

## CABINET FOR HEALTH AND FAMILY SERVICES DEPARTMENT FOR PUBLIC HEALTH

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Steven J. Stack, MD
Commissioner

July 9, 2020

On March 6, 2020, Governor Andy Beshear signed Executive Order 2020-215 declaring a state of emergency in the Commonwealth due to the outbreak of the COVID-19 virus, a public health emergency.

Therefore, pursuant to the authority in KRS Chapter 39A, KRS 194A.025, KRS 214.020 and Executive Order 2020-215 the Cabinet for Health and Family Services, the Department for Public Health states as follows:

In recognition of the current state of emergency and the importance of COVID-19 testing being available to the citizens of the Commonwealth of Kentucky, the Cabinet for Health and Family Services, Department of Public Health hereby Orders:

- 1. That a licensed clinician's order shall not be required within the Commonwealth of Kentucky for a laboratory services provider to perform and bill for a SARS-CoV-2 molecular diagnostic test that is approved, cleared, or authorized under section 510(k), 513, 515 or 564 of the Federal Food, Drug, and Cosmetic Act. In the interest of clarity, this order applies only to molecular diagnostic testing and does <u>not</u> apply to serology (i.e., antibody) and/or antigen testing;
- 2. That health insurers shall not require from beneficiaries or laboratories a licensed clinician's order as a precondition of covering the cost of testing described in item #1 above;
- 3. That clinicians participating solely in the processes necessary to collect, submit patient specimens, and/or perform point of care COVID-19 molecular diagnostic testing shall not have established a formal clinician-patient relationship unless professional medical advice beyond providing this testing service is otherwise explicitly provided.



Additionally, health insurers are reminded of U.S. Public Law 116 - 127, The Families First Coronavirus Response Act in which sections 6001 - 6007 explicitly <u>require</u> that all varieties of group health plans, commercial plans, Medicare, Medicare Advantage, Medicaid, CHIP, and others:

"shall provide coverage, and shall not impose any cost sharing (including deductibles, copayments, and coinsurance) requirements or prior authorization or other medical management requirements, for the following items and services furnished during any portion of the emergency period defined in paragraph (1)(B) of section 1135(g) of the Social Security Act (42 U.S.C. 1320b-5(g)) beginning on or after the date of the enactment of this Act:

(1) In vitro diagnostic products (as defined in section 809.3(a) of title 21, Code of Federal Regulations) for the detection of SARS–CoV–2 or the diagnosis of the virus that causes COVID–19 that are approved, cleared, or authorized under section 510(k), 513, 515 or 564 of the Federal Food, Drug, and Cosmetic Act, and the administration of such in vitro diagnostic products."

The Secretary for the Cabinet for Health and Family Services has been designated by the Governor to deliver these directives during this public health emergency.

The Cabinet for Health and Family Services will continue to provide information and updates to healthcare providers during the duration of this Public Health Emergency.

Eric Friedlander

Secretary

Governor's Designee

Steven J. Stack, MD

Commissioner