

**STATE OF NEW JERSEY**  
**DEPARTMENT OF HEALTH**  
**CORRECTED NOTICE OF RULE WAIVER/MODIFICATION**  
**PURSUANT TO EXECUTIVE ORDER NO. 103 (MURPHY)(MARCH 9, 2020)**  
**COVID-19 STATE OF EMERGENCY**

Temporary Rule **WAIVER/MODIFICATION OF N.J.A.C. 8:43G-31.11 – RESPIRATORY CARE SUPPLIES AND EQUIPMENT**, adopted by **THE COMMISSIONER OF THE DEPARTMENT OF HEALTH**

Date Corrected: **May 28, 2020**

Authority: N.J.S.A. App.A:9-45 & App. A:9-47; Executive Order No. 103 (Murphy)(“EO 103”); Executive Order No. 119 (Murphy)(“EO 119”)

Effective Date: **May 8, 2020**

Expiration Date: Forty-five (45) days after the end of the Public Health Emergency

This is an emergency adoption of a temporary rule waiver/modification of N.J.A.C. 8:43G-31.11 regarding the maintenance of respiratory care equipment in hospitals. Section 6 of EO 103, which was issued in response to the COVID-19 pandemic, authorizes agency heads to waive, modify or suspend any existing rule, where the enforcement of the rule would be detrimental to the public welfare during the emergency, notwithstanding the provisions of the Administrative Procedure Act or any law to the contrary. EO 119 extended this authorization. Pursuant to that authority, as well as the Emergency Health Powers Act, N.J.S.A. 26:13-1 to -31, and with the approval of the Governor and in consultation with the State Director of Emergency Management, the Commissioner of the Department of Health is waiving its rules as follows:

COVID-19 is a contagious, and at times fatal, respiratory disease that is responsible for the 2019 novel coronavirus outbreak. The Centers for Disease Control and Prevention (CDC) expects that additional cases of COVID-19 will be identified in the coming days, including more cases in the United States, and that person-to-person spread is likely to continue to occur. As of May 8, 2020, there were at least 135,454 positive cases of COVID-19 in New Jersey, with at least 8,952 of those cases having resulted in death. As COVID-19 has spread throughout New Jersey, it has greatly strained hospital resources and medical equipment, including the number ventilators available to treat patients ill with COVID-19.

N.J.A.C. 8:43G-31.11 sets forth certain criteria for the maintenance of respiratory care equipment, which includes ventilators, in hospitals. As hospitals are receiving ventilators that have been in State storage or from Federal stockpiles for several years, often with expired

preventative maintenance tags, it is necessary to waive/modify the requirements of N.J.A.C. 8:43G-31.11(c) and (d).

Pursuant to this temporary rule waiver/modification, hospitals shall perform a mechanical and electrical function test on a ventilator released from State storage or from the federal stockpile prior to placing it into service and using it for the first time. The ventilator mechanical and electrical equipment function test shall consist of the following: performance of standard preoperational checks as recommended by the manufacturer; performance of a power-on self-test; and running the ventilator for a minimum of 15 minutes. Upon successful completion of the test, the hospital shall affix a sticker indicating the date that the ventilator passed the test. Hospitals shall create and maintain records showing that each State storage or federal stockpile ventilator placed into service met these requirements prior to being placed into service.

Hospitals that take action under the terms of this waiver must also provide a written report to the Department detailing the number of ventilators placed into service and any adverse outcomes attributable to these actions. This temporary waiver/modification is effective only during the period of the Public Health Emergency declared by Governor Philip D. Murphy in Executive Order Nos. 103. This temporary rule waiver/modification shall expire forty-five (45) days after the Public Health Emergency has ended. Upon the expiration of this temporary rule waiver/modification, hospitals will be required to resume operating in accordance with all licensure standards and perform the required equipment checks and maintenance. The remaining provisions set forth in N.J.A.C. 8:43G-31.11 shall remain in effect.

Full Text of the affected regulations follows, with additional terms and conditions indicated in boldface:

#### **8:43G-31.11 Respiratory care supplies and equipment**

...

(c) There shall be a documented system for preventive maintenance of all respiratory therapy equipment.

(d) All mechanical and electrical equipment shall be tested before using for the first time or after repairs.

**(e) Notwithstanding the requirements of (c) and (d) above, hospitals receiving ventilators from State storage or from the federal stockpile shall comply with the following before releasing a ventilator into service:**

- 1. Perform a mechanical and electrical equipment function test on the ventilator; which shall consist of:**
  - i. performing a standard preoperational check of the ventilator in the manner recommended by the manufacturer of the ventilator;**
  - ii. performing a power-on self-test; and**
  - iii. running the ventilator for a minimum of 15 minutes; and**
- 2. Affix a sticker indicating the date that the ventilator received a mechanical and electrical function test and passed.**

