EXECUTIVE DIRECTIVE NO. 20-016 (REVISED)

COVID-19 PROTOCOLS FOR AMBULATORY SURGERY CENTERS RESUMING ELECTIVE SURGERY AND INVASIVE DIAGNOSTIC PROCEDURES

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 and Prevention (CDC) 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 multiple times by Governor Murphy pursuant to various Executive Orders over the following fifteen months; and

WHEREAS, on June 4, 2021, Governor Murphy signed Assembly Bill No. 5820 into law as P.L.2021, c.103 and issued Executive Order No. 244, which among other things, resulted in the termination of the Public Health Emergency declared in Executive Order No. 103 (2020) but maintained the State of Emergency declared in that same Order; and

WHEREAS, despite the continuation of the State of Emergency, P.L.2021, C.103 requires that, following the termination of the Public Health Emergency originally declared under Executive Order No. 103 (2020), any administrative order, directive, or waiver issued by the head of a State agency that relied on the existence of the Public Health Emergency shall expire on January 11, 2022, but may be continued and modified unless explicitly revoked until January 11, 2022; and

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WHEREAS, by its own terms, P.L.2021, c.103 does not diminish, limit, or impair the powers of any head of a State agency pursuant to the provisions of the Civilian Defense and Disaster Control Act; 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

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 2020. 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; and

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/hcp/disposition-hospitalized-patients.html; and

WHEREAS, COVID-19 cases have been on the decline and as of May 15, 2021 and the statewide COVID-19 Activity Level Index (CALI) score is two (2), meaning moderate or low COVID-19 activity in most of the state: https://www.nj.gov/health/cd/documents/topics/NCOV/COVID_19_Report_Week_2021_19.pdf; and

WHEREAS, hospitalizations and ventilator use have also been on the decline; and

WHEREAS, the State of New Jersey has lifted the majority of remaining COVID-19 restrictions over the last few months, with limited protocols remaining in effect in certain higher risk settings; and
WHEREAS, because of the significant improvement in critical COVID-19 metrics and the progress of the State’s vaccination program, it is appropriate at this time to amend the restrictions placed on ambulatory surgery centers; and

WHEREAS, P.L.2021, c.104 permits such amendments, even though the Public Health Emergency has been terminated.

NOW, THEREFORE, I, JUDITH PERSICHILLI, Commissioner of the Department of Health, 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, Centers for Medicare and Medicaid Services (CMS) and CDC guidelines to protect against further spread of COVID-19;

   b. Institute screening of all healthcare personnel (HCP) for symptoms of COVID-19 and have policies in place for removal of symptomatic employees from the workplace, regardless of COVID-19 vaccination status;

   c. Enforce physical distancing and use of well-fitting source control (e.g., well-fitting facemasks) requirements in work areas and common areas following CDC and NJDOH guidelines, whenever practicable;

   d. Require use of well-fitting source control for all healthcare personnel (HCP) and patients regardless of COVID-19 vaccination status, except patients receiving services that prevent the use of a mask or are unable to wear a mask in accordance with CDC guidance: [https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover-guidance.html](https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover-guidance.html);

   e. Continue to maintain an established plan for cleaning and disinfecting the facility, including equipment and high touch surfaces prior to use and in between patients; and

   f. Continue to monitor community surge status and be prepared to modify clinical services as appropriate.


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

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

   i. The physical layout and flow of care delivery areas must be configured so that physical distancing is maintained as per CDC and NJDOH guidelines.

iii. PPE, Staffing, and other 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 NJDOH recommendations for patient and patient support person use of PPE.

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

      1) Universal source control is required for all employees in the facility, regardless of COVID-19 vaccination status.

   iii. Healthcare workers treating COVID-19 positive and presumptive positive patients and patients under investigation must have competency-based training for utilization of, 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 workers, etc.).

   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) Competency-based staff training on PPE and optimized use of PPE according to non-crisis standards of care.

      3) Policies for the conservation of PPE and surge capacity must be developed and include provisions for any extended use or reuse as well as policies for any extended use or reuse of PPE per CDC and FDA emergency use authorizations (EUAs).
b. Staffing

Ambulatory surgery centers must:

i. Be staffed with employees who are trained and educated appropriate to planned surgical procedures, patient population and facility resources.

ii. Implement guidance which addresses the requirements for and frequency of patient and staff testing. Available testing must be utilized as needed to ensure patient and staff safety.

iii. Provide qualified staff that are readily available to safely perform procedures, provide care to patients and provide follow up to patients as needed.

c. Disinfection Protocols, Supplies and Equipment Maintenance

Facilities shall implement the following disinfection and cleaning protocols:

i. Confirm that cleaning and disinfecting supplies are EPA approved SARS-CoV-2 surface disinfectant products (https://www.epa.gov/coronavirus/about-list-n-disinfectants-coronavirus-covid-19-0).

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. Check all supplies for expiration dates.

iv. Take needed action such as removing magazines from waiting areas.

v. Confirm/update all preventive infection prevention and control policies and procedures in compliance with current CDC guidelines and NJDOH requirements.

d. Staff COVID-19 Screening


ii. Institute screening of all healthcare personnel (HCP) for symptoms of COVID-19 and have policies in place for removal of symptomatic employees from the workplace, regardless of COVID-19 vaccination status.
1) Institute screening of healthcare staff for higher-risk exposure to SARS-CoV-2 and have policies in place for removal or exclusion from the workplace. Refer to NJDOH Guidance for COVID-19 Diagnosed and/or Exposed Healthcare Personnel at: https://www.nj.gov/health/cd/documents/topics/NCOV/Guidance_for_COVID-19_Diagnosed_andor_Exposed_HCP.pdf.

2) Urge all staff and providers in the facility to get vaccinated against COVID-19 as soon as they can, please visit: https://covid19.nj.gov/pages/vaccine for vaccination locations.

iv. **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.

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

a. Scheduling must be coordinated to promote physical distancing:

i. Minimize time in waiting area and organize chairs and furniture in a manner to accommodate current physical distancing recommendations.

ii. Signage which addresses hand hygiene, respiratory hygiene, cough etiquette and to immediately report signs/symptoms of illness, or fever to staff must be posted in language(s) appropriate to those served at all entrances and in waiting areas.

b. Testing

i. Patients are exempt from pre-procedural COVID-19 testing and self-quarantine if the patient:

1) Provides proof of full COVID-19 vaccination (2 weeks after their second dose in a 2-dose series or 2 weeks after a single-dose vaccine) and is currently asymptomatic. Facilities may keep a copy of the card or note vaccination status in the patient’s chart; or

2) Has tested positive for SARs-CoV-2 within the last 90 days and completed the appropriate isolation and is currently asymptomatic.
3) However, facilities may elect to use COVID-19 testing of these individuals as results might continue to be useful in some situations to inform the type of infection control precautions used (e.g., room assignment/cohorting, or PPE used). CDC guidance for testing vaccinated individuals can be found here: https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-after-vaccination.html#anchor_1619116637758.

ii. For patients who do not meet the testing requirement in section (b)(i.) above, the facility must ensure that each patient has been tested (specimen collected and negative result received) within a six-day maximum before a scheduled procedure. If a negative test result is not received by the facility before or on 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 in section (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-19 positive during the procedure. The physician performing the assessment must note the rationale why awaiting the test result is not necessary and it is appropriate to move forward with the procedure in the patient’s medical record. The facility shall follow the infection control requirements in section (e)(ii) below when performing a procedure in these circumstances.

iii. Any specimen collection method (e.g., swab or saliva) is acceptable. The test performed must be for viral detection, with a preference for nucleic acid amplification 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, or approved by the New Jersey Clinical Laboratory Improvement Services as permitted by the FDA.

iv. Further information about testing can be found in the letter below from the NJDOH Public Health Laboratories: https://www.nj.gov/health/cd/documents/topics/NCOV/COVID_SerologyLetter_PHEL.pdf

v. Antibody tests, which determine whether or not antibodies (IgG, IgA, IgM, etc.) to COVID-19 are present, may not be used to fulfill the requirements of this Directive.
vi. All facilities that perform COVID-19 point of care tests (such as antigen tests) in their facilities must possess a federal Clinical Laboratory Improvement Amendment (CLIA) Certificate. Additional information and application instructions for a CLIA Certificate can be found at: https://www.nj.gov/health/phel/clinical-lab-imp-services/federal_clia.shtml.

vii. Retesting a patient who has tested positive in the last three months 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/hcp/disposition-hospitalized-patients.html. Such testing should be performed if a clinician has the reasonable suspicion that the patient may be infectious for COVID-19.

viii. 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 six (6) days after specimen collection.

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

i. Unvaccinated or partially vaccinated patients need to 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, physical distancing is necessary and use of source control is necessary when physical 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.

d. Time-sensitive procedures that would endanger the health of the patient if delayed may be performed on a patient without a current test result, if:

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 air 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.

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

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

i. Pediatric patients may have both parents or guardians;

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 while following all recommended infection prevention and control requirements (e.g. well-fitting source control, physical distancing) regardless of COVID-19 vaccination status, 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, physical or other cognitive disability requiring support; and

iv. Support person(s), parents or guardians must be screened for exposure to and symptoms of COVID-19, must be asymptomatic at the time of the procedure, and must follow all recommended infection prevention and control requirements (e.g., well-fitting source control, physical distancing), regardless of COVID-19 vaccination status.
vi. **Policies Surrounding Visitors, Vendors, Consultants and Students**

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

   b. **Visitors with COVID-19 symptoms are not allowed in an ambulatory surgical center.** Visitors must be screened and encouraged to be vaccinated. All visitors must adhere to physical distancing and masking requirements. Please visit: [https://covid19.nj.gov/pages/vaccine](https://covid19.nj.gov/pages/vaccine) for information on how to receive a free COVID-19 vaccine.

vii. **Policies Surrounding Discharge of Patients After the Procedures are Completed**

   a. Ambulatory surgical center discharge policies are not changed.

viii. **Appendix - Key Resources, Recommendations and Guidance Documents**


Planning:


Infection Prevention and Control:


PPE:

Staffing:


Pre-Procedure Testing:


j. Regarding insurance coverage and billing for testing:


This Directive shall take effect immediately. The provisions of this Directive shall remain in force and effect pursuant to P.L.2021, C.104 until January 11, 2022, unless otherwise modified, supplemented and/or rescinded.

Dated: June 16, 2021

Judith M. Persichilli, RN, BSN, MA
Commissioner