

2025 Regular Session

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

BY REPRESENTATIVE OWEN

PUBLIC HEALTH: Provides relative to emergency use authorization

1 AN ACT

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

8 Be it enacted by the Legislature of Louisiana:

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

10 §5.13. Rules for administration of medical activities under Emergency Use  
11 Authorization

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

16 B. For the purposes of this Section:

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

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

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

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

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

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

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

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

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

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



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.

Proposed law specifies that the surgeon general shall begin the rulemaking process as required by proposed law no later than six months after the effective date of proposed law.

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

(Adds R.S. 40:5.13)