

STATE OF NEW HAMPSHIRE OFFICE OF THE GOVERNOR

STATE OF NEW HAMPSHIRE BY HIS EXCELLENCY CHRISTOPHER T. SUNUNU, GOVERNOR

Emergency Order #39 Pursuant to Executive Order 2020-04 as extended by Executive Orders 2020-05 and 2020-08

Temporary allowance for agents to consent to clinical trials

WHEREAS, on Friday, March 13, 2020, the President of the United States declared a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak; and

WHEREAS, on Friday, March 13, 2020, the Governor issued Executive Order 2020-04, An order declaring a state of emergency (the "State of Emergency") due to the Novel Coronavirus (COVID-19), which has been extended by Executive Orders 2020-05 and 2020-08; and

WHEREAS, on Friday, March 13, 2020, the Governor activated the Emergency Operations Center at the Incident Planning and Operations Center in Concord to assist in the State's response to the COVID-19 outbreak; and

WHEREAS, in the days since the Governor declared a State of Emergency and activated the Emergency Operations Center, the COVID-19 outbreak in New Hampshire has expanded significantly; and

WHEREAS, experts anticipate that while a high percentage of individuals affected by COVID-19 will experience mild flu-like symptoms, some will have severe symptoms and require hospitalization, particularly individuals who are elderly or already have underlying chronic health conditions; and

WHEREAS, on Monday, March 23, 2020, the first New Hampshire death resulting from COVID-19 occurred and there have been more than 65 additional deaths in New Hampshire since that date; and

WHEREAS, as of April 29, 2020, according to the CDC, there were 1,0005,147 confirmed or probable cases of COVID-19 in the United States and territories, with 57,505 of those confirmed or probable cases resulting in death; and

WHEREAS, as of April 29, 2020, New Hampshire Division of Public Health reported that there have been 2,054 confirmed positive cases of COVID-19 and that of these cases, 259 individuals have required hospitalization; and

WHEREAS, New Hampshire, in RSA 137-J, recognizes that a person has a right, founded in the autonomy and sanctity of the person, to control the decisions relating to his or her own medical care. In order to respect these rights, even after a person lacks the capacity to make healthcare decision for himself

or herself, the State recognizes the right of a competent person to make a written directive that delegates the authority to make healthcare decisions to an agent named in the written directive; and

WHEREAS, New Hampshire, in RSA 137-J, also recognizes that not all people will take advantage of having a written healthcare directive in place but would allow a surrogate to ensure that healthcare decisions can be made in a timely manner by the person's next of kin or loved one without involving court action; and

WHEREAS, the State of Emergency's requirements limiting activities and the devastating medical impacts of COVID-19 make it difficult for people to create or update healthcare directives; and

WHEREAS, RSA 137-J:5, V(d) and RSA 137-J:37, V limit agents' or surrogates' authority so that these individuals cannot consent to experimental treatments of any kind; and

WHEREAS, as part of the treatment advances for COVID-19, there are experimental treatments being developed under review of Institutional Review Boards that can save individuals' lives. To protect the public's health and increase access to medical care in New Hampshire, hospitals are performing recognized Institutional Review Board-approved experimental trials on patients with severe COVID-19 disease; and

WHEREAS, an Institutional Review Board is a type of committee that applies research ethics, under regulations promulgated by the Federal Drug Administration and the United States Department of Health and Human Service, by reviewing the methods proposed for research to ensure that the research methods are ethical. The purpose of an Institutional Review Board is to assure that appropriate steps are taken to protect the rights and welfare of the people participating in a research study, including experimental treatments; and

WHEREAS, the State of New Hampshire believes it is important to allow access to these experimental treatments for individuals who have agents or surrogates who could make informed decisions regarding these experimental treatments for them when they are unable to make those decisions for themselves; and

WHEREAS, the State of New Hampshire also recognizes that when an individual does not have an agent or surrogate to make these important healthcare decisions, emergency guardianship petitions with requests for allowing experimental treatments can be filed with the Probate Court that has jurisdiction over the individual.

Now therefore, pursuant to Section 18 of Executive Order 2020-04 as extended by Executive Orders 2020-05 and 2020-08, it is hereby ordered, effective immediately, that:

- 1. For any patient experiencing severe, advanced COVID-19 symptoms or COVID-19 complications who does not have the capacity to consent himself or herself to an experimental treatment, it is hereby ordered that the provisions of RSA 137-J:5, V(d) are waived and that an agent, as defined in RSA 137-J:2, III and RSA 137-J:5, shall have the authority to consent to experimental treatments, authorized by an Institutional Review Board, on the patient for COVID-19 symptoms or complications for the duration of the State of Emergency as extended and in accordance with the terms of Paragraph 3 below.
- 2. For any patient experiencing severe, advanced COVID-19 symptoms or COVID-19 complications who does not have the capacity to consent himself or herself to an experimental treatment, it is hereby ordered that the provisions of RSA 137-J:5, V(d) and RSA 137-J:37, V are waived, and surrogates, as defined in RSA 137-J:2, XXII-a and RSA 137-J:35, shall have the

authority to consent to experimental treatments, authorized by an Institutional Review Board, on the patient for COVID-19 symptoms or complications for the duration of the State of Emergency as extended.

- 3. For an agent or surrogate to approve the use of an experimental treatment, approved by an Institutional Review Board, the agent or surrogate must be informed of all risks and side effects and follow all Institutional Review Board instructions regarding consent as if the agent or surrogate were the individual receiving the treatment, including the completion of all consent documentation required by the Food and Drug Administration. An agent or surrogate shall not consent unless the following three factors exist:
 - a. The patient is confronted by a life-threatening situation necessitating the use of the experimental treatment; and
 - b. Informed consent cannot be obtained from the patient because of an inability to communicate with, or obtain legally effective consent from, the patient; and
 - c. There is no alternate method of approved or generally recognized therapy available that provides an equal or greater likelihood of saving the life of the patient.
- 4. If a patient has a living will, the agent must follow the directions of the living will. In addition, if the hospital or agent has actual knowledge that the patient wished to decline the experimental treatment, the agent does not have the authority to consent to treatment.
- 5. All healthcare decisions by an agent or surrogate shall be made pursuant to RSA 137-J:6 which requires that the decisions be made in accordance with the patient's best interests.

Given under my hand and seal at the Executive Chambers in Concord, this 30th day of April, in the year of Our Lord, two thousand and twenty, and the independence of the United States of America, two hundred and forty-four.

COVERNOR OF NEW HAMPSHIRE