The Louisiana State Board of Medical Examiners.

25                   (4) The Louisiana Hospital Association.

26                   (5) The Louisiana Board of Pharmacy.

27                   (6) The Louisiana State Medical Society.

28                   (7) The Louisiana State Board of Nursing.

29                   (8) Any other agencies or organizations deemed appropriate by the surgeon  
30                  general.

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

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

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SPEAKER OF THE HOUSE OF REPRESENTATIVES

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PRESIDENT OF THE SENATE

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GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: \_\_\_\_\_