

# State of North Carolina

### **ROY COOPER**

**GOVERNOR** 

### September 2, 2021

#### **EXECUTIVE ORDER NO. 232**

### DIRECTING THE ISSUANCE OF A STATEWIDE STANDING ORDER TO EXPAND ACCESS TO MONOCLONAL ANTIBODY TREATMENT FOR COVID-19

WHEREAS, on March 10, 2020, the undersigned issued Executive Order No. 116, 34 N.C. Reg. 1744-1749 (April 1, 2020), which declared a State of Emergency to coordinate the State's response and protective actions to address the Coronavirus Disease 2019 ("COVID-19") public health emergency and provide for the health, safety, and welfare of residents and visitors located in North Carolina ("Declaration of a State of Emergency"); and

WHEREAS, on March 11, 2020, the World Health Organization declared COVID-19 a global pandemic; and

WHEREAS, on March 13, 2020, the President of the United States issued an emergency declaration for all states, tribes, territories, and the District of Columbia, retroactive to March 1, 2020, and the President declared that the COVID-19 pandemic in the United States constitutes a national emergency; and

**WHEREAS**, on March 25, 2020, the President approved a Major Disaster Declaration, FEMA-4487-DR, for the State of North Carolina; and

**WHEREAS**, in responding to the COVID-19 pandemic, and for the purpose of protecting the health, safety, and welfare of the people of North Carolina, the undersigned has issued Executive Order Nos. 116-122, 124-125, 129-131, 133-136, 138-144, 146-153, 155-157, 161-165 169-177, 180-181, 183-185, 188-193, 195, 197-198, 200, 204-207, 209-212, 215-217, 219-221, 224-225, and 228-230; and

**WHEREAS**, more than one million two hundred and twenty-eight thousand (1,228,000) people in North Carolina have had COVID-19, and over fourteen thousand six hundred (14,600) people in North Carolina have died from the disease; and

**WHEREAS**, COVID-19 continues to infect thousands of North Carolinians every day, and a State of Emergency remains in place for the purpose of maintaining the state's ability to meet challenges presented by COVID-19; and

WHEREAS, the State of Emergency allows North Carolina to receive federal funding; to provide increased regulatory flexibility to the North Carolina Department of Health and Human Services ("NCDHHS") and health care facilities, which allows health care providers to expand their capacity to treat patients and assist with vaccination efforts; and to respond to any spikes in spread of the disease; and

WHEREAS, the undersigned has taken a science and data-driven approach to implementing public health measures to curb the spread of the virus and to advance the state's economy in a safe and effective way, which is in the best interests of all North Carolinians; and

Need for Statewide Standing Order to Expand Access to Monoclonal Antibodies for the Treatment and Prevention of COVID-19

WHEREAS, COVID-19 cases, and COVID-19 associated hospitalizations are rising and nearing peak levels close to those of January 2021; and

WHEREAS, the use of monoclonal antibodies can decrease the risk that an individual will experience severe illness, need emergency department care or hospitalization, or die from COVID-19; and

WHEREAS, the Food and Drug Administration has issued an Emergency Use Authorization for the use of monoclonal antibodies in treatment of persons diagnosed with COVID-19 who are experiencing mild to moderate symptoms and who are at high-risk for severe illness and for the use of monoclonal antibodies for the prevention of illness in certain persons at high-risk for infection and disease severity; and

WHEREAS, the National Institutes of Health COVID-19 Treatment Guidelines Panel now strongly recommends the use of monoclonal antibody therapy to treat outpatients diagnosed with COVID-19 who are experiencing mild to moderate symptoms and who are at high-risk for clinical progression; and

WHEREAS, North Carolinians may have limited access to monoclonal antibody treatment and there is a need to increase equitable access to this medication; and

WHEREAS, the State Health Director has been assigned authority by the North Carolina Department of Health and Human Resources ("NCDHHS"), pursuant to N.C. Gen. Stat. § 130A-3, to exercise authorities under N.C. Gen. Stat. § 130A-5, including to investigate the causes of communicable diseases affecting the public health in order to control and prevent those diseases; to provide, under the rules of the North Carolina Commission of Public Health, for the prevention, detection, reporting, and control of communicable diseases; and to develop and carry out programs necessary for the protection and promotion of the public health and control of the disease; and

WHEREAS, accordingly, the State Health Director may issue statewide standing orders to facilitate the response to COVID-19; and

WHEREAS, the undersigned now desires to direct the State Health Director to issue, and affirms her flexibility to issue, a statewide standing order for the use of monoclonal antibodies; and

WHEREAS, a statewide standing order for the use of monoclonal antibodies will enable those health care providers and health care facilities who need to rely on the statewide standing order to administer monoclonal antibody treatment to do so, per the terms of the standing order; and

WHEREAS, a statewide standing order for monoclonal antibody therapy will remove barriers to access and increase North Carolinians' access to potentially life-saving treatment; and

WHEREAS, to facilitate the provision of monoclonal antibody treatment, it is also important that those licensed or otherwise authorized to administer the treatment and those issuing the standing order directed hereunder are insulated from liability to the maximum extent permitted by law; and

### Statutory Determinations and Authority

WHEREAS, Executive Order No. 116 invoked the Emergency Management Act, and authorizes the undersigned to exercise the powers and duties set forth therein to direct and aid in the response to, recovery from, and mitigation against emergencies; and

WHEREAS, pursuant to N.C. Gen. Stat. § 166A-19.10(b)(2), the undersigned may make, amend, or rescind necessary orders, rules, and regulations within the limits of the authority conferred upon the Governor in the Emergency Management Act; and

WHEREAS, N.C. Gen. Stat. § 166A-19.10(b)(3) authorizes and empowers the undersigned to delegate any Gubernatorial vested authority under the Emergency Management Act and to provide for the subdelegation of any authority; and

WHEREAS, pursuant to N.C. Gen. Stat. § 166A-19.10(b)(7), the officers and personnel of the departments, offices, and agencies of the state and its political subdivisions are required to cooperate with the undersigned and extend their services to the undersigned so that they can be utilized upon request; and

WHEREAS, pursuant to N.C. Gen. Stat. § 166A-19.30(a)(1), the undersigned may utilize all available state resources as reasonably necessary to cope with an emergency, including the transfer and direction of personnel or functions of state agencies or units thereof for the purpose of performing or facilitating emergency services; and

WHEREAS, pursuant to N.C. Gen. Stat. § 166A-19.30(b)(2), the undersigned, with the concurrence of the Council of State, may establish a system of economic controls over resources, materials, and services, including shelter and rents; and

WHEREAS, pursuant to N.C. Gen. Stat. § 166A-19.30(b)(5), the undersigned, with the concurrence of the Council of State, may perform and exercise other such functions, powers and duties as are necessary to promote and secure the safety and protection of the civilian population; and

WHEREAS, the undersigned has sought and obtained concurrence from the Council of State consistent with the Governor's emergency powers authority in N.C. Gen. Stat. § 166A-19.30 for those provisions of this Executive Order requiring concurrence.

**NOW, THEREFORE**, by the authority vested in me as Governor by the Constitution and the laws of the State of North Carolina, and for the reasons and pursuant to the authority set forth above, **IT IS ORDERED**:

# <u>Section 1. Statewide Standing Order for Use of Monoclonal Antibodies for Treatment and Prevention of COVID-19.</u>

In order to further protect the public health by providing greater access to COVID-19 treatment, the undersigned orders the State Health Director, in addition to and in accordance with her powers set out in N.C. Gen. Stat. Chapter 130A, to issue any statewide standing order needed in her medical judgement that would allow individuals who meet the criteria in the Food and Drug Administration Emergency Use Authorization to access and receive monoclonal antibodies, subject to the terms of the standing order.

## Section 2. Expressly Providing that Administration of Monoclonal Antibody Treatment Is Among the Subjects for Limitation of Liability Under N.C. Gen. Stat. § 166A-19.60.

- A. Amendment. Subsections 3(C)(1)-(2) of Executive Order No. 130 and Subsections 2(B)(1)-(2) of Executive Order No. 193 are each amended to read as follows:
  - 1. All persons who are licensed or otherwise authorized under an Executive Order to perform vaccinations, COVID-19 testing, or administer monoclonal antibody treatment; issue medical standing orders for vaccinations, testing, or the administration of monoclonal antibody treatment; or perform professional skills in the field of health care are hereby requested to provide emergency services to respond to the COVID-19 pandemic and, to the extent they are providing emergency services, therefore constitute "emergency management workers" to the extent allowed under N.C. Gen. Stat. § 166A-19.60(e).

- 2. Therefore, the undersigned intends that all such emergency management workers should be insulated from civil liability to the maximum extent authorized by N.C. Gen. Stat. § 166A-19.60, except in cases of willful misconduct, gross negligence, or bad faith.
- B. <u>Intent</u>. For the avoidance of doubt, and notwithstanding Section 1 of Executive Order No. 225, Section 2 of this Executive Order is intended to extend the above-referenced provisions, as amended herein, through the expiration date of this Executive Order.

### Section 3. No Private Right of Action.

This Executive Order is not intended to create, and does not create, any individual right, privilege, or benefit, whether substantive or procedural, enforceable to law or in equity by any party against the State of North Carolina, its agencies, departments, political subdivisions, or other entities, or any officers, employees, or agents thereof, or any emergency management worker (as defined in N.C. Gen. Stat. § 166A-19.60) or any other person.

### Section 4. Distribution.

The undersigned hereby orders that this Executive Order be: (1) distributed to the news media and other organizations calculated to bring its contents to the attention of the general public; (2) promptly filed with the Secretary of the North Carolina Department of Public Safety, the Secretary of State, and the superior court clerks in the State of North Carolina; and (3) distributed to others as necessary to ensure proper implementation of this Executive Order.

### Section 5. Savings Clause.

If any provision of this Executive Order or its application to any person or circumstances is held invalid by any court of competent jurisdiction, this invalidity does not affect any other provision or application of this Executive Order, which can be given effect without the invalid provision or application. To achieve this purpose, the provisions of this Executive Order are declared to be severable.

### Section 6. Effective Date.

This Executive Order is effective immediately and shall remain in effect until November 30, 2021, unless repealed, replaced, or rescinded by another Executive Order. An Executive Order rescinding the Declaration of State of Emergency will automatically rescind this Executive Order.

**IN WITNESS WHEREOF**, I have hereunto signed my name and affixed the Great Seal of the State of North Carolina at the Capitol in the City of Raleigh, this 2<sup>nd</sup> day of September in the year of our Lord two thousand and twenty-one.

Roy Cooper Governor

ATTEST:

Elaine F. Marshall Secretary of State