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Commissioner

EXECUTIVE DIRECTIVE NO. 20-016 (REVISED)[1]

COVID-19 PROTOCOLS FOR AMBULATORY SURGERY CENTERS RESUMING ELECTIVE SURGERY AND INVASIVE DIAGNOSTIC PROCEDURES PURSUANT TO EXECUTIVE ORDER NO. 145

WHEREAS, Coronavirus disease 2019 ("COVID-19") is a contagious, and at times fatal, respiratory disease caused by the respiratory illness caused by the SARS-CoV-2 virus; and

WHEREAS, symptoms of the COVID-19 illness include fever, cough, shortness of breath, loss of smell or taste, and other symptoms identified by the Centers for Disease Control at https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html, which may appear in as few as two or as long as 14 days after exposure, and can spread from person to person via respiratory droplets produced when an infected person coughs or sneezes; and

WHEREAS, on March 9, 2020, Governor Philip D. Murphy issued Executive Order 103, declaring the existence of a Public Health Emergency, pursuant to the Emergency Health Powers Act, N.J.S.A. 26:13-1 et seq., and a State of Emergency, pursuant to the Disaster Control Act, N.J.S.A. App A:9-33 et seq., in the State of New Jersey for COVID-19; and

WHEREAS, the Public Health Emergency was extended by Governor Murphy under Executive Order Nos. 119, 138, 151 and 162; and

WHEREAS, as confirmed cases of COVID-19 and related fatalities continued to rise, on March 23, 2020, Governor Murphy issued Executive Order No. 109 (2020) which ordered that as of 5:00 p.m. on Friday, March 27, 2020, all "elective" surgeries performed on adults, whether medical or dental, and all "elective" invasive procedures performed on adults, whether medical or dental, would be suspended in New Jersey; and

WHEREAS, this step was necessary at the time because hospitalizations, intensive care unit admissions, and ventilator usage was rapidly spiking, and these surgeries and procedures, whether undertaken in a hospital, ambulatory surgery center or providers office, necessarily drew upon the skill and time of critical health care and involved the use of equipment and supplies that were needed to treat those who were critically ill; and

[1] This *revised* Executive Directive amends and supersedes Executive Directive No. 20-2016 dated June 24, 2020 and July 28, 2020.

WHEREAS, the suspension of these surgeries and procedures preserved the capacity of our healthcare system to deal with the surge of COVID-19 cases, which reached its maximum impact on the healthcare system in the middle of April. Since then, however, the rate of confirmed COVID-19 cases in New Jersey has decreased substantially; and

WHEREAS, the provision in Executive Order 109 that the Executive Order shall not be construed in any way to limit access to the full range of family planning services and procedures, including terminations of pregnancies, whether in a hospital, ambulatory surgery center, physician office, or other location, remains in effect and waives COVID-19 testing requirements for these patients; and

WHEREAS, Governor Murphy issued Executive Order No. 145 (2020) on May 15, 2020 permitting the resumption of elective surgeries and invasive procedures in hospital and ambulatory surgery centers beginning on May 26, 2020, subject to a Directive developed by the Department of Health.

WHEREAS, for the purpose of this document a COVID-19 positive patient is defined as a patient who has been diagnosed with COVID-19 but has not yet had isolation precautions discontinued as defined at https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html and https://www.cdc.gov/coronavirus/2019-ncov/community/strategy-discontinue-isolation.html.

NOW, THEREFORE, I, JUDITH PERSICHILLI, Commissioner of the Department of Health, pursuant to the powers afforded to me under the Emergency Health Powers Act, hereby ORDER and DIRECT the following:

i. **Ambulatory surgery centers resuming elective surgeries and invasive procedures are required to take these additional steps to protect the healthcare workforce and patients being served:**

   a. Comply with State and CDC guidelines to protect against further spread of COVID-19;

   b. Institute screening of healthcare staff for symptoms of COVID-19 and have policies in place for removal of symptomatic employees from the workplace;

   c. Enforce social distancing requirements in work areas and common areas;

   d. Require masks for patients, except patients receiving services that would not allow for the use of a mask, and for any patient support person;

   e. Have an established plan for cleaning and disinfecting prior to using facilities to serve non-COVID-19 patients; and

f. Facilities should be prepared to modify resumption of clinical services in conjunction with surge status (i.e., as surge status increases, access to non-urgent care should decrease so as to not overwhelm the healthcare system) and to repurpose and redeploy staff to urgent care roles to the extent feasible. The facility plans for potential future surges shall be guided by the following documents and others listed in the Appendix:

i. CDC Framework for Healthcare Systems Providing Non-COVID-19 Clinical Care During the COVID-19 Pandemic: https://www.cdc.gov/coronavirus/2019-ncov/hcp/framework-non-COVID-care.html;

ii. CDC Preparedness Tools for Healthcare Professionals and Facilities Responding to COVID-19: https://www.cdc.gov/coronavirus/2019-ncov/hcp/preparedness-checklists.html; and

iii. CDC COVID-19Surge tool: https://www.cdc.gov/coronavirus/2019-ncov/hcp/covidsurge.html.

ii. Ambulatory Surgical Centers are Eligible to Resume Elective Surgeries and Invasive Procedures, Based Upon Current or Potential Capacity

a. Ambulatory surgery centers can resume procedures based on the following capacity data on the date of each procedure from at least one hospital that the facility has a transfer agreement with as required in **iv.d.** below, provided that at least one such transfer hospital:

i. Shall not be on divert (as listed in NJDOH's Hippocrates system: https://hippocrates.nj.gov/); and

ii. Shall be located in a region (as displayed in the NJ COVID-19 Data Dashboard: https://www.nj.gov/health/cd/topics/covid2019_dashboard.shtml) that has a downward or horizontal trajectory in hospitalizations.

b. The statewide data (as displayed in the NJ COVID-19 Data Dashboard: https://www.nj.gov/health/cd/topics/covid2019_dashboard.shtml) demonstrates a downward or horizontal trajectory in the following:

i. Hospitalizations;

ii. Intensive Care Unit (ICU)/Critical Care utilization;

iii. Medical Surgical bed utilization; and

iv. Ventilator utilization.

iii. Standards to Guide Prioritization Decisions

a. Ambulatory surgery centers are encouraged to gradually resume full scope of services when possible and safe to do so, based on the following guidelines:

i. Before services resume, the physical layout and flow of care delivery areas shall be configured so that social distancing is maintained.

b. There shall be a process for determining the priority of types of services delivered that shall incorporate care prioritization and scheduling.

c. Facilities shall establish a prioritization policy for providing care and scheduling. All cases shall be reviewed by a site-based governance group to ensure consistency. The governance group:

i. Shall develop and review prioritization of surgical and procedural care for essential cases;

ii. Model capacity based on extended turnover and spacing out of procedures and any pre-/post-procedure appointments; and

iii. May consider the following:

1) Prioritizing previously cancelled and/or postponed cases;

2) Specialties' prioritization;

3) Strategy for allotting daytime "OR/procedural time";

4) Identification of essential healthcare professionals and medical device representatives when necessary for procedures;

5) Strategy for increasing "OR/procedural time" availability (e.g., extended hours or weekends); and

6) Issues associated with increased OR/procedural volume:

a. Ensure primary personnel/service availability (e.g., surgery, anesthesia, nursing, housekeeping, engineering, sterile processing, etc.);

b. Ensure adjunct personnel/contracted services availability (e.g., pathology, radiology, etc.);

c. Ensure supply availability for planned procedures (e.g., anesthesia drugs, procedure-related medications, sutures, disposable and nondisposable surgical instruments); and

d. New staff training.

iv. PPE, Staffing, and Transfer Requirements for Facilities that Resume these Procedures

a. Personal Protective Equipment (PPE) is essential to protect healthcare workers and patients. Therefore, the following shall be followed when resuming services:

i. Facilities shall have a plan, consistent with CDC and DOH recommendations, for patient and patient support person use of PPE;

ii. Healthcare workers must wear appropriate PPE consistent with CDC and DOH recommendations;

1) Universal masking is required for all employees in the facility;

iii. Healthcare workers treating COVID-19 positive and presumptive positive patients must have appropriate training on, and access to, appropriate PPE;

iv. COVID-19 PPE policies and procedures shall be in place for healthcare workers who are not in direct patient care roles (i.e. front desk registration, schedulers, environmental cleaning people, etc.); and

v. Facilities should implement policies for PPE that account for:

1) Adequacy of available PPE supply, with a minimum seven (7) day supply on hand;

2) Staff training on and optimized use of PPE according to non-crisis standards of care; and

3) Policies for the conservation of PPE must be developed as well as policies for any extended use or reuse of PPE per CDC and DOH recommendations and FDA emergency use authorizations.

b. Staffing
Ambulatory surgery centers must:

i. Possess trained and educated staff appropriate for the planned surgical procedures, patient population and facility resources;

ii. Use available testing to protect staff and patient safety whenever possible and implement guidance addressing requirements and frequency for patient and staff testing; and

iii. Have available qualified staff to safely perform procedures, provide care and provide any needed follow up.

c. Disinfection Protocols, Supplies and Equipment Maintenance
Facilities shall implement the following disinfection and cleaning protocols:

i. Confirm that cleaning and disinfecting supplies are COVID-19 compatible;

ii. Ensure adequate supply of hand sanitizer, tissues, and non-touch trash receptacles with disposable liners in all restrooms and patient areas;

iii. Ensure all equipment is up to date on preventative maintenance and tested before use/reopening;

iv. Check all supplies for expiration dates;

v. Take needed action such as removing magazines from waiting areas; and

vi. Confirm/update all preventive infection policies and procedures.

d. Transfer Agreements
In anticipation for a potential second wave of COVID-19, each ambulatory surgery center must confirm that it has a transfer agreement with an acute healthcare facility partner and confirm and document before each surgery day that its acute healthcare facility partner has appropriate number of intensive care unit (ICU) and non-ICU beds to support its potential need for emergent transfers, personal protective equipment (PPE), ventilators, medications, and trained staff to treat all patients.

Ambulatory surgery centers that have a transfer agreement with more than one hospital must confirm that at least one hospital is available.

e. Staff COVID-19 Screening

Staff shall be screened per Centers for Medicare & Medicaid Services recommendations in the document available at https://www.cms.gov/files/document/covid-flexibility-reopen-essential-non-covid-services.pdf.

v. Cohorting COVID-19 and Non-COVID-19 Patients

Ambulatory surgical centers shall not perform procedures on COVID-19 positive patients, unless excepted in Executive Order 109 as an urgent case and nothing in this directive shall be construed to limit access to the full range of family planning services and procedures, including terminations of pregnancies, whether in a hospital, ambulatory surgery center, physician office, or other location. Facilities shall cohort COVID-19 patients and non-COVID-19 patients.

vi. Requirements that Patients Seeking these Procedures Must Undergo Testing, Self-Quarantine, and Other Preventive Measures

a. Scheduling must be coordinated to promote social distancing:

i. Minimize time in waiting area;

ii. Stagger appointment hours; and

iii. Post signs at entrances in appropriate language(s) for signs/symptoms of illness, fever and precautions.

b. Testing

i. Facilities must ensure that each patient has been tested (specimen collected and result received) within a six-day maximum before a scheduled procedure. If a negative test result is not received by the facility by day six, after collection, then the facility has the following options:

1) To reschedule the procedure until after the test results are received as long as the patient continues to follow the requirements of **f.** below while awaiting the test results; or

2) To proceed with the procedure as scheduled, provided the decision to proceed with the procedure as scheduled without a test result is based on a clinical assessment performed by a physician prior to surgery evaluating the risk involved if the patient is COVID positive during the procedure.

The physician performing the assessment must note the rationale why awaiting the testing result is not necessary and it is appropriate to move forward with the procedure in the patient's medical record.

a) The facility shall follow the infection control requirements in **h.ii.** below when performing a procedure in these circumstances.

c. Any specimen collection method (e.g. swab or saliva) is acceptable. The test performed by the laboratory must be a molecular test (such as PCR). All tests shall be either approved by the U.S. Food and Drug Administration (FDA), authorized by the FDA through an Emergency Use Authorization EUA), and/or approved by the New Jersey Clinical Laboratory Improvement Services as permitted by the FDA.

i. Antigen tests may not be used to fulfill the reuirements of this directive.

ii. Antibody tests, which determine whether or not antibodies (IgG, IgA, IgM, etc.) to Sars-CoV-2 are present, may not be used to fulfill the requirements of this Directive.

iii. Point of care (POC) molecular tests, which can be performed in medical office settings among other sites, are acceptable only if they are capable of providing a negative result. Some POC molecular tests return only presumptive negative results which must be confirmed as true negatives using a second method

d. Retesting a patient who has tested positive in the last six weeks is not required or routinely recommended if the patient remains asymptomatic and has completed appropriate isolation as defined at https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html and https://www.cdc.gov/coronavirus/2019-ncov/community/strategy-discontinue-isolation.html Such testing should be performed if a clinician has the reasonable suspicion that the patient may be infectious for COVID-19.

e. It is recommended that facilities contract with a laboratory and that the contract includes prioritization of testing to ensure that results are received in a timely manner and no later than 6 days from specimen collection.

i. Further information about testing can be found at https://www.nj.gov/health/cd/topics/covid2019_healthcare.shtml, including NJDOH COVID-19 Testing Guidance and 4-28-29 letter from the NJDOH Public Health and Environmental Laboratories.

f. Facilities shall counsel patients that the following is required for the patient's procedure to be performed as scheduled:

   i. Self-quarantine in their residence or other location following testing and up until the day of surgery is necessary;

   ii. Within the location of self-quarantine, social distancing is necessary and wearing a mask is necessary when social distancing is not possible;

   iii. Immediately inform the facility if there is any close contact with a suspected or confirmed case of COVID-19;

   iv. Immediately inform the facility if there is any close contact with a person with symptoms consistent with COVID-19; and

   v. Immediately inform the facility if the patient develops any symptoms consistent with COVID-19 during the time between when the COVID-19 test was collected and when the procedure is performed.

g. Facilities must have a process:

   i. To screen patients for symptoms of COVID-19 or Influenza-Like Illness (ILI) prior to scheduled procedures; and

   ii. To ensure that the patient has worn a mask, has self-quarantined and social distanced since testing.

h. Consistent with the Standards set in EO 109, time-sensitive procedures that would endanger the health of the patient if delayed may be performed on a patient without a current test result so long as:

   i. The physician documents that the patient's health will be endangered if the procedure is delayed; and

   ii. The following infection control protocols are followed:

      1) All persons should refrain from entering the vacated procedure room until sufficient time has elapsed for enough air exchanges to remove potentially infectious particles (more information on clearance rates under differing ventilation conditions is available at https://www.cdc.gov/infectioncontrol/guidelines/environmental/appendix/air.html#tableb1). The time to enter the room depends on the procedure that was performed, the type of PPE the staff entering the room is wearing,

and the exchange rate of the room. For aerosol generating procedures, follow CDC guidelines for aerosol generating procedures including administrative and engineering controls, and use of appropriate PPE. https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-faq.html#surgical; and

2) After the time for air exchanges in 1 above has elapsed, the room should undergo appropriate cleaning and surface disinfection before it is returned to routine use. If air exchange information is not currently available, the surgery center should refer to policies and procedures established for care of an active tuberculosis patient.

vii. Support Persons for Patients Undergoing Same-Day Surgery or Procedures

a. **Support persons will be allowed, as permitted below or in waivers from DOH available at** https://nj.gov/health/legal/covid19/:

i. Pediatric patients may have at least one parent or guardian;

ii. Patients undergoing same-day surgery or procedure may be accompanied to the facility by a companion and that companion may remain with the patient through the initial intake process, and may rejoin the patient for discharge;

iii. Support person(s) may not be present during procedures or in the recovery room **except for pediatrics, childbirth, and patients with an intellectual, developmental, or other cognitive disability requiring support; and**

iv. Support person(s), parents or guardians must be screened for symptoms of COVID-19 and must be asymptomatic at the time of the procedure.

viii. Policies Surrounding Visitors

a. Ambulatory Surgical Centers must continue to prioritize the safety and well-being of patients, patient support persons, and staff.

b. Until further notice visitors are not allowed in an ambulatory surgical center.

ix. Policies Surrounding Discharge of Patients After the Procedures are Completed
Ambulatory surgical center discharge policies are not changed.

x. Reporting Metrics Regarding the Resumption of these Procedures

To ensure the ability of health systems and hospitals to surge during a potential second wave of COVID-19, facilities must:

a. Comply with Governor Murphy's Executive Order No. 111 (2020) concerning reporting of data, including PPE inventory on a weekly basis. The portal designated by the New Jersey Office of Emergency Management under Executive Order No. 111 (2020) is maintained by the New Jersey Hospital Association and is accessible here: https://report.covid19.nj.gov/ ; and

b. Report data associated with this Executive Directive through the same NJHA portal (https://report.covid19.nj.gov/).

xi. Appendix - Key Resources, Recommendations and Guidance Documents

a. The latest DOH Executive Directives and Waivers: https://nj.gov/health/legal/covid19/ and guidance: https://www.nj.gov/health/cd/topics/covid2019_healthcare.shtml.

b. The latest guidance from the Centers for Disease Control and Prevention (CDC): https://www.cdc.gov/coronavirus/2019-ncov/communication/guidance-list.html.

Planning:

c. CDC Guidance for U.S. Healthcare Facilities about Coronavirus (COVID-19) by Facility Type: https://www.cdc.gov/coronavirus/2019-ncov/hcp/us-healthcare-facilities.html.

d. CDC Preparedness Tools for Healthcare Professionals and Facilities Responding to COVID-19: https://www.cdc.gov/coronavirus/2019-ncov/hcp/preparedness-checklists.html.

Infection Prevention and Control:

e. CDC Information for Healthcare Professionals about Coronavirus (COVID-19): https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html.

f. CDC Guidance for Cleaning and Disinfecting: https://www.cdc.gov/coronavirus/2019-ncov/community/clean-disinfect/index.html.

PPE:

g. DOH Infection Prevention & Control Resources for COVID-19: https://www.nj.gov/health/cd/documents/topics/NCOV/COVID19_Infection_Prevention_and_Control_Resources.pdf.

Staffing:

h. DOH Guidance for COVID-19 Diagnosed and/or Exposed Healthcare Personnel: https://www.nj.gov/health/cd/documents/topics/NCOV/Guidance_for_COVID19_Diagnosed_andor_Exposed_HCP.pdf

i. DOH Protocols for Essential Personnel to Return to Work: https://www.nj.gov/health/cd/documents/topics/NCOV/COVID_essential_personnel_return_to_work.pdf.

Pre-Procedure Testing:

j. DOH Laboratory Testing Information and Guidance: https://www.nj.gov/health/cd/topics/covid2019_healthcare.shtml#6.

k. Regarding insurance coverage and billing for testing:
   i. Community-based and local testing locations: https://covid19.nj.gov/faqs/nj-information/general-public/where-and-how-do-i-get-tested-for-covid-19-in-new-jersey-who-should-get-testing.

   ii. Information on insurance enrollment: https://nj.gov/governor/getcoverednj/ and information for the uninsured or undocumented residents: https://nj.gov/health/cd/documents/topics/NCOV/COVID-19_Resources_forUndocumented_and_UninsuredFactsheet.pdf.

This Directive shall take effect immediately. The provisions of this Directive shall remain in force and effect for the duration of the public health emergency originally declared in Executive Order No. 103 (2020), and as extended by Executive Order, unless otherwise modified, supplemented and/or rescinded.

Judith M. Persichilli

Dated: July 29, 2020

Judith Persichilli, RN, BSN, MA
Commissioner