

STATEMENT OF EMERGENCY

902 KAR 2:230E.

This emergency administrative regulation is being promulgated to establish COVID-19 antibody administration centers (CAACs) throughout the Commonwealth, including protocols for appropriate patient eligibility criteria for receiving treatment and the administration of treatment. This emergency administrative regulation is needed pursuant to KRS 13A.190(1)(a)1. to protect public health, safety, and welfare, and KRS 13A.190(1)(a)3. as directed by 2021 Extra. Sess. Ky. Acts Ch. 5. This emergency administrative regulation will not be replaced by an ordinary administrative regulation.

ANDY BESHEAR, Governor

ERIC C. FRIEDLANDER, Secretary

CABINET FOR HEALTH AND FAMILY SERVICES
Department for Public Health
Division of Epidemiology and Health Planning
(New Emergency Administrative Regulation)

902 KAR 2:230E. COVID-19 antibody administration center.

RELATES TO: KRS 39A.350 to 39A.366, 194A.050, 211.180, 216B.015, 21 U.S.C. 360 bbb-3(b)(1)

STATUTORY AUTHORITY: 2021 Extra. Sess. Ky. Acts Ch. 5

NECESSITY, FUNCTION, AND CONFORMITY: 2021 Extra. Sess. Ky. Acts Ch. 5 Section 2 requires the Cabinet for Health and Family Services to assist and support established and additional COVID-19 antibody administration centers (CAACs) throughout the Commonwealth, develop protocols for appropriate patient eligibility criteria for receiving treatments, and proper protocol for the administration of treatments. 2021 Extra. Sess. Ky. Acts Ch. 5 Section 4 requires the cabinet to promulgate an emergency administrative regulation to implement Section 2. This emergency administrative regulation establishes the CAAC process, patient eligibility criteria, and treatment protocols.

Section 1. A COVID-19 antibody administration center shall abide by the most current guidance on monoclonal antibody treatment issued by the federal Food and Drug Administration available online at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs>.

Section 2.

(1) The Kentucky Department for Public Health shall establish a program to support, through direct financial support and other coordinating activities, CAACs for the work associated with inclusion on a state-published antibody administration Web site.

(2) The program established in subsection (1) of this section shall be available to all sites that agree to join this statewide network, subject to the available supply of monoclonal antibody treatments provided by the federal government through its established distribution program.

STEVEN J. STACK, MD, MBA, Commissioner
ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: September 27, 2021

FILED WITH LRC: October 1, 2021 at 10:03 a.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on November 22, 2021, at 9:00 a.m. using the CHFS Office of Legislative and Regulatory Affairs Zoom meeting room. The Zoom invitation will be emailed to each requestor the week prior to the scheduled hearing. Individuals interested in attending this virtual hearing shall notify this agency in writing by November 15, 2021, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends virtually will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until November 30, 2021. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of

consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Krista Quarles, Policy Analyst, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.