

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF HEALTH CARE QUALITY

Statutory Authority: 16 Delaware Code, Section 1119C and 29 Delaware Code, Section 10119
(16 **Del.C.** §1119C & 29 **Del.C.** §10119)
16 **DE Admin. Code** 4409

EMERGENCY

EMERGENCY SECRETARY'S ORDER

Pursuant to 16 **Del.C.** §1119C and 29 **Del.C.** §10119

16 **DE Admin. Code** 4409 Prescribed Pediatric Extended Care Centers

4409 Prescribed Pediatric Extended Care Centers (PPECC)

AUTHORITY

Pursuant to 16 **Del.C.** §1119C and 29 **Del.C.** §10119, the Department of Health and Social Services ("Department") is adopting emergency regulatory amendments to 16 **DE Admin. Code** 4409 Prescribed Pediatric Extended Care Centers. Additionally, 29 **Del.C.** §10119 authorizes the Department to adopt emergency regulations where an agency determines that an imminent peril to the public health, safety or welfare requires the amendment of a regulation with less than the notice required by 29 **Del.C.** §10115. Moreover, 16 **Del.C.** §1119C authorizes the Department to adopt, amend, repeal, or issue regulations for prescribed pediatric extended care centers.

REASON FOR THE EMERGENCY ORDER

Rapid and widespread transmission of COVID-19 has significantly impacted many vulnerable individuals receiving healthcare services throughout the community.

While the availability of COVID-19 vaccines has helped to mitigate some of the risk, health and safety protocols must continue. To protect our most vulnerable citizens from COVID-19, a comprehensive infection control and prevention program based upon guidance from the Centers for Disease Control and Prevention and other nationally recognized sources is imperative to prevent or significantly decrease transmission of COVID-19 and other infections. Emergency regulations to require this infection prevention and control program were published in the July 2021 *Register* at 25 **DE Reg.** 33 (07/01/21).

In addition, prescribed pediatric extended care center staff must either provide evidence of COVID-19 vaccination, or undergo regular testing to prevent the transmission of COVID-19. While the state's requirements will offer employees the choice between getting vaccinated or getting tested, employers should encourage vaccination and federal guidance permits employers to require vaccinations. This emergency order adds language to the July amendment of Section 8.7.

EFFECTIVE DATE OF ORDER

It is hereby ordered, that 16 **DE Admin. Code** 4409 Prescribed Pediatric Extended Care Centers, specifically, Section 8.7 which expands the infection prevention and control program requirements, is temporarily modified as shown by underline as follows:

8.7 Infection Control

8.7.5 Specific Requirements for COVID-19

8.7.5.1 Before their start date, all new staff, vendors and volunteers must be tested for COVID-19 in accordance with Delaware Division of Public Health Guidance.

8.7.5.2 All staff, vendors and volunteers must be tested for COVID-19 in a manner consistent with Division of Public Health Guidance.

8.7.5.3 The facility must follow recommendations of the Centers for Disease Control and Prevention and the Division of Public Health regarding the provision of care or services to patients by staff, vendor or volunteer found to be positive for COVID-19 in an infectious stage.

8.7.6 The facility shall amend their policies and procedures to include:

8.7.6.1 Work exclusion and return to work protocols for staff tested positive for COVID-19.

8.7.6.2 Staff refusals to participate in COVID-19 testing;

8.7.6.3 Staff refusals to authorize release of testing results or vaccination status to the facility.

8.7.6.4 Procedures to obtain staff authorizations for release of laboratory test results to the facility to inform infection control and prevention strategies; and

8.7.6.5 Plans to address staffing shortages and facility demands should a COVID-19 outbreak occur.

This Emergency Order shall take effect on September 30, 2021 and shall remain in effect for 120 days. At the expiration of 120 days, the Department may choose to renew this Emergency Order once for a period not exceeding 60 days, consistent with 29 **Del.C.** §10119(3).

PETITION FOR RECOMMENDATIONS

The Department will receive, consider, and respond to petitions by any interested person for recommendations or revisions of this Order. Petitions should be presented to the Division of Health Care Quality, 3 Mill Road, Suite 308, Wilmington, DE 19806, by email to Kathryn.Evinger@Delaware.gov, or by fax to 302-421-7401.

ORDER

It is hereby ordered, this 10th day of September, 2021, that the above referenced amendment to 16 **DE Admin. Code** 4409 Prescribed Pediatric Extended Care Centers, a copy of which is hereby attached, is adopted, pursuant to 16 **Del.C.** §1119C and 29 **Del.C.** §10119, as referenced above, and supported by the evidence contained herein.

Molly K. Magarik, MS

Cabinet Secretary

4409 Prescribed Pediatric Extended Care Centers (PPECC)

1.0 Definitions

“Advisory Board” means a group of health care professionals and at least one consumer approved by the PPECC Medical and Nursing Directors to review PPECC policies and procedures related to licensure and certification requirements, and to provide consultation regarding operational and programmatic components of the PPECC.

“American Academy of Pediatrics Red Book” means the Report of the Committee on Infectious Diseases published by the American Academy of Pediatrics to provide guidelines for the effective control of infectious diseases of children.

“Child Life Specialist” means an individual with baccalaureate preparation in Child Life, Early Childhood Education, or a related field and at least 2 years current experience in planning and implementing developmental stimulation programs for children.

“Current Experience” means full-time employment experience during the two years immediately preceding employment or contract with a PPECC facility.

“Delacare” means Requirements for Day Care Center, State of Delaware, Department of Services for Children, Youth and Their Families, as authorized by 31 **Del.C.** Ch. 3, Section 2.

“Developmentalist” means a master's prepared individual with 3 years current experience in multi-disciplinary evaluation and treatment planning for children who are at risk for or experiencing developmental delay.

“Functional Assessment” means an evaluation of the child's abilities and needs related to self care, communication skills, social skills, motor skills, preacademic areas, play with toys/objects, growth and development appropriate for age.

“Medical Director” means a Board-certified pediatrician licensed in Delaware who serves as the liaison between the PPECC and the medical community, reviews the quality and appropriateness of PPECC services, and is available for consultation to the PPECC staff.

“Nursing Director” means a licensed registered nurse, in the State of Delaware responsible for providing continuous supervision of PPECC services and managing the daily operations of the facility.

“Occupational Therapist” means a licensed individual in the State of Delaware who is registered with the American Occupational Therapy Association with at least 2 years current experience in evaluation and treatment planning for children with neuromuscular and developmental needs.

“Prescribed Pediatric Extended Care Center (PPECC)” means out-patient health care service prescribed by a physician for children who are medically and/or technologically dependent. As part of the continuum of care for medically dependent children, the PPECC includes an array of services focused on meeting the physiological as well as developmental, physical, nutritional and social needs of the children served. Children are placed in a PPECC facility because their medical condition requires continuous therapeutic interventions. The PPECC provides a less-restrictive alternative to institutionalization and reduces the isolation which the home-bound, medically dependent child may experience.

“Protocol of Care” means the comprehensive plan for implementation of medical, nursing, psychosocial, developmental, and educational therapies to be provided by the PPECC. An individualized Protocol of Care will be developed upon admission and will be revised to include recommended changes in the therapeutic plans. The disposition to be followed in the event of emergency situations will be specified in the Protocol of Care.

“Psychiatrist” means a Board-certified psychiatrist licensed in the State of Delaware with experience in child psychiatry.

“Psychologist” means a licensed individual in the State of Delaware with doctoral preparation in child or developmental counseling psychology, or a related field, and at least 2 years current experience in evaluation and management of children.

“Physical Therapist” means a licensed individual in the state of Delaware who is a graduate of an American Physical Therapy Association approved program with at least 2 years current experience in evaluating and designing therapeutic programs for children with developmental disabilities.

“Primary physician” means the physician who signs the order admitting the child to the PPECC and who maintains overall responsibility for the child's medical management and is available for consultation and collaboration with the PPECC staff.

“Quality Assurance” means a mandatory program which all PPECC facilities must have to assure periodic review and determination of the quality and appropriateness of care rendered in the facility.

“Social Worker” means an individual licensed in the State of Delaware who has a Master's degree in social work with at least 2 years current experience in assessing, counseling and planning interventions for children and their families or guardians.

“Speech Pathologist” means a licensed individual in the State of Delaware who is certified by the American Speech, Hearing and Language Association with at least 2 years current experience in evaluating and treating children at risk for, or experiencing problems with, communication skills.

“Technologically Dependent Child” means a person from birth through 21 years of age who has a chronic disability which requires the routine use of a specific medical device to compensate for the loss of a life-sustaining body function and requires daily, ongoing care or monitoring by trained personnel.

2.0 Licensure Requirements

- 2.1 Separate licenses are required for centers maintained in separate locations, even though operated under the same management.
- 2.2 License is not transferable from person to person nor from one location to another.
- 2.3 License will be conspicuously posted.
- 2.4 All applications for renewal of licenses shall be filed with the Department of Health and Social Services at least thirty (30) days prior to expiration.
 - 2.4.1 Annual license. An annual license may be renewed yearly if the holder is in full compliance with this chapter and the rules and regulations of the Department of Health and Social Services.
 - 2.4.2 Provisional license. A provisional license shall be granted for a term of 90 days only and shall be granted only to a facility which, although not in full compliance, is nevertheless demonstrating evidence of improvement.
 - 2.4.3 Restricted license. A restricted license shall be granted for a term of 90 days when the facility is not in compliance with this chapter, and does not demonstrate evidence of improvement. The holder of a restricted license may not admit patients to the facility to which the restricted license applies during the period of restriction, but the facility may remain in operation until such license is revoked, expires, becomes annual or provisional.
 - 2.4.4 Fees. The application fee is \$100.00 and the annual license fee is \$50.00
- 2.5 No rules will be adopted by the licensee which are in conflict with these regulations.
- 2.6 The Department of Health and Social Services will be notified, in writing, of any changes in the Medical Director or Nursing Director.

- 2.7 Authorized staff from the Department of Health and Social Services and the Department of Services for Children, Youth and Their Families shall have access to facility, staff, children receiving services and client records.
- 2.8 The Department of Health and Social Services may revoke, suspend, deny, restrict or make provisional a license for reasons which include, but are not limited to:
- 2.8.1 Failure to comply with the provisions of 16 Del.C. 122 (q) and the Department's rules and regulations pertaining to the law; or
 - 2.8.2 Violation of the terms and conditions of a license; or
 - 2.8.3 Use of fraud or misrepresentation in obtaining a license or in the subsequent operation of the facility; or
 - 2.8.4 Refusal to furnish the Department with files, reports or records as required by the law; or
 - 2.8.5 Refusal to permit an authorized representative of the Department to gain admission to the Center during operating hours; or
 - 2.8.6 Any conduct or practice, engaged in or permitted, which adversely affects or presents a serious or imminent danger to the health, safety and wellbeing of any child attending the Center; or
 - 2.8.7 Any conduct or practice which is in violation of State law related to abuse or neglect of children.
- 2.9 Appeals
- 2.9.1 Any person or Center who has been denied a license or whose license has been revoked, suspended or restricted shall be notified in writing of the reason(s) for such a decision and setting forth the person's or Center's right to an appeal of the decision.
 - 2.9.2 Any person or Center who has been denied a license or whose license has been revoked, suspended or restricted by the Department of Health and Social Services, shall be entitled to a hearing and a review before the Department of Health and Social Services or its designee.
 - 2.9.3 The Department of Health and Social Services shall give ten (10) days notice specifying reasons for proposed revocation, suspension, restriction or denial before a revocation, suspension, restriction or denial occurs. If a request for a hearing, either written or verbal, is received within the ten-day period, a hearing shall be held within 30 days.
 - 2.9.4 The Department of Health and Social Services or its designee may change the status of a license to provisional without affording the licensee the benefit of a special hearing; however, the licensee shall be given an opportunity to address its licensure status at the next regularly scheduled meeting of the Department of Health and Social Services.
 - 2.9.5 If the health or safety of children in care is in serious or imminent danger, as determined by the Department of Health and Social Services or its designee in its sole discretion, the Department of Health and Social Services or its designee may immediately suspend or restrict the license upon the issuance of written notice. If there is an immediate suspension or restriction, a hearing shall be held within ten (10) days of the written notice to the Center.
- 2.10 Upon written request by a Center, the Department of Health and Social Services or its designee may grant a variance from a specific requirement if there is documentation that the requested alternative complies with the intent of the requirement for which variance is sought.
- 2.10.1 The decision of the Department of Health and Social Services, including any qualification under which the variance is granted, shall be documented through a written agreement with the Department of Health and Social Services and a signed copy shall be sent to the Center. A variance may remain in effect for as long as a Center continues to comply with the intent of the requirement(s) or may be timelimited.
 - 2.10.2 The agreement shall contain provisions for a regular review of the variance.

3.0 Administration

- 3.1 The administrative structure of the PPECC shall include a policy and procedure manual to assure that standards for licensure and certification are maintained.
- 3.2 All PPECCs must have the following documents on the premises and available to staff: American Academy of Pediatrics Red Book, Delacare Requirements for Day Care Centers, Approved Standards for Prescribed Pediatric Extended Care, Procedure Manual and a Personnel Manual.
- 3.3 Personnel policies and procedures shall include at least: a current personnel file; position descriptions; employee benefits; policies for overtime, compensatory time, performance evaluations, termination of employment; etc.
- 3.4 A formal orientation shall be required for all PPECC employees; staff development programs for all categories of personnel shall be held monthly and documented in the individual personnel file.

- 3.5 The facility shall be administered on a sound financial basis consistent with good business practice. There shall be financial records which identify all income by source and describe all expenditures by category in such a manner as to be auditable by commonly recognized procedures. Annual budget must be developed and available at the facility.
- 3.6 Each PPECC facility shall have an Advisory Board. Membership in the Advisory Board shall include, but not be limited to:
 - 3.6.1 Physician familiar with PPECC services;
 - 3.6.2 Registered nurse with special expertise in the care of medically/technologically dependent children;
 - 3.6.3 Developmentalist or child life specialist with expertise in the care of medically/technologically dependent children and their families;
 - 3.6.4 Social worker with expertise in the care of medically/technologically dependent children and their families;
 - 3.6.5 Consumer representative who may be a parent or guardian of a child placed in the PPECC;
 - 3.6.6 An independent or outside program professional.
- 3.7 Responsibilities of the Advisory Board shall include:
 - 3.7.1 Review of policy and procedure components of the PPECC to assure conformance with the standards for licensure and certification;
 - 3.7.2 Consultation regarding the operational and programmatic components of the PPECC.
- 3.8 Policies and Procedures pertaining to PPECC services shall be available and shall include the following.
 - 3.8.1 A procedure manual with specifications for each therapeutic intervention shall be available for use by all staff involved in the care of the children; the manual shall be reviewed every six months to assure that procedures conform to prevailing and acceptable treatment modalities.
 - 3.8.2 An admission and discharge register, listing children admitted by name with identifying information about each and the source from which the child was admitted, the reason for disposition, adequate identifying information and the place to which the individual is to be discharged.
 - 3.8.3 A daily census record.
 - 3.8.4 An accident and incident record.
 - 3.8.5 An individual record for each child. All details of the referral, admission, correspondence, and papers concerning each child shall also be maintained. A general fiscal record for each child, including copies of all agreements or contracts and account records. The record shall also include a protocol for care, physician's orders, progress notes, medications dispensed, medical history, including allergies, special precautions, and an immunization record. Record entries shall be in ink and signed by an RN or MD.
 - 3.8.6 Periodic review of each child's protocol of care to update the protocol in consultation with other professionals involved in the child's care. Changes in the orders must be documented and signed by the primary prescribing physician.
 - 3.8.7 Prior to a discharge, conferences involving PPECC staff, the primary physician, the parent(s) or guardians) and staff of other agencies involved in the child's care shall be held to discuss postdischarge care and follow-up.
 - 3.8.8 A discharge order written by the primary physician shall be documented and entered in the child's record. A discharge summary, which includes the reason for discharge, shall also be included in the record.
 - 3.8.9 Except in emergency situations, other agencies involved in the care of the child/family shall be notified prior to the discharge date.
- 3.9 The PPECC shall conform to the Patient Bill of Rights and a copy shall be posted in a conspicuous place.

4.0 Children's/Parents' Rights

- 4.1 Every child shall be treated with consideration, respect, and full recognition of his/her dignity and individuality.
- 4.2 Each child shall receive care, treatment and services which are adequate and appropriate for his/her therapeutic plan.
- 4.3 Parent(s) or legal guardian(s) shall, prior to or upon admission, and during the period of service to his/her child, receive a written statement of the services provided by the Center including those required to be offered on an "as needed" basis. They shall also receive a statement of related charges including any charges for services not covered under the facility's basic per diem rate.
- 4.4 Each child's medical care program shall be conducted discreetly and in accordance with the parent's/guardian's need for privacy. Personal and medical records shall be treated confidentially and shall not be made public without written consent of parent(s) or legal guardian(s).

- 4.5 Every child shall be free from mental and physical abuse and also chemical and physical restraints, unless authorized by a physician according to clear and indicated medical requirements.
- 4.6 Every parent or legal guardian has the right, personally or through others, to present grievances to local or state authorities without reprisal, interference, coercion or discrimination of the child as results of such grievance or suggestion.

5.0 Requirements for Designation as PPECC

- 5.1 All Prescribed Pediatric Extended Care Centers shall be equipped and staffed to accommodate no fewer than six (6) medically/technologically dependent children and shall meet standards established herein and shall meet or exceed the licensure requirements and standards for child care as specified in "Delacare Requirements for Day Care Centers". When there is a contradiction between the standards, the PPECC standards shall prevail.
- 5.2 All PPECC Centers shall have a minimum full-time equivalent staff of two (2) registered nurses and one (1) nursing assistant. Thereafter the ratio of staff to children shall be maintained at a ratio of one (1) FTE staff for every three (3) children or one that meets the individual medical needs of the client.

6.0 Criteria For Admission

- 6.1 Infants and children considered for admission to the PPECC facility shall be those with complex medical conditions requiring continual care, including, but not limited to, ventilator dependence, seizure disorders, chronic lung disorder, supplemental oxygen, I.V. therapy, malignancy, tracheotomy, heart disease, etc.
- 6.2 The primary physician, in consultation with the parent(s) or legal guardian(s), shall recommend placement in PPECC facility, taking into consideration medical, emotional, psychosocial and environmental factors.
- 6.3 The child must not present significant risk of infection to other children or personnel.
- 6.4 The child must be medically stabilized, require skilled nursing care, and/or other interventions, and be appropriate for out-patient care.
- 6.5 If the child meets the preceding criteria, the primary physician or his/her designee shall contact the medical and/or nursing director of the PPECC to schedule a preadmission conference.
 - 6.5.1 If the child is hospitalized at the time of referral pre-admission planning shall include relevant hospital, medical, nursing, social services and developmental staff in coordination with the nursing director of the PPECC to assure that the discharge plans shall be accommodated following placement in the PPECC.
 - 6.5.2 If the child is not hospitalized at the time of the referral, pre-admission planning shall be conducted with the referring physician, medical director, parent(s) or guardian(s), and representatives of other relevant agencies as determined by the primary physician and nursing director of the PPECC.
 - 6.5.3 Pre-admission planning must be, scheduled in a timely manner and allow sufficient time to assure that a written therapeutic plan shall be developed and implemented upon placement in the PPECC.
 - 6.5.4 The protocol for care shall be developed by the PPECC staff following pre-admission planning.
 - 6.5.5 The protocol for care shall include specifications of criteria for discharge from the PPECC.
 - 6.5.6 A PPECC consent form, outlining the purpose of a PPECC facility, family responsibilities, authorized treatment and appropriate liability releases, and emergency disposition plans shall be signed by the parent(s) or guardian(s). Confidentiality of PPECC records shall be maintained in accordance with Standards of Medical Practice active in the State of Delaware.

7.0 Admission Procedure

- 7.1 Infants and children shall be considered for admission to the PPECC facility if they have complex medical conditions such as seizure disorders, chronic lung disorder, malignancy and heart disease and/or complex medical conditions requiring continual care including, but not limited to, ventilator dependence, supplemental oxygen, I.V. therapy, tracheotomy, etc.
- 7.2 All children placed in the PPECC facility shall have documentation of a physician's written order placed in the child's medical record. A copy of the order shall be provided to the child's parent(s) or guardian(s).
- 7.3 The protocol for care shall be developed under the direction of the PPECC nursing director and shall specify the treatment plan needed to accommodate the medical, nursing, psychosocial and educational needs of the child and family. Specific goals for care shall be identified. Plans for achieving the goals shall be determined and a schedule for evaluation of progress shall be established. The protocol shall include specific discharge criteria.

- 7.4 The protocol shall be signed by the physician, the authorized representative(s) of the PPECC and the parent(s) or guardian(s). Copies of the protocol shall be given to the parent(s) or guardian(s), primary physician, PPECC staff, and other agencies as appropriate.

8.0 Services Available

8.1 Medical Services

- 8.1.1 Children shall be admitted to the PPECC upon prescription by the child's primary physician or by the medical director.
- 8.1.2 The child's primary physician shall maintain responsibility for the overall medical therapeutic plan and shall be available for consultation and collaboration with the PPECC medical and nursing directors.
- 8.1.3 Communication with the child's primary physician shall be provided by the nursing director or designee on a monthly or quarterly basis.
- 8.1.4 Prescribed therapies shall be adjusted, in consultation with the primary physician, to accommodate the child's condition.

8.2 Nursing Services

- 8.2.1 The PPECC nursing director shall participate in pre-admission planning along with other appropriate nursing staff.
- 8.2.2 Nursing personnel, under the direction of the nursing director, shall be responsible for implementing the nursing care.
- 8.2.3 Nursing personnel shall be responsible for monitoring and documenting the effects of prescribed therapies.
- 8.2.4 Nursing personnel shall participate in interdisciplinary staff meetings regarding the child's progress.
- 8.2.5 Nursing personnel shall be responsible for maintaining the child's record in accordance with facility policies and procedures.
- 8.2.6 Nursing personnel shall instruct the parent(s) or guardian(s) in how to provide the necessary therapies in the home.

8.3 Developmental Services

- 8.3.1 Each child shall have a functional assessment and an individualized program plan to include developmentally appropriate areas.
- 8.3.2 The child's program plan shall include specific programs and action steps to facilitate developmental progress and shall be reviewed at least quarterly.
- 8.3.3 The child's developmental and educational needs shall be incorporated into protocol for care.
- 8.3.4 The child's program plan shall include:
 - 8.3.4.1 Measurable goals in needs areas and/or goals to enhance and normalize independent functioning in daily activities and to promote socialization in order to minimize difficulties in being assimilated into the home/community environment;
 - 8.3.4.2 A description of the child's strengths and present performance level with respect to each goal;
 - 8.3.4.3 Skills areas in priority order;
 - 8.3.4.4 Anticipatory planning for specific areas identified as at-risk for problems even though a specific delay or problem may not yet be demonstrable.
- 8.3.5 The developmentalist and/or child life specialist shall participate in regularly scheduled interdisciplinary staff meetings.
- 8.3.6 A program for parent(s) or guardian(s) shall be provided to prepare parent(s) or guardian(s) to accommodate the child's needs.

- 8.4 The PPECC shall assist parent(s) or guardian(s) by including them in care-related conferences and teaching them how to perform necessary therapies and how to meet the developmental and psychosocial needs of their child at home.

- 8.5 PPECC staff shall make referrals to appropriate resources, facilitate access to community, social, educational and financial services, and shall provide assistance to enhance coping skills, interpersonal relationships and family functioning.

8.6 Nutrition Services

- 8.6.1 A dietitian/nutritionist shall be available for consultation regarding the nutritional needs and special diets of individual children.
- 8.6.2 All food and formula shall be provided by PPECC staff under the supervision of the nursing director.
- 8.6.3 Prepared foods shall be kept under refrigeration with identifying dates and the child's name.

8.7 Infection Control

- 8.7.1 PPECC shall have written policies and procedures for infection control in accordance with the Delacare Requirements for Day Care, and the needs of all children being treated.
- 8.7.2 The PPECC shall establish an infection prevention and control program which shall be based upon Centers for Disease Control and Prevention and other nationally recognized infection prevention and control guidelines.
 - 8.7.2.1 The infection prevention and control program must include all services and all areas of the PPECC, including provision of the appropriate personal protective equipment for all patients, staff, and visitors.
- 8.7.3 There needs to be an individual designated to lead the PPECC's infection prevention and control program, must develop and implement a comprehensive plan that includes actions to prevent, identify, and manage infections and communicable diseases. The plan must include mechanisms that result in immediate action to take preventive or corrective measures that improve the PPECC's infection control outcomes.
- 8.7.4 All PPECC staff shall receive orientation at the time of employment and annual in-service education regarding the infection prevention and control program.

8.7.5 Specific Requirements for COVID-19

- 8.7.5.1 Before their start date, all new staff, vendors and volunteers must be tested for COVID-19 in accordance with Delaware Division of Public Health Guidance.
 - 8.7.5.2 All staff, vendors and volunteers must be tested for COVID-19 in a manner consistent with Division of Public Health Guidance.
 - 8.7.5.3 The facility must follow recommendations of the Centers for Disease Control and Prevention and the Division of Public Health regarding the provision of care or services to patients by staff, vendor or volunteer found to be positive for COVID-19 in an infectious stage.
- 8.7.6 The facility shall amend their policies and procedures to include:
- 8.7.6.1 Work exclusion and return to work protocols for staff tested positive for COVID-19.
 - 8.7.6.2 Staff refusals to participate in COVID-19 testing;
 - 8.7.6.3 Staff refusals to authorize release of testing results or vaccination status to the facility.
 - 8.7.6.4 Procedures to obtain staff authorizations for release of laboratory test results to the facility to inform infection control and prevention strategies; and
 - 8.7.6.5 Plans to address staffing shortages and facility demands should a COVID-19 outbreak occur.

8.8 Transportation Services.

- 8.8.1 If transportation is provided by a PPECC and prescribed by the primary physician, a procedure delineating personnel and equipment to accompany the child shall be included in the PPECC procedure manual.

9.0 Quality Assurance

- 9.1 A Quality Assurance Committee shall be established and shall include a Board-certified pediatrician familiar with PPECC services, a registered nurse with special expertise in the care of medically/technologically dependent children, and one of the following: a developmentalist, child life specialist, or a social worker with expertise in the care of medically/technologically dependent children and their families.
- 9.2 All PPECCs shall have a quality assurance program and its QA Committee shall conduct quarterly reviews of the complete records for at least half of the children served by the PPECC at the time of the quality assurance review.
- 9.3 Each quarterly review shall include:
 - 9.3.1 A review of the goals in each child's protocol;
 - 9.3.2 A review of the steps, process, and success in achieving the goals;
 - 9.3.3 Identification of goals not being achieved as expected, reasons for lack of achievement and plans to promote goal achievement;
 - 9.3.4 Documentation of the results of the quality assurance review and records review.
 - 9.3.5 Within fifteen (15) working days of its review, the Quality Assurance Committee shall furnish copies of its report to the PPECC medical and nursing directors.
 - 9.3.6 Evidence that revisions have been made as recommended by the quality assurance report shall be forwarded to the Quality Assurance Committee within one week.
 - 9.3.7 Implementation of the revisions to the protocol shall be documented on the child's record.
 - 9.3.8 Maintenance of a high standard of patient care shall be evidenced by:
 - 9.3.8.1 Case record for each child containing:

- 9.3.8.1.1 Comprehensive protocol for care specifying the goals for care and methods for goal achieving and time frame for reviewing and revising the plan;
- 9.3.8.1.2 A properly executed consent form;
- 9.3.8.1.3 A medical history for the child including notations from visits to health care providers and copy of a recent physical exam (updated annually);
- 9.3.8.1.4 Immunization record, documentation of allergies and special precautions;
- 9.3.8.1.5 Physician orders, properly signed;
- 9.3.8.1.6 Flow chart of treatment administered;
- 9.3.8.1.7 Concise, accurate information and initialed case notes reflecting progress toward protocol goal achievement or reasons for lack of progress;
- 9.3.8.1.8 Documentation of nutritional management and special diets, as appropriate;
- 9.3.8.1.9 Documentation of physical, occupational, speech and/or other special therapies.
- 9.3.8.2 Evidence of parent(s) or guardian(s) involvement including:
 - 9.3.8.2.1 Pre-admission planning to develop a protocol for care to be rendered in the PPECC;
 - 9.3.8.2.2 Interdisciplinary staffing conferences shall be scheduled on monthly or as necessary basis;
 - 9.3.8.2.3 parent(s) or guardian(s) training and education, including:
 - 9.3.8.2.3.1 Clearly written, practical and appropriately targeted training materials;
 - 9.3.8.2.3.2 Scheduled individual and/or group education sessions for parent(s) or guardian (s) and other family members.
 - 9.3.8.2.3.3 Evidence of formal discharge procedure, including:
 - 9.3.8.2.3.3.1 Documentation that placement in the PPECC is no longer appropriate for the child;
 - 9.3.8.2.3.3.2 Physician's discharge order;
 - 9.3.8.2.3.3.3 Notification of anticipated discharge to the other agencies involved in the child's care;
 - 9.3.8.2.3.3.4 Evidence of a pre-discharge conference involving the parent(s) or guardian(s), representatives of the PPECC professional staff and agencies involved in child care after discharge.
 - 9.3.8.2.3.3.5 A written discharge summary signed by the primary physician and nursing director of the PPECC must be prepared within 1 week of the child's discharge.
 - 9.3.8.2.4 Evidence of the disposition procedure to be followed in the event of an emergency medical situation.

10.0 In-Service Training for Staff/Parent(s) and Guardian(s)

- 10.1 Monthly staff development programs appropriate to the category of personnel shall be conducted to maintain quality patient care.
- 10.2 All staff development programs shall be documented.
- 10.3 All personnel shall be required to maintain certification in basic life support.
- 10.4 Each new employee shall participate in orientation to acquaint the employees with the philosophy, organization, program, practices, and goals of the PPECC facility.
- 10.5 A comprehensive orientation to acquaint the parent(s) and/or guardian(s) with the philosophy and services shall be provided at the time of child's placement in the PPECC.
- 10.6 Staff development programs shall be provided to:
 - 10.6.1 Facilitate the ability of the staff to function as a member of an interdisciplinary team which includes health professionals and the parent(s) and/or guardian(s);
 - 10.6.2 Improve communication skills to facilitate a collaborative relationship between parent (s) and/or guardians and professionals;
 - 10.6.3 Increase understanding the effects childhood illness has on the child's development and the parent(s) and/or guardian(s);
 - 10.6.4 Increase understanding and coping with the effects of childhood illnesses and shall cover a variety of topics including: issues of death and dying; awareness of services available at the hospital, school, community, state, and professional organizations; and fostering of advocacy skills;
 - 10.6.5 Develop case management skills to assist the family in setting priorities and planning and implementing the child's care at home;

- 10.6.6 Provide training in the implementation of new technology;
- 10.6.7 Develop a comprehensive Protocol for Care to include the medical, nutritional, developmental and psychosocial needs of medically/technologically dependent children;
- 10.6.8 Prepare for management of emergency medical situations in a PPECC setting.

11.0 Medications

- 11.1 All medications administered to children shall be ordered, in writing, by a physician.
- 11.2 All medications shall be stored in a locked cabinet, located in or convenient to the nurse's station/center.
- 11.3 Internal medications shall be stored separately from external medications.
- 11.4 Schedule II substances shall be kept in separately locked, securely fixed boxes or drawers in the locked medication cabinet; hence, under two (2) locks.
- 11.5 Medications requiring refrigeration shall be kept in a separate locked box within the refrigerator and separate from foods.
- 11.6 Barrel, plunger and needle of disposable hypodermic syringes must be rendered useless, immediately after use and then properly discarded.
- 11.7 Administrator/director shall notify the office of Narcotics and Dangerous Drugs, Division of Public Health, of any theft or unexplained loss of any controlled substances, syringes, or needles or prescription pads within 48 hours of discovery of such loss or theft.
- 11.8 Emergency Crash Cart equipped as per acceptable medical standards.

12.0 Facility

- 12.1 The PPECC shall conform with or exceed the minimum standards for physical facilities specified in Delacare Requirements For Day Care Centers. Where there is a contradiction between the PPECC standards and the child care standards, the PPECC standards shall prevail. All facilities licensed as PPECCs must be able to accommodate no fewer than six medically/technologically dependent children.
- 12.2 Specifications for a PPECC facility shall include:
 - 12.2.1 Location shall be central to major thoroughfares and public transportation. Emergency transportation to hospital (with pediatric unit) can be achieved in ten minutes or less.
 - 12.2.2 Entrance shall be barrier free, have a wheelchair ramp, provide for traffic flow with driveway area for entering and exiting, and have storage for supplies from home;
 - 12.2.3 Adequate parking for staff and families to comply with applicable state laws.
- 12.3 The building specifications shall be in accordance with Delacare requirements.
- 12.4 All rooms and every part of the building shall be kept clean, orderly, and free of offensive odors.

13.0 Equipment As per Delacare Requirements for Day Care Centers

- 13.1 Fire Safety
 - 13.1.1 Fire extinguishers and smoke detectors;
 - 13.1.2 Emergency generator (portable).
- 13.2 Nursing Equipment and Supplies - There shall be sufficient equipment and supplies for nursing care to meet the needs of each patient. It shall be the responsibility of the administrator/ director to obtain specific items required for individual cases when so requested by the physician. The following items should be available as needed:
 - 13.2.1 Nebulizers/Vaporizers - cool mist type - one at bedside of each child with a respiratory diagnosis as prescribed;
 - 13.2.2 Mist tents - one per child with respiratory diagnosis as prescribed;
 - 13.2.3 Mechanical percussors and hand percussors as prescribed;
 - 13.2.4 Basic emergency equipment according to recommendations of the Medical Director, advisory board and primary physicians for individual children. Minimal emergency equipment to be available in a PPECC is listed in Emergency Equipment, **Section K**;
 - 13.2.5 oxygen - in two portable tanks with appropriate tubing, pediatric ambu bag and masks for faces and tracheotomies;
 - 13.2.6 Oxygen concentrators - for children on continuous O₂ therapy;
 - 13.2.7 Ventilator with provision for mixing of gases to provide prescribed oxygen concentration as specifically prescribed shall be available as a back-up unit when a ventilator-dependent child is in the facility;

13.2.8 Electronic thermometers - no glass thermometers;

13.2.9 Sphygmomanometers, stethoscopes, otoscopes;

13.2.10 Apnea monitoring supplies - i.e., belts, leads to apply to monitors from home;

13.2.11 Supplies of disposable equipment shall be on hand at the facility but not routinely provided if the family obtains supplies elsewhere. Disposable equipment/ supplies shall include suction catheters, gastrostomy tubes, nasogastric tubes, foley catheters, dressing supplies, syringes, needles.

13.2.12 All medical equipment will be safely stored when not in use.

14.0 Severability

Should any section, sentence, clause or phrase of these regulations be legally declared unconstitutional or invalid for any reasons, the remainder of said regulations -shall not be affected thereby.

25 DE Reg. 352 (10/01/21) (Emer.)