

1 AN ACT relating to information on emergency use drugs and declaring an  
2 emergency.

3 *Be it enacted by the General Assembly of the Commonwealth of Kentucky:*

4 ➔SECTION 1. A NEW SECTION OF KRS 217.005 TO 217.215 IS CREATED  
5 TO READ AS FOLLOWS:

6 *(1) As required in 21 U.S.C. sec. 360bbb-3, any person who administers an*  
7 *unapproved drug, device, or biologic that has been approved for emergency use*  
8 *by the secretary of the United States Food and Drug Administration shall inform*  
9 *the individual to whom the drug, device, or biologic is administered of the*  
10 *following:*

11 *(a) That the drug, device, or biologic has been authorized for emergency use;*

12 *(b) The significant known and potential benefits and risks of such use, and the*  
13 *extent to which such benefits and risks are unknown;*

14 *(c) The option to accept or refuse administration of the drug, device, or*  
15 *biologic;*

16 *(d) Medical consequences, if any, of refusing administration of the drug,*  
17 *device, or biologic; and*

18 *(e) Alternatives to the drug, device, or biologic that are available and their*  
19 *benefits and risks.*

20 *(2) An individual in the Commonwealth shall not be required by any person, as*  
21 *defined in KRS 446.010, to have administered to the individual an unapproved*  
22 *drug, device, or biologic that has been approved for emergency use by the*  
23 *secretary of the United States Food and Drug Administration.*

24 ➔Section 2. Whereas the Commonwealth of Kentucky has a paramount interest in  
25 protecting the rights of all citizens to make informed decisions about their health, an  
26 emergency is declared to exist, and this Act takes effect upon its passage and approval by  
27 the Governor or upon its otherwise becoming a law.