

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.

SPEAKER OF THE HOUSE OF REPRESENTATIVES

PRESIDENT OF THE SENATE

GOVERNOR OF THE STATE OF LOUISIANA

APPROVED: _____