

RULE ADOPTIONS

HEALTH AND SENIOR SERVICES

SENIOR SERVICES AND HEALTH SYSTEMS BRANCH

DIVISION OF HEALTH FACILITIES EVALUATION AND LICENSING

OFFICE OF CERTIFICATE OF NEED AND HEALTHCARE FACILITY LICENSURE

Adopted Amendments: *N.J.A.C. 8:43E-10.2* and *8:43F*

Adopted Repeal: *N.J.A.C. 8:43F-19*

Adopted New Rules: *N.J.A.C. 8:43J*

General Licensure Procedures and Standards Applicable to All Licensed

Facilities: Patient or Resident Safety Requirements and Reportable Events:

Scope

Standards for Licensure of Adult and Pediatric Day Health Services Facilities

Standards for Licensure of Pediatric Medical Day Care Facilities

**Statewide Respite Care Program: Sponsors and Providers: Qualifications and
Requirements for Provider Agencies**

Proposed: November 3, 2008 at *40 N.J.R. 6266(a)*.

Adopted: October 20, 2009 by Heather Howard, Commissioner, Department of
Health and Senior Services.

Filed: October 21, 2009 as R.2009 d.345, **with substantive and technical changes**
not requiring additional public notice and comment (see *N.J.A.C. 1:30-6.3*),
with proposed *N.J.A.C. 8:82-5.2* not adopted.

Authority: *N.J.S.A. 26:2H-1* et seq.

Effective Date: November 16, 2009.

Operative Date: April 1, 2010.

Expiration Dates: August 18, 2011, *N.J.A.C. 8:43E*;
March 19, 2012, *N.J.A.C. 8:43F*; and
November 16, 2014, *N.J.A.C. 8:43J*.

Summary of Public Comments and Agency Responses:

The Department of Health and Senior Services (Department) received
comments from the following:

1. Lauren Agoratus, M.A., NJ Coordinator, Family Voices at the Statewide Parent Advocacy Network, Newark, NJ
2. Michelle Bunting, President, Horizon Pediatric Systems, Inc., Bordentown, NJ
3. Amanda Curchin, LSW, Administrator, The Pediatric Day Health Center at Manchester, Manchester, NJ
4. Edward Curtin, R.Ph., CCP, Senior Account Executive, Pharma-Care, Inc., Clark, NJ
5. Karen DeWitt, Ed.D, CNAA, Vice President, Patient Care, Children's Specialized Hospital, New Brunswick, NJ
6. Susan E. Dignan, General Counsel, Peditria HealthCare, LLC, Norcross, GA
7. Theresa Edelstein, MPH, LNHA, Vice President, Continuing Care Services, New Jersey Hospital Association (NJHA), Princeton, NJ, on behalf of the following NJHA Pediatric Medical Day Center Members: Weisman Children's' Rehabilitation Hospital, Weisman Children's Medical Day Care Center at Marlton, Weisman Children's Medical Day Care Center at Pennsauken, Weisman Children's Medical Day Care Center at Atlantic City, Voorhees Pediatric Facility, Voorhees Pediatric Medical Day Care, NuVision Management Company, Children's Specialized Hospital, Children's Specialized Hospital--Pediatric Medical Day Care, Pediatric Day Health Center at Galloway, The Millhouse Pediatric Day Health Service Program, the Pediatric Day Health Center at the Millhouse II, and the Pediatric Day Health Center at Manchester
8. William Gill, RN, BSN, Administrator, The Pediatric Day Health Center at the Millhouse II, Trenton, NJ
9. John W. Indyk, Director of Governmental Affairs, Healthcare Association of New Jersey, Hamilton, NJ
10. Steven Kairys, MD, MPH, Chairman of Pediatrics, K. Hovnanian Children's Hospital, Neptune, NJ
11. Jacqueline Kreydt, CTRS, Wilmington, DE

12. Amy Long, President, New Jersey/Eastern Pennsylvania Therapeutic Recreation Association, Schnecksville, PA

13. Marilyn McGuinness, R.N., B.S.N., Administrator, Anna's Angels Pediatric Medical Daycare, Gloucester City, NJ

14. Michael A. Norwick, Esq., Lowenstein Sandler PC, Roseland, NJ

15. Lana Nugent, BSN, Administrator, Pediatric Day Health Center at Galloway, Galloway, NJ

16. Mary O'Rourke, RN, BSN, Administrator, The Pediatric Day Health Center at the Millhouse, Trenton, NJ

17. Leeanna Roman, President, Providence Pediatric Medical DayCare, Inc., West Berlin, NJ

18. Richard W. Shepherd, Administrator, Weisman Children's Rehabilitation Hospital, Marlton, NJ

19. Angela Vauter, Ed.D., CTRS, Associate Professor, East Stroudsburg University, East Stroudsburg, PA

The number in parentheses following each comment, below, corresponds to the commenter number, above.

1. COMMENT: A commenter states, "Asthma is a large issue for New Jersey's Children and an especially large issue in Trenton. Three times as many children are seen in emergency rooms and hospitalized for asthma in Trenton compared to the rest of Mercer County."

The commenter further states, "there is real importance to medical day care able to manage and support children with a chronic disease not ill enough for hospitalization but too symptomatic for regular day care. A medical day care provides support for the child and the family and hopefully is one more tool available in the community to improve health outcomes."

The commenter hopes "the regulations can be modified to include support for medical day care centers." (10)

RESPONSE: The Department is aware of the growing number of children with asthma and of the disparity in the New Jersey demographic communities that it affects. See, for example, the discussion of the impact of "Asthma in New Jersey" in

the New Jersey Asthma Strategic Plan 2008-2013 at 6 through 16. New Jersey Department of Health and Senior Services, New Jersey Asthma Strategic Plan 2008-2013 (Asthma Strategic Plan), released May 20, 2009, available at www.nj.gov/health/fhs/asthma/documents/asthma_strategic_plan2008-2013.pdf. For additional information on the Asthma Strategic Plan, see "DHSS Releases Asthma Strategic Plan; May is Asthma Awareness Month," Department of Health and Senior Services News Release, May 20, 2009, available at http://www.state.nj.us/cgi-bin/dhss/njnewsline/view_article.pl?id=3371.

The proposed definitions at N.J.A.C. 8:87-1.2 would establish that PMDC is a health care service for certain children "whose medical condition requires treatment and services beyond the scope provided to children with special health care needs by day care centers or preschool programs." The Department disagrees with the commenter's assertion that regular child care providers are unable to handle the special needs of children with mild to moderate asthma. In fact, child care providers generally have a legal obligation to accommodate the needs of children with disabilities with a view toward "mainstreaming" them into the general population. As the New Jersey Inclusive Child Care Project (NJICC Project), funded by the New Jersey Department of Human Services, Division of Family Development, and administered by the Statewide Parent Advocacy Network, notes, "the Americans with Disabilities Act (ADA) and Section 504 of the Vocational Rehabilitation Act prohibit discrimination by child care and after-school care providers against children with special needs." <http://www.spannj.org/njiccp/>. Among other services, the NJICC Project provides "free on-site technical assistance and support to child care providers on including children with special needs." *Id.*

The technical guidance issued by the United States Department of Justice, "Commonly Asked Questions About Child Care Centers and the Americans with Disabilities Act," available at <http://www.ada.gov/childq&a.htm>, states, "Child care centers cannot just assume that a child's disabilities are too severe for the child to be integrated successfully into the center's child care program. The center must make an individualized assessment about whether it can meet the particular needs of the child without fundamentally altering its program . . . If a child who needs one-to-one

attention due to a disability can be integrated without fundamentally altering a child care program, the child cannot be excluded solely because the child needs one-to-one care . . . In some circumstances, it may be necessary to give medication to a child with a disability in order to make a program accessible to that child."

As part of the Department's participation in the national Healthy Child Care America campaign, aimed at assuring a safe, healthy child care environment for all children, including those with special health needs, the Department collaborates with the Department of Human Services in a program of "Child Care Health Consultation Services." Child Care Health Consultation Services are available "to childcare providers, and the families and children they serve. Upon request, health consultation can be designed to meet individual needs."

<http://www.state.nj.us/health/fhs/newborn/childcare.shtml>. Child care health and safety issues for which consultation services are available include: "Visiting on-site with child care providers; Providing information and advice by telephone; Evaluation educational training needs; Giving educational trainings and/or information about topics such as: allergies, giving medication, nutrition, oral health; Providing information and reviewing children's health records; Fostering linkages with community resources, such as finding a health care provider or applying for health insurance; Assisting with the development of health and safety related policies and procedures; [and] Helping in planning for the inclusion of children with special needs." *Id.*

One can request Child Care Health Consultation Services by contacting the Child Care Health Consultant Coordinator in each county's Child Care Resource and Referral Center. A list of the county Child Care Resource and Referral Centers and Consultant Coordinators is available at:

www.state.nj.us/humanservices/dfd/programs/child/ccrr/.

Cognizant that "Asthma represents a serious and compelling public health problem in New Jersey," the Department established as a major goal (Goal) of the Asthma Strategic Plan that the State "improve the prevention and management of asthma and asthma triggers among members of child care . . . community including children, their care givers and all individuals with whom they interact." Asthma

Strategic Plan at 6 and 30. One objective the Department has established toward achieving the Goal is to give "child care providers . . . access to education and resources necessary to prevent and manage asthma in child care . . . settings." *Id.* at 30. Specific strategies the Department, in collaboration with several partners, will implement toward the achievement of the Goal are "to provide training on management of children with asthma to child care providers and child care center directors, and pilot an Asthma Friendly Child Care Award"; to "[ensure] the availability of asthma training materials and a team capable of providing consultation and education on asthma management to child care providers [Statewide]"; to "[develop a Statewide] team of facilitators trained to deliver 'Policies and Practices for Asthma Friendly Child Care' to reach the 9,000 child care providers and directors in the [State]"; and to develop "a specific strategy to incorporate preschool children in outreach and education for child care staff members." *Id.* at 30-31. Another objective the Department established toward achieving the Goal is to "Provide asthma education and promote system change to create asthma[-]friendly child care settings [Statewide] in New Jersey" through the strategy of development and implementation of a program for "Asthma[-]Friendly Child Care." *Id.* at 32.

In summary, the Americans with Disabilities Act and other laws generally require providers of routine child care programs to accommodate children with special needs, such as asthma medication administration. Systems and programs are in place and available to assist regular childcare providers in addressing the needs of children with asthma, including training in medication administration and mechanisms to link children and their families to other community resources. Moreover, as the Asthma Strategic Plan describes, the Department, in collaboration with several partners, is developing and implementing additional resources specifically targeted at assisting regular child care providers in serving the needs of children with asthma.

For the foregoing reasons, the Department will make no change on adoption in response to the comment.

2. COMMENT: Several commenters appreciate "the opportunity to provide these comments and looks forward to continuing to work with the Department of

Health and Senior Services on these proposed regulations. Overall, [the pediatric medical day care centers the commenters represent] support the establishment of licensure standards that are separate and distinct from the adult day health center regulations, and . . . appreciate the effort that has gone into the development of these proposed standards." (3, 4, 7, 8, 15, 16 and 18)

RESPONSE: The Department thanks the commenters for their support of the proposed new rules at N.J.A.C. 8:43J.

3. COMMENT: A commenter states as a "trade association representing long-term care facilities, [it appreciates] the work of the Department-designated 'PMDC Study Team' and generally [supports] the Department's efforts to provide for the licensure of PMDC facilities distinct from the licensure of adult day health services facilities." The commenter states that its members have "expressed concerns over various proposed provisions. In particular, proposed new rules at N.J.A.C. 8:43J make numerous changes from existing practices that would prove burdensome for these facilities as they struggle to provide care for an extremely fragile population. When viewed in combination with proposed new rules *N.J.A.C. 8:87* . . . the financial constraints and new mandates under which these facilities would be expected to operate may very well jeopardize their future viability. The end result . . . would be a reduction in access to the level of care required by the population that they currently serve." (9)

RESPONSE: The proposed new rules at N.J.A.C. 8:43J would require an appropriate level of care for the vulnerable population served by a pediatric medical day care. *N.J.A.C. 8:87* would require cost reporting, which would ensure equitable reimbursement for facilities based on the expenses a facility would incur.

4. COMMENT: A commenter requests an extension from the January 2, 2009 deadline for submitting comments. The commenter states that "due to the holidays, [it has] had some trouble gathering information from all the relevant persons who may assist us. (14)

RESPONSE: The Department informed the commenter that it would not grant an extension of the 60-day comment period.

5. COMMENT: A commenter states that the proposed rules "still contain an institutional and adult bias, which should not be applicable to pediatric medical day care. The staffing model is too intensive, and is similar to institutional care. There is no attempt in the rules to integrate Early Intervention Services, or require an individual service plan. One of the primary purposes of child care is to integrate a child into the normal education system in a timely manner, even if those children have medical needs that cannot be met in regular daycare." (6)

RESPONSE: The Department disagrees with the commenter's assertion that the staffing model would be "too intensive." The clients of PMDC facilities would be vulnerable children who have intensive care needs. These children would meet the criteria for institutional care, and would be eligible for institutionalization but for the services provided by their families and other caregivers, including PMDC facilities. These children often face prolonged hospitalizations.

The commenter is incorrect in asserting that an individual service plan is not required. Proposed new N.J.A.C. 8:43J-5.3 would require the development of an initial plan of care, and proposed new N.J.A.C. 8:43J-5.4 would require the development of an interdisciplinary plan of care, for each child.

The New Jersey Early Intervention Program provides services and support to certain children from birth to age three, and to their families, to enhance the children's development and the children's families' capacity to meet the children's needs. See generally *N.J.A.C. 8:17*. To the maximum extent appropriate to the needs of the children, providers of early intervention services must provide these services in natural environments, which include home settings and settings in which children without disabilities participate. *Id.* Provision of early intervention services in settings other than a child's natural environment can only occur if the provision of early intervention services cannot occur in the child's natural environment. *Id.*

PMDC facilities are not natural environments within the meaning of Part C of IDEA and *N.J.A.C. 8:17*. Therefore, the New Jersey Early Intervention Program can provide early intervention services in PMDC facilities only if no satisfactory natural environments exist. Thus, the provision of early intervention services would not occur in PMDC facilities, except as an unlikely last resort. PMDC facilities and the New

Jersey Early Intervention Program are responsible to assist families with referral for services, and, as appropriate, to coordinate PMDC interdisciplinary plans of care with individualized family service plans (IFSPs) to meet the needs of participating children and their families. However, the New Jersey Early Intervention Program rules and the IDEA prohibit sharing of client-specific information absent parental consent. *Id.*

Based on the foregoing, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43F-3.3 and 4.2

6. COMMENT: The commenter states that *N.J.A.C. 8:43F-3.3(d)8iii* and 4.2(c) are unclear as what abuse reporting facilities are to undertake for children under age 16. (1)

RESPONSE: The proposed amendments, repeal and new rules would delete all references to pediatric services from *N.J.A.C. 8:43F* and the chapter would address only adult day health services. Adult day health services do not provide services to those under the age of 16, therefore no reporting requirements are necessary for those under the age of 16. Child abuse reporting standards for children attending PMDC facilities would appear in proposed new *N.J.A.C. 8:43J-3.4(e)17i*.

N.J.A.C. 8:43J-1.2 Definitions

7. COMMENT: Several commenters ask for the sake of clarity that the Department change the definition of "consultant pharmacist" to indicate that the definition applies only to this subchapter. (3, 4, 7, 8, 15, 16 and 18)

RESPONSE: Proposed new *N.J.A.C. 8:43J-1.2* would define the terms therein "for purposes of this chapter." Thus, the change the commenters suggest would be redundant and unnecessary. Therefore, the Department will make no change on adoption in response to the comment.

8. COMMENT: For purposes of meeting the definition of "consultant pharmacist" at proposed new *N.J.A.C. 8:43J-1.2*, which would require a consultant pharmacist to have had "one year of experience in full-time practice of pharmacy in a licensed pediatric healthcare facility," a commenter requests that a pharmacist's service as a consultant pharmacist in a "pediatric day health services facility," prior to

the effective date of the proposed new rules at N.J.A.C. 8:43J, count toward this experience requirement. (4)

RESPONSE: The period of service during which a pharmacist served as a full-time consultant pharmacist for one or more pediatric medical day health services facilities would count on a day-for-day equivalency basis toward meeting the experience requirement for a consultant pharmacist for a PMDC facility at proposed new N.J.A.C. 8:43J-1.2.

9. COMMENT: Several commenters state that the "proposed definition of 'initial plan of care' is a 'care plan based on an initial assessment completed prior to or the day of admission that guides a child's care until an interdisciplinary plan of care is completed.' However, proposed N.J.A.C. 8:43J-5.3 requires the initial plan of care to be completed within two business days of admission. [The commenters] request a clarification as to the timeframe in which the initial plan of care is to be completed." (3, 4, 7, 8, 15, 16 and 18)

RESPONSE: The definition of "initial plan of care" at proposed new N.J.A.C. 8:43J-1.2 would require that the initial assessment be performed prior to or the day of admission. Proposed new N.J.A.C. 8:43J-5.3 would require the facility to develop the initial plan of care based on the initial assessment and to complete it within two business days of admission.

10. COMMENT: A commenter appreciates that the definition of "family" at proposed new N.J.A.C. 8:43J-1.2 is inclusive and recognizes diverse families. (1)

RESPONSE: The Department acknowledges the commenter's support for the definition of "family" at proposed new N.J.A.C. 8:43J-1.2.

11. COMMENT: A commenter asks for clarification of Medicaid as "to whether this also covers children who are Medicaid eligible by utilizing the split application process. (1)

RESPONSE: The licensure rules at proposed new N.J.A.C. 8:43J would not address determinations as to Medicaid eligibility for PMDC. The proposed new rules at *N.J.A.C. 8:87* would contain applicable Medicaid eligibility standards. The Department addresses the commenter's concerns, in response to an identical comment submitted with respect to proposed new *N.J.A.C. 8:87*, in the notice of

adoption of *N.J.A.C. 8:87* that appears elsewhere in this issue of the New Jersey Register.

N.J.A.C. 8:43J-2.2 Licensure Application Procedures and Requirements

12. COMMENT: A commenter states that proposed new N.J.A.C. 8:43J-2.2(a)2 "requires that scaled plans of a proposed facility be submitted for preliminary review, but does not give a time period for preliminary approval of plans." The commenter states, "(i) it is difficult for a tenant to ask a potential landlord to wait for an unspecified period of time prior to the effectiveness of the lease and, therefore, the rules should have a specified time period for approval or rejection of preliminary plans; and (ii) no other states with [PMDC facility] legislation have any requirement for submission of preliminary plans." The commenter states that in other states a facility "either meets those specifications and is approved for licensure upon inspection, or does not meet the specifications and is rejected with specific reasons." (6)

RESPONSE: The process at proposed new N.J.A.C. 8:43J-2.2(a)2 would require submission of plans for preliminary review. The Department declines to limit by rule the time within which it would have to respond because the number of Department staff available for review is finite, while the number of submissions for review potentially has no limit. Therefore, the Department will make no change on adoption in response to the comment.

13. COMMENT: A commenter requests that the Department develop standards in the rules respecting the availability of technical assistance from the Department that is or could be made available to prospective applicants prior to the submission of an application which could assist prospective applicants in assessing the merits of an individual project prior to incurring substantial development and/or property acquisition costs for projects that ultimately may not be approved for licensure." (17)

RESPONSE: Proposed new N.J.A.C. 8:43J-2.2(e) recommends that applicants contact the Department for a functional review for proposed projects, which review would include, but not limited to, physical plant plans, policies and procedures, licensing protocols and the applicability of rules to the project. If the

commenter is suggesting that the Department establish rules requiring Department review as to project feasibility, the Department declines to establish such a rule because that would exceed the role of Department staff.

14. COMMENT: A commenter states, "failing to call 911 in an emergency or past institutional abuse including inappropriate use of aversive interventions, restraints and seclusion should fall under" the category of offenses included in proposed new N.J.A.C. 8:43J-2.2." (1)

RESPONSE: While the circumstances the commenter describes would generally constitute "abuse and/or neglect" within the meaning of proposed new N.J.A.C. 8:43J-2.2(b)12, the Department declines to attempt to list by rule every possible act or omission that could constitute abuse and/or neglect, because one could construe the failure to include within the list a particular action or omission as excluding it from the meaning of abuse and/or neglect. Therefore, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-2.3 License

15. COMMENT: A commenter states that the limitation for pediatric medical day care to 27 slots at proposed new N.J.A.C. 8:43J-2.3(b) "is not reasonably related to the objectives of protecting the health, safety and welfare of pediatric medical day care participants and the Department has not come forward with any evidence, studies, testimony or any other reasonable basis for its claim that it does."

The commenter states that the "objective of creating a smaller environment can be achieved by promulgating regulations that only limit classroom size ([that is,] participants per room), not the size of the entire facility" and that the "proper level of supervision and size of the facility are already addressed by the [three-to-one] staff-to-child ratio, and the 35 [square feet] per child facility size requirement."

The commenter further states that while a facility attached to a larger medical facility may be able to survive, "it is simply impossible for a stand-alone PMDC facility to survive, much less make a reasonable rate of return on investment, with only 27 filled slots."

The commenter urges the Department to eliminate the 27-slot maximum at proposed new N.J.A.C. 8:43J-2.3(b). (2)

16. COMMENT: With respect to proposed new N.J.A.C. 8:43J-2.3(b), a commenter states that that the "maximum daily census of 27 seems arbitrary. Our company would suggest a maximum [of] 50 slots based on total square footage, number of classrooms and staffing ratios. No other states require a maximum of 27 children, and two states allow 60 children." The commenter states, "other states have higher capacities, and capacity is based upon square footage and number of classrooms." (6)

RESPONSE TO COMMENTS 15 AND 16: For the reasons stated in response to similar comments as to proposed new N.J.A.C. 8:87-2.1(a)3, adopted elsewhere in this issue of the New Jersey Register and for the reasons stated in the discussion that follows, the Department disagrees with the commenter's assertions that the maximum daily census limitation at proposed new N.J.A.C. 8:43J-2.3(b) has no reasonable basis.

Following is a summary of the historical basis of the limitation of daily census in facilities to 27.

The PMDC model in New Jersey evolved from a pilot supported by the Robert Wood Johnson Foundation. Executive Summary of Grant Project Number 14486, Medical day care for handicapped infants, (1989 to 1992) (Executive Summary), available from the Robert Wood Johnson Foundation Information Center, Route One and College Road East, P O Box 2316, Princeton, NJ 08543. The original project grantee was the Visiting Nurse and Health Services, Inc., of Elizabeth, New Jersey. Executive Summary. The purpose of the project was to "demonstrate a model for providing comprehensive medical day care to infants and toddlers who are medically involved and physically handicapped. This represents an alternative to long-term hospitalization for these children . . . The program, under the direction of a pediatric nurse specialist, will provide comprehensive health, social, and education services. The objectives are: 1) to make [20] day care slots available, although as many as 30 children may be serviced if some attend on a part-time basis; and 2) provide ongoing education and support for parents, home visits, and case management." Executive Summary.

The grantee center, operating as "The Rosemary Cuccaro Pediatric Medical Day Care Center" in Roselle Park, New Jersey, opened in 1990, and in its fifth year of operation was serving 16 children. Pediatric Day Care Center Marks Fifth Anniversary, THE TIMES (Scotch Plains and Fanwood) at 2 (May 25, 1995); United Fund Spotlights Community Service Provider, THE TIMES OF SCOTCH PLAINS AND FANWOOD at 17 (January 16, 1997) (both articles available for download at <http://www.thejointlibrary.org/archives/TheTimes>).

As the commenter notes, the notice of proposal at *40 N.J.R. 6328(a)*, 6330 (November 3, 2008) describes the subsequent regulatory history and rationale of the Department of Human Services (DHS) in establishing the facility census limitation at 27.

Proposed new N.J.A.C. 8:43J-2.3(b), viewed in concert with proposed new N.J.A.C. 8:87-2.1(a)3, would authorize facilities to attain a maximum average daily census of 27 children per service day over a calendar quarter, and would authorize facilities to attain an actual daily census of no more than 30 children. As stated in the notice of proposal Summary, the proposed new rules would provide flexibility for facilities to address enrollment fluctuations and absenteeism while addressing health and safety concerns.

A considerable body of research supports a finding that a smaller facilitywide census mitigates health and safety concerns in ordinary (that is, non-medical) childcare facilities. See, for example, the research collected and analyzed addressing the quality indicator of staff-to-child ratio and group size in the publication "13 Indicators of Quality of Child Care: Research," Richard Fiene, Ph.D., 2002 (Fiene Report), prepared for the Office of the Assistant Secretary for Planning and Evaluation and the Health Resources and Services Administration, Maternal and Child Health Bureau of the U.S. Department of Health and Human Services. The publication is available from the U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, 200 Independence Ave. SW, Room 450G, Washington, DC 20201, Fax: (202) 690-5514, and is available for download at <http://aspe.hhs.gov/hsp/ccquality-ind02>.

The Fiene Report, in its survey, analysis, and summary of the available research, generally concludes that smaller facilitywide census enhances quality of care. For example, the Fiene Report states, "Review of all the major research in child care clearly demonstrates the importance of maintaining appropriate child [to] staff ratios and group sizes. Child [to] staff ratios and group sizes are two of the best indicators for determining the quality of a child care program and they significantly [affect] many other health and safety issues. Smaller group size is associated with a lower risk of infection in child care. The risk of illness in children between the ages of one and three years of age increases as the group size increases to four or more . . . Smaller child care centers, not just those with smaller class sizes, have lower rates of disease. Outbreaks of Hepatitis A occur at the rate of [three percent] in centers that enroll less than 20 children but 53 [percent] in those that enroll 51 or more children . . . Smaller group size improves the caregiving behaviors of staff and the safety of children. [One state's study of its licensed child care facilities] found that the severity and frequency of complaints (such as reports of severity and frequency of complaints or reports of abuse and neglect) were higher in child care centers serving 30 or more children." *Id.*

The critical importance of preventing the spread of disease and maintaining the quality of caregiving is magnified in the context of caring for the technology-dependent and medically complex children who attend PMDC facilities.

In addition, the ability of the State to respond to the needs of technology-dependent and medically complex children in an emergency is a factor that has an impact on all facilities, regardless of their size. In disasters and other local or regional emergencies, such as fires, floods, and the like, survival may depend on where one is at the time of the disaster or emergency. Greater facility census of medically complex and technology-dependent children would be likely to complicate safe and efficient evacuation of PMDC facilities and other emergency management and response efforts. The following list of resources generally acknowledge that there continue to be weaknesses nationwide in disaster response planning addressing the particular needs of children, particularly children with special needs and children attending day care:

(1) Testimony provided during Congressional Hearing on "Focusing on Children in Disasters: Evacuation Planning and Mental Health Recovery" before the United States Senate Committee on Homeland Security and Governmental Affairs, Ad Hoc Subcommittee on Disaster Recovery, on August 4, 2009 (Senate Hearing), available at http://hsgac.senate.gov/public/index.cfm?FuseAction=Hearings.Hearing&Hearing_ID=aa8241f6-6f0e-41a5-87c3-07c9a58ecbfa (Senate Hearing web page);

(2) The objectives of the "Children's Working Group" of the Federal Emergency Management Administration, identified in FEMA Announces Creation of Children's Working Group, FEMA Press Release Number: HQ-09-094 (August 4, 2009); FEMA to focus on children's needs during disasters, ASSOCIATED PRESS (August 3, 2009), available at <http://www.mywire.com/a/AP/FEMA-to-focus-childrens-needs/12095567/>; and Editorial: FEMA to focus on children, THE TIMES-PICAYUNE (August 6, 2009), available at <http://www.nola.com/news/t-p/editorials/index.ssf?/base/news-5/1249536964306950.xml&coll=1>;

(3) The interim report of the National Commission on Children and Disasters, an entity established by an Act of Congress (The Consolidated Appropriations Act, 2008 (Public Law 110-161)), at <http://www.childrenanddisasters.acf.hhs.gov/home.html>; and

(4) The report card addressing child care disaster planning requirements across the states issued by Save the Children's United States Programs, The Disaster Decade: Lessons Unlearned for the United States, Save the Children U.S. Programs, available at <http://www.savethechildren.org/publications/usa/disaster-decade-lessons.pdf> and Save the Children Report Reveals Government Unprepared to Protect Children During Disasters: Save the Children's U.S. Programs Finds Only Seven States Prepared to Protect Children; Five-point Plan is Unveiled, Save the Children U.S. Programs Press Release (June 17, 2009), available at <http://www.savethechildren.org/newsroom/2009/disaster-report.html>.

The Department intends to monitor the work of these and other entities involved in disaster planning for childcare centers and to consider implementing the recommendations of those entities into the proposed new rules in future rulemaking activity.

Thus, at least until the Nation and, in turn, the State, address weaknesses in disaster response capabilities with respect to children's needs generally, and child care centers and children with special needs specifically, it would be inappropriate for the Department to propose to enlarge the maximum allowable census.

Therefore, as more fully described above, the rationale of proposed new N.J.A.C. 8:43J-2.3(b) and 8:87-2.1(a)3 is supported by historical practice, and reflects both scientific data identifying best practices in protecting the health and safety of vulnerable populations and evolving approaches and attitudes with respect to disaster preparedness and planning for children.

Moreover, the Department anticipates that limiting the census in PMDC facilities would have an additional favorable impact on maintaining quality by enhancing competition. As one study noted, "the effect of the marketplace on . . . small programs is strong . . ." Susan D. Russell and Richard M. Clifford, *Child Abuse and Neglect in North Carolina Day Care Programs*, 66 *CHILD WELFARE* 149, 156 (March--April 1987).

The Department takes no position as to the commenter's representation as to the maximum census that other states may authorize. The Department is without sufficient information to respond to this comment because the particular circumstances, eligibility criteria and population served in other states may not be comparable to the model the proposed new rules would establish.

However, the Department generally disagrees with the conclusion that a greater facility census would pose no threat to health and safety and quality of care for the medically complex and technology-dependent population that PMDC facilities would serve under the proposed new rules. The proposed new rules would establish enhanced clinical eligibility and prior authorization standards for PMDC eligibility standards that would result in PMDC facilities serving children who would be medically complex and/or technology-dependent. The health status and care needs of the children in PDHS facilities operating under the existing rules at *N.J.A.C. 8:86* proposed for repeal may not have been as medically complex as the proposed new rules. Thus, there is insufficient data to evaluate and come to a conclusion with

respect to the relative health and safety issues that present in PMDC facilities as compared to PDHS facilities.

The Department has determined to rely, at least at the outset of the State's first major regulatory effort focusing specifically on pediatric medical day care, on available scientific research, to some of which the Department refers above, on the historical census requirements and to evolving National standards with respect to disaster preparedness.

As the notice of proposal Summary for proposed new *N.J.A.C. 8:87* describes, one impetus for the proposed new rules at *N.J.A.C. 8:87* and at *N.J.A.C. 8:43J* was the Office of Legislative Services (OLS) Audit recommendation that the Department modify and segregate adult and pediatric medical day care program rules to achieve compliance with each program's respective objectives and Medicaid requirements. *40 N.J.R. 6328(a)* (November 3, 2008). Moreover, as the Social Impact and Economic Impact of the notice of proposal for proposed new *N.J.A.C. 8:87* describe, the Department anticipates that the proposed new rules' establishment of more stringent clinical eligibility criteria and the requirement of prior authorization for PMDC services would reduce the pool of eligible applicants, and the corresponding demand for services, resulting in some PMDC facilities experiencing lower enrollments. *Id.* at 6333. Thus, the proposed new rules would help to ensure that fiscal resources and facility spaces are efficiently used and available for those children who truly need PMDC services.

The Department intends to monitor the responsiveness of the proposed new rules to meet the needs of the regulated community, particularly with respect to the issues of health and safety and the rules' effect on the demand for and availability of PMDC services. As the Department's experience with the proposed new rules develops, the Department intends to make appropriate revisions over time to ensure and maintain the rules' continued responsiveness to the needs of the regulated community and effectiveness in achieving program objectives.

For the foregoing reasons, the Department will make no change on adoption in response to the comments.

17. COMMENT: A commenter requests that the Department delete the provision at proposed new N.J.A.C. 8:43J-2.3(d) that permits PMDC facilities to offer only one session every calendar day because parents and caregivers "may benefit from evening programs." The commenter states that there are no such prohibitions included in *N.J.A.C. 8:86* and *8:43F* for adult day health services. (17)

RESPONSE: Proposed new *N.J.A.C. 8:87* would prohibit reimbursement for more than a monthly average of 27 children per day, but would not prohibit facilities from having staggered arrival and departure times. The proposed new rules would not mandate a certain schedule for PMDC facilities. Based on the foregoing, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-2.5 Requirement for Criminal Background Investigation

18. COMMENT: Several commenters state that the Department should revise proposed new N.J.A.C. 8:43J-2.5(d)1 to permit an individual awaiting a criminal background investigation (CBI) determination to count toward a facility's minimum required staffing level. The commenters state that if the facility cannot count this new hire toward its staffing level, the permission to work becomes irrelevant. (3, 4, 7, 8, 9, 15, 16, 17 and 18)

RESPONSE: The governing statute, *N.J.S.A. 30:5B-6.13*, provides, "A staff member shall not be left alone as the only adult caring for a child at the center until the criminal history record background has been reviewed by the department pursuant to P.L. 2000, c.77 (*[N.J.S.A.] 30:5B-6.10 et seq.*)." Staff members awaiting a CBI determination would always need supervision by a staff member with CBI clearance when with children. Therefore, staff members awaiting a CBI determination cannot perform all the functions of a staff member and cannot count towards a facility's staffing level. Therefore, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-2.11 Hearings

19. COMMENT: A commenter requests that the Department add a provision at proposed new N.J.A.C. 8:43J-2.11 that is equivalent to *N.J.A.C. 8:43F-2.9*, which provides that the Department may schedule a conference in an attempt to settle a matter prior to transmitting a hearing request to the Office of Administrative Law. (17)

RESPONSE: The proposed new rules would not prohibit the Department from electing to schedule a conference in an attempt to settle a matter prior to transmitting a hearing request to the Office of Administrative Law. Therefore, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-3.1 Appointment of the Administrator

20. COMMENT: With respect to proposed new N.J.A.C. 8:43J-3.1(d), several commenters support "the need for the designation of an alternate [administrator]," and "recommend that some flexibility be considered with respect to the designee being able to continue to act in [his or her] primary role in the center." The commenters state that in most circumstances the designee would be the director of nursing and "given the size of the programs and that the director of nursing could perform both sets of duties for a time-limited period. It becomes more difficult when multiple designees must be available because of the domino effect of the administrator being absent, which then would cause a need for both a designated alternate administrator and a designated alternate director of nursing or director of social work." The commenters recommend that the Department change proposed new N.J.A.C. 8:43J-3.1(d) to provide, "The administrator shall not perform the duties of any other position at the facility." (3, 4, 7, 8, 15, 16 and 18)

21. COMMENT: With respect to proposed new N.J.A.C. 8:43J-3.1(d), a commenter "supports the designation of alternate administrator to act in the absence of the administrator." However, the commenter believes that the prohibition of the alternate from performing the duties of another position "would necessitate a facility having to find an alternate for yet another position. Moreover, allowing the alternate to continue to perform their regular duties would less likely disrupt facility operations as they relate to that position."

The commenter "[sees] merit in prohibiting a full-time administrator from performing the duties of another position at the facility, but [asks] that the alternate be permitted to perform [his or her] regular duties, provided, perhaps, that [he or she is] not serving as the alternate administrator for an extended period of time." (9)

22. COMMENT: A commenter requests that the Department eliminate proposed new N.J.A.C. 8:43J-3.1(b)1, which would require "the designated alternate

administrator [to] meet the same qualification standards as the administrator," because "this requirement could be unnecessarily burdensome and costly to PMDC facilities without any demonstrable benefit to the quality of care or supervision at a PMDC facility," as alternate administrators "generally function as administrators during short periods when the administrator is absent." The commenter would support the "notification of the Department and making arrangements acceptable to the Department for administrative supervision" during a prolonged absence of the administrator. (17)

RESPONSE TO COMMENTS 20, 21 AND 22: A designated alternate must have the credentials required for PMDC administrator, as that individual would serve as the administrator when filling in for the regular PMDC administrator. The alternate administrator, when acting as the administrator, will be responsible for performing all of the duties of the administrator as delineated at proposed new N.J.A.C. 8:43J-3.3. When filling in for the administrator, the Department does not expect that the alternate would have time to perform the alternate's original duties in an appropriate manner in addition to performing the duties of the administrator.

The Department will monitor the impact and effectiveness of this requirement on the regulated community as its experience with the new rules develops over time and will consider whether revisions may be appropriate to provide exceptions for short-term absences from a facility.

Therefore, the Department will make no change on adoption in response to the comments.

23. COMMENT: Several commenters recommend that the Department change proposed new N.J.A.C. 8:43J-3.1 to provide that a director of nursing not be required to hold a Bachelor of Science in Nursing (BSN) or advanced nursing degree to be eligible to act as the designated alternate of an administrator, "since this would be required at N.J.A.C. 8:43J-3.2(a)3iv and v if the administrator is a nurse." (3, 4, 7, 8, 15, 16 and 18)

RESPONSE: Proposed new N.J.A.C. 8:43J-3.1(b)1 would require a director of nursing designated as the alternate administrator to have a BSN because the director of nursing would be acting as the facility's administrator and would therefore need to

meet the requirements at proposed new N.J.A.C. 8:43J-3.1. Therefore, the Department will make no change on adoption in response to the comment.

24. COMMENT: With respect to proposed new N.J.A.C. 8:43J-3.1(d), a commenter states, "no other States with [PMDC facility] legislation require both an administrator and a nursing director, neither of which are counted towards staffing levels in the facility. In other States, the administrator/nursing director can fill in if necessary on a non-routine basis." The commenter recommends, "that the Administrator be a Registered Nurse with clinical pediatric/neonatal experience. As the census grows, [the commenter suggests] adding a Clinical Coordinator/Director of Nursing who staffs the center but who also oversees the clinical care in the facility." (6)

RESPONSE: Proposed new N.J.A.C. 8:43J-3.3 and 7.3 would require the administrator to oversee the administrative aspects of a PMDC facility and the director of nursing to oversee the clinical aspects of the facility. These would be two distinct, non-interchangeable positions. In light of the care needs of children receiving services in a PMDC facility, two individuals need to perform the functions of these positions.

25. COMMENT: Several commenters request "clarification regarding whether the . . . prohibition against the performing the duties of any other position in the facility [at proposed new N.J.A.C. 8:43J-7.1(c)] would mean that a director of nursing could not administer a medication or treatment or provide and document an assessment of a child, or that a social work administrator could not document a social work concern in a child's medical record." (3, 4, 7, 8, 15, 16 and 18)

RESPONSE: Proposed new N.J.A.C. 8:43J-7.1(c) would not prohibit a nursing director from administering a medication or treatment or from providing and documenting the assessment of a child. It would not prohibit a social work administrator from documenting a social work concern in a child's medical record. While the primary role of the nursing director in a PMDC would be administration and supervision, not providing hands-on care, N.J.A.C. 8:43J-7.1(c) would not prohibit a nursing director from providing hands-on care.

N.J.A.C. 8:43J-3.2 Qualifications of the Administrator of a Pediatric Medical Day Care Facility

26. COMMENT: Several commenters request clarification with respect to proposed new N.J.A.C. 8:43J-3.2(b), which would require an administrator to have had at least one year of experience in the last five years in the care of children with special healthcare needs. The commenters ask, "should this requirement be interpreted to mean direct clinical care? Does an MBA or BA in business now meet the requirements for an administrator of if the candidate with an MBA or BA has worked in a pediatric skilled nursing facility or a pediatric rehabilitation hospital?" (3, 4, 7, 8, 15, 16 and 18)

RESPONSE: The Department would recognize a variety of settings across the care spectrum at which an administrator could obtain the experience necessary to meet the requirement at proposed new N.J.A.C. 8:43J-3.2(b) to be knowledgeable regarding the physical, social and health care needs of young children. Proposed new N.J.A.C. 8:43J-3.2(b) would not specify a setting for this non-clinical position. Such settings could include, for example, special education facilities, pediatric day care facilities, hospitals, long-term care facilities, outpatient rehabilitative facilities and home care services.

27. COMMENT: Several commenters inquire how "a facility [should] define 'being knowledgeable' regarding the physical, social and health needs of children with special needs," as proposed new N.J.A.C. 8:43J-3.2(b) would require. (3, 4, 7, 8, 15, 16 and 18)

RESPONSE: The Department has reconsidered the requirement at proposed new N.J.A.C. 8:43J-3.2(b) that an administrator "be knowledgeable regarding [the] physical, social and medical health needs" of children with special health care needs, and has determined this standard is redundant of the experiential requirement in the rule. An individual with "at least one year of experience in the last five years in the care of children with special health care needs" would be knowledgeable regarding the physical, social and medical health needs of children who would receive services at a PMDC facility. Therefore, the Department will make a change on adoption at

proposed new N.J.A.C. 8:43J-3.2(b) to delete the phrase, "and be knowledgeable regarding their physical, social and medical health needs."

28. COMMENT: A commenter fails "to see why the administrator needs to be in-house at all times." The commenter states that because the facility on behalf of which the commenter comments operates an 11-hour day, the facility would be required to employ two administrators "at a cost that would be prohibitive to the daycare. In the acute care hospital[,] the administrator is not on site at all hours of operation, but is on call. Why then would a chronic care facility need more oversight than the acute care facility?" (13)

RESPONSE: The commenter is incorrect in asserting that there is only one administrator in an acute care hospital. These facilities have numerous layers of administrative oversight, a situation that is not mirrored in a PMDC facility. An acute care hospital has numerous administrative, support and clinical staff in the building on a 24-hour basis, and therefore it is possible for them to move staff from other areas of the hospital in the event of an emergency, something that a PMDC facility cannot do. The Department does not require PMDC facilities to operate a 12-hour day. Each PMDC facility would have flexibility to set the hours of the facility's program session. Based on the foregoing, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-3.3 Responsibilities of the Administrator

29. COMMENT: A commenter states that administrators and other staff at a PMDC facility "should be able to rely on prior authorization conducted by the Department in satisfaction of the requirements" of proposed new N.J.A.C. 8:43J-3.3(c)7, which would require that the administrator ensure that each child satisfies the requirements of N.J.A.C. 8:43J-6.1(c) prior to admission. The commenter suggests that the following language be added, "For the purposes of this section, the administrator shall be entitled to rely on any prior authorization performed by the Department for the Medicaid beneficiary in accordance with *N.J.A.C. 8:87*." (17)

RESPONSE: The Department intended proposed new N.J.A.C. 8:43J-3.3(a)7 to require a PMDC facility administrator to ensure that a child had a valid prior authorization prior to admission, hence proposed new N.J.A.C. 8:43J-6.1(c)1, which

would require compliance with *N.J.A.C. 8:87* for Medicaid beneficiaries. To clarify the obligation proposed new *N.J.A.C. 8:43J-3.3(c)7* would impose, the Department will make a change on adoption to the rule to permit an administrator to meet this obligation by relying on a valid authorization letter from the fiscal agent.

N.J.A.C. 8:43J-3.4 Administrative Policies and Procedures

30. COMMENT: A commenter recommends that the Department amend proposed new *N.J.A.C. 8:43J-3.4(e)3i* to require the review of the manual of specifications for each therapeutic intervention to be "changed from a review every six months to annually, unless best practices with respect to a particular therapeutic intervention change. Upon any change in best practices, the manual may be reviewed to be in conformance with the revised best practices." (17)

RESPONSE: In light of the potentially rapid changes in children's health needs, a review of a child therapeutic intervention plan at least every six months would be appropriate. In addition, this standard would require review of changes in best practices at least every six months, not on an annual basis as the commenter suggests. Therefore, the Department will make no change on adoption in response to the comment.

31. COMMENT: A commenter states that proposed new *N.J.A.C. 8:43J-3.4(e)8i* through *v* and *10* "appear to apply to an individual child's record and not to the more general requirements of [*N.J.A.C. 8:43J-3.4*], which govern the contents of a facility procedure manual." The commenter suggests that these "provisions be deleted and/or incorporated into section governing individual participant medical records." (17)

RESPONSE: Proposed new *N.J.A.C. 8:43J-3.4(e)8i* through *v* and *10* would address record content and would require that an interdisciplinary review of each child's plan of care occur every two months. As these are administrative standards, it is appropriate that a facility's administrative policies and procedures address them. Therefore, the Department will make no change on adoption in response to the comment.

32. COMMENT: A commenter states that proposed new *N.J.A.C. 8:43J-3.4(e)8v* requires medical histories to be prepared in ink. The commenter states, "any

medical record documentation standards should also include procedures for completion of electronic medical records [and] for accepting and recording facsimile transmissions or other electronic means of entering data into a child's record." (17)

RESPONSE: The Department agrees with the commenter's general assertion that use of electronic health records technology for purposes of maintaining a child's medical history is a commonly accepted practice in the health care industry. The system of electronic records creation and maintenance that a PMDC facility, like any other health care facility, might elect to implement would need to contain appropriate safeguards to ensure the authenticity of, and to prevent tampering with, a child's medical record, and to meet other standards for safeguarding medical records in accordance with the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. §§1301 et seq. (HIPAA), and the Federal regulations promulgated pursuant thereto by the United States Department of Health and Human Services at 45 CFR Parts 160, 162 and 164 (hereinafter collectively referred to as "HIPAA") and applicable State standards relating to licensed health care professionals' documentation responsibilities.:

For purposes of the proposed new rules at N.J.A.C. 8:43J and 8:87, a PMDC facility maintaining medical records electronically would need to be able generate hard copies of medical records as needed for use by the Department, other health care providers involved in a child's care, parents and/or others as necessary and appropriate.

If the Department were to need a hard copy of a child's medical record, appropriate persons authorized to verify the authenticity of the record would need to sign and date a hard copy of the record in ink, to attest to its veracity as a true statement of the child's record. It would not be necessary for the Department's purposes for the entire record to be in ink, as proposed new N.J.A.C. 8:43J-3.4(e)8v would require. Therefore, in response to the comment, the Department will make a change on adoption at proposed new N.J.A.C. 8:43J-3.4(e)8v to require a medical history to be "signed and dated," rather than "prepared," in ink. This change on adoption would acknowledge that some PMDC facilities might elect to maintain medical records electronically. HIPAA and applicable State laws would continue to

require PMDC facilities to create and maintain medical records accurately and securely.

Subject to the discussion above, the establishment of administrative standards applicable to the creation and maintenance of electronic medical records would exceed the scope of this rulemaking; especially considering that rulemaking with respect to this issue would be likely to have an impact on all health care facilities the Department licenses. To the extent the Department might develop standards relating to electronic medical records, those standards would be the subject of a separate rulemaking of general applicability to all health care facilities that the Department licenses.

Except as described above, the Department will make no change on adoption in response to the comment.

33. COMMENT: A commenter requests that the Department clarify the intended outcome and result of [proposed new N.J.A.C. 8:43J-3.4(e)9] related to referral procedures." (17)

RESPONSE: Proposed new N.J.A.C. 8:43J-3.4(e)9 would require PMDC facilities to have procedures in place to address the facilities' responsibilities with respect to referrals from children's primary health care providers.

34. COMMENT: Several commenters support "the Department's intent to include the primary healthcare provider in the interdisciplinary plan of care process" as proposed new N.J.A.C. 8:43J-3.4(e)10 would require. The commenters request that "the written approval of the child's primary healthcare provider would only pertain to changes the primary healthcare provider makes to the interdisciplinary plan of care summary and recommendations, and that a signature would NOT be required from the child's primary healthcare provider if [he or she] agreed with the plan as it was communicated." The commenters ask the Department to "recognize the difficulty PMDC staff face in their efforts to maintain prompt communications with children's primary healthcare providers." (3, 4, 7, 8, 15, 16 and 18)

RESPONSE: Proposed new N.J.A.C. 8:43J-3.4(e)10 is essential. It would require a PMDC beneficiary's primary health care provider to document on a regular basis the provider's review of the interdisciplinary care plan submitted by a PMDC

facility at least every 60 days, regardless of whether the plan were to need modification. Children who would receive services at PMDC facilities would be vulnerable and each child's primary health care provider would need to remain apprised of the child's care plan to maintain proper medical supervision of the services the PMDC facility would be providing. Proposed new N.J.A.C. 8:43J-3.4(e)10 would require the primary care provider's signature as acknowledgement of the primary care provider's review and approval of the plan of care. Based on the foregoing, the Department will make no change on adoption in response to the comment.

35. COMMENT: With respect to proposed new N.J.A.C. 8:43J-3.4(e)10, several commenters request, to "facilitate the primary care provider's approval and signature of modifications he or she makes to the interdisciplinary plan of care . . . that the approval and signature be considered acceptable by the Department whether it is provided in writing, generated by computer with authorization safeguards, or communicated by fax." (3, 4, 7, 8, 15, 16 and 18)

RESPONSE: Proposed new N.J.A.C. 8:43J-3.4(e)10 would require a PMDC facility to develop a protocol, memorialized in its policies and procedures manual, by which it would process a child's interdisciplinary plan of care, and would need to address procedures by which a facility would obtain the child's primary health care provider's approval or modification of the plan. This protocol could address whether and how a facility would accept communications from a provider that are transmitted electronically or by telefacsimile. For example, a facility may elect to establish a protocol in which it would accept a document that the child's primary health care provider transmits by telefacsimile, subject to the PMDC facility's receipt of a hard copy of the document by regular mail, and/or subject to a follow-up telephone call by the PMDC facility to the provider to confirm that the document is authentic and that it accurately reflects the provider's approval or modification of the plan.

For the reasons stated more fully above in response to the previous comment, the establishment of standards governing electronic medical records would exceed the scope of this rulemaking.

Subject to the foregoing, the Department will make no change on adoption in response to the comment.

36. COMMENT: A commenter states that proposed new N.J.A.C. 8:43J-3.4(e)10 is excessive in requiring the review of every child's interdisciplinary care plan every two months. The commenter states that review every 90 days, in accordance with existing requirements, would be "more than adequate to ensure that the needs of each child [are] met. More frequent reviews are unnecessary because: (1) the assessment and adjustment of medical needs of participants is done on a daily basis; and (2) the Center's nurse practitioner already provides physicals with assessment of medical needs every two months. Based on [the commenter's] experience, it is extremely rare for children with asthma to have their [medical, physical and/or developmental] needs change in any significant way in two months. While some children with more severe asthma or other serious conditions may require more frequent reviews and changes to their interdisciplinary plan, this should be done on a [case-by-case] basis. Mandating interdisciplinary reviews, across the board, every two months would be redundant and unnecessary, and would needlessly require the hiring of additional staff, at considerable expense, to keep up with the paperwork." (2)

RESPONSE: The commenter is incorrect in asserting that the existing rules governing pediatric day health services facilities require review only every 90 days. Existing *N.J.A.C. 8:43F-19.1(e)* requires review of most ongoing medical services every 60 days. A child whose medical condition were not severe enough to require review every 60 days would generally not be clinically eligible for services at a PMDC facility. Therefore, the Department will make no change on adoption in response to the comment.

37. COMMENT: A commenter states that proposed new N.J.A.C. 8:43J-3.4(e)14 appears to apply to "individual [employees'] records and not to the more general requirements which would be contained in a facility procedure manual." The commenter suggests "that these provisions be deleted and/or incorporated into rules having to do with the content of employee records at proposed [N.J.A.C.] 8:43J-6." (17)

RESPONSE: A facility's procedure manual governs the facility's operations. It would be appropriate to address personnel issues identified at proposed new N.J.A.C. 8:43J-3.4(e)14 in this manual. Therefore, the Department will make no change on adoption in response to the comment.

38. COMMENT: A commenter suggests that the Department clarify proposed new N.J.A.C. 8:43J-3.4(e)17 by requiring a facility's policies and procedures manual to address "Procedures for compliance," instead of "Compliance," with applicable statutes and protocols for abuse reporting. (17)

RESPONSE: The Department agrees that the change the commenter suggests would clarify this section. The Department will make a change on adoption to add the phrase, "procedures for," before the word, "compliance" at the beginning of proposed new N.J.A.C. 8:43J-3.4(e)17

39. COMMENT: A commenter states that proposed new N.J.A.C. 8:43J-3.4(e)17 would include reporting of abuse under the Division of Youth and Family Services (DYFS) and children of all ages. (1)

RESPONSE: The Department agrees with the commenter's statement, which is why the Department included this provision governing reporting of child abuse to DYFS in the proposed new rules.

40. COMMENT: With respect to proposed new N.J.A.C. 8:43J-3.4(e)17v, a commenter states, "hospitals and physicians should report birth defects, not [PMDC facilities, which] do not diagnose birth defects." (6)

RESPONSE: Existing to *N.J.A.C. 8:20-1.2(c)* has required and would continue to require all licensed healthcare facilities to establish reporting procedures for birth defects. The Department generally does not have direct enforcement authority over individual licensed healthcare practitioners who fail or refuse to report, whereas licensed health care facilities are under the direct authority of the Department. Children eligible to participate in PMDC are more likely than other groups of children to be appropriate for reporting to the birth defects registry. While proposed new N.J.A.C. 8:43J-3.4(e)17v might result in redundant reporting, this redundancy helps to ensure that the birth defects registry captures children in the community whose

primary health care providers might be unaware of the obligation to report. Therefore, the Department will make no change upon adoption in response to the comment.

41. COMMENT: Several commenters suggest that the Department should delete the requirement of a bulletin board at proposed new N.J.A.C. 8:43J-3.4(h) and change the rule to require notices to be posted together in a location accessible to the public." (3, 4, 7, 8, 9, 15, 17 and 18)

RESPONSE: The Department uses the term "bulletin board" in the generic sense of a formally designated wall device at which a facility posts the notices that proposed N.J.A.C. 8:43J would require. The Department takes no position as to whether this device be made of cork or magnetic material or some other material. A designated device would ensure that these notices are together in one location and not randomly taped to walls. This in turn would serve to ensure that interested persons know with confidence where to look for required notices. Therefore, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-3.5, Childcare Policies and Procedures, and N.J.A.C. 8:43J-14.3, Maintenance of Medical Records

42. COMMENT: Several commenters question the applicability of "advance directives" to the clients of PMDC facilities and request that the Department delete the reference to "advance directives" from proposed new N.J.A.C. 8:43J-3.5(c) and 14.3(a)7 because advance directives are legally permitted to be used by competent adults, but not by children. (3, 4, 6, 7, 8, 9, 15, 16 and 18)

43. COMMENT: A commenter "requests a legal citation which governs the preparation of advance directive by children. In the absence of such citation, please amend the rules to provide procedures and relevant citations which govern emergency procedures and measures to be taken for or on behalf of a child in such emergent situations including but not limited to the forms of documentation to effectuate these procedures and consent of the child's primary caregiver." (17)

RESPONSE: Proposed new N.J.A.C. 8:43J-3.5(c) and 14.3(a)7 would require facilities to have necessary policies and procedures in place to respect, support and empower parents to participate actively in decisionmaking for their children. In using the term "advance directive," proposed new N.J.A.C. 8:43J-3.5(c) and 14.3(a)7 would

refer generically to legal documents recording health care decisions executed by a parent on behalf of a child. Therefore, the Department will make no change on adoption in response to the comments.

Proposed new N.J.A.C. 8:43J-8.7 would address medical emergencies. Specifically, proposed new N.J.A.C. 8:43J-8.7(c) would require a child's healthcare provider to develop an emergency plan that includes orders for the use of emergency medications. The Department anticipates that a child's primary healthcare provider would have discussed these provisions with the child's parent. As the proposed new rules would address the commenter's concerns, the Department will make no change on adoption in response to the comment.

44. COMMENT: A commenter asks if the intent of proposed new N.J.A.C. 8:43J-3.5(c)5 is the same as that contained in proposed new N.J.A.C. 8:43J-3.4(e)11, and suggests that the Department delete this provision. (17)

RESPONSE: The intent of the two requirements is not identical. Proposed new N.J.A.C. 8:43J-3.5(c)5 would govern discharges, transfers and readmissions of children, and would identify the criteria facilities would need to develop for each of these events. Proposed new N.J.A.C. 8:43J-3.4(e)11 would establish additional criteria for discharges, but these would not be the only criteria for discharges that a facility may establish by policy and procedure. For example, proposed new N.J.A.C. 8:43J-3.4(e)11 would not address involuntary discharges, but proposed new N.J.A.C. 8:43J-3.5(c)5 would address them. Therefore, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-3.9 Involuntary Discharge

45. COMMENT: A commenter states that the 30-day time within which to appeal an involuntary discharge at proposed new N.J.A.C. 8:43J-3.9(a) would be sufficient in most situations but "may not be sufficient in situations where the family timely appeals the decision to discharge or the determination that the child is a danger to himself or others, and due to circumstances beyond their control, the issue is not decided by the expiration of the 30-day period. In these instances, if the family has begun the process of challenging the determinations/decisions, there should be pendency placement until the resolution of these challenges." The commenter states

that requiring 30 days' advance written notice protects the child as well as other children in the facility. (1)

RESPONSE: The commenter appears to have misunderstood the discharge requirements at proposed new N.J.A.C. 8:43J-3.9(c), which would govern situations in which a facility was to discharge a child involuntarily for reasons of the welfare of the child or other children. The proposed new rule would cross-refer to proposed new N.J.A.C. 8:43J-4.2(a)4, which would establish standards for emergency discharges. These immediate discharges would occur if a child were a threat to himself or herself or other children. If a child were a risk to himself or herself or other children, it would be inappropriate and irresponsible of a facility to retain that child or for the Department to require a facility to retain the child during the pendency of the appeal. For the same reasons, the Department disagrees with the commenter's suggestion that an emergency discharge be "stayed" pending an appeal, if the discharge were based on a facility's determination that the child was a risk to himself or herself or to other children. Therefore, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-3.13 Required Documents

46. COMMENT: A commenter states that proposed new N.J.A.C. 8:43J-3.13(a) "requires PMDC facilities to maintain copies of various chapters of the New Jersey Administrative Code (N.J.A.C.). Most PMDC facilities are small business and do not have access to current versions of N.J.A.C. [and the commenter] requests that the Department make the required chapters available on its website for download by the PMDC facility and the address where hard-copy of such chapters may be obtained [should be] incorporated into [N.J.A.C.] 8:43J-3.13." The commenter further suggests that the Department change proposed new N.J.A.C. 8:43J-3.13(a)5 to state that the manuals are those required by [N.J.A.C.] 8:43J-3.4(e). (17)

RESPONSE: Proposed new N.J.A.C. 8:43J-3.13 would require PMDC facilities to have available any policy and procedure manuals that govern the facility's operation. LexisNexis® publishes the authoritative version of the New Jersey Administrative Code. In accordance with the contract between the State and LexisNexis®, the New Jersey Register and the New Jersey Administrative Code can

be accessed on-line, on a subscription or transactional fee basis, at www.lexis.com. In addition, LexisNexis® provides free on-line public access to the New Jersey Administrative Code and the New Jersey Register at <http://www.lexisnexis.com/njoal>. Moreover, larger public libraries throughout the State maintain the New Jersey Administrative Code.

Information on ordering the New Jersey Administrative Code is available at lexisnexis.com or by writing LexisNexis® Matthew Bender®, 744 Broad Street, Newark, NJ 07102 or by telephoning (973) 820-2000 or (800) 252-9257.

For more information about obtaining the New Jersey Administrative Code, see <http://nj.gov/oal/rules.html>.

Based on the foregoing, the Department will not make a change as the commenter suggests but will make a change on adoption at proposed new N.J.A.C. 8:43J-3.4(e) to include information on obtaining copies of the New Jersey Administrative Code from LexisNexis®.

N.J.A.C. 8:43J-4.1 Policies and Procedures Regarding the Rights of Children

47. COMMENT: A commenter states that proposed new N.J.A.C. 8:43J-4.1(c), which requires the reporting of suspected child abuse to the Department of Children and Families, Division of Youth and Family Services, "should cover children of all ages and the reporting of institutional abuse by staff." (1)

RESPONSE: The Department agrees with the commenter, and this is why proposed new N.J.A.C. 8:43J-4.1(c) would include the reporting requirement.

N.J.A.C. 8:43J-4.2 Rights of Each Child

48. COMMENT: With respect to proposed new N.J.A.C. 8:43J-4.2(a)6, which provides for the use of restraints only when ordered by the child's primary health care provider and that medication not be used as punishment or for the convenience of facility personnel, a commenter requests that the Department change the rule to require parental consent to the use of restraints, and to provide that "parental refusal of use of restraints not be a condition of initial or continuing placement. [The commenter agrees] that drugs can be inappropriately used as 'chemical restraints' and support the language prohibiting the use of medication for punishment or for convenience of facility staff." (1)

RESPONSE: The proposed new rules govern the use of restraints at proposed new N.J.A.C. 8:43J-17.2, which establish specific guidelines for the use of restraints. The Department will not make the change the commenter suggests, because a PMDC facility could use restraints only on an order from a child's primary health care provider. A child's primary health care provider would have the clinical expertise, and, by virtue of the provider's licensing, the authority to order the use of restraints when medically indicated. A PMDC is a licensed healthcare facility and healthcare providers should be making the medical decisions. Therefore, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-5.1 Pre-admission Assessment

49. COMMENT: A commenter suggests that, after the phrase, "home visit" at proposed new N.J.A.C. 8:43J-5.1(a), the Department add the phrase, "or hospital visit." The commenter states, "Most assessments are done in a hospital setting prior to discharge of the child and are done in coordination with the hospital team from various disciplines." (6)

50. COMMENT: A commenter requests that the "requirement for facility staff to conduct a home visit by a member of the interdisciplinary team be amended to provide that an "assessment of the home environment" be performed rather than a home visit. The commenter states that "any benefit derived from a home visit rather than an assessment is more than offset by the costs associated with paying the transportation costs of the staff person to go to a child's home and the necessity to provide the requisite staffing coverage" for the staff member who is doing the home assessment." (17)

RESPONSE TO COMMENTS 49 AND 50: In addition to providing facility staff an opportunity to assess a child's physical condition, a home visit pursuant to proposed new N.J.A.C. 8:43J-5.1(a) would enable facility staff to assess the child's home environment to ascertain whether additional services would be appropriate. While facility staff could perform an assessment of a child's physical condition at a hospital, if that is where the child is located, a home visit is essential to provide a complete understanding of a child's situation. The potential benefit to the child from a

facility conducting a home visit would outweigh the cost. Therefore, the Department will make no change on adoption in response to the comment.

51. COMMENT: A commenter states that proposed new N.J.A.C. 8:43J-5.1 is "inconsistent with the requirement of proposed new *N.J.A.C. 8:87* in that PMDC facility staff are required to make an assessment of the clinical eligibility of a program participant. Determinations of clinical eligibility are within the jurisdiction of the decision makers of the applicable [payer] source . . . such delegation is not generally permissible." The commenter asks that the Department articulate its position as to what if any benefit a preadmission assessment adds in light of the fact that nursing facility staff conduct initial assessments . . . followed shortly thereafter by the development of an interdisciplinary plan of care." The commenter asks that the Department change proposed new N.J.A.C. 8:43J-5.1 to require the conduct of a home assessment instead of a home visit because of the transportation and staffing expenses incurred by a facility in conducting the home visit. (17)

RESPONSE: The commenter appears to have misunderstood proposed new N.J.A.C. 8:43J-5.1. Proposed new N.J.A.C. 8:43J-5.1(b)1 would require a PMDC facility to perform a pre-admission assessment to screen a child for clinical eligibility prior to submitting a prior authorization request. The benefit derived by this process is that facilities would not submit prior authorization requests for children who were readily discernible to be ineligible for PMDC services. A home visit would also be valuable to determine eligibility and to assess whether other services may be required. Ensuring that a technology-dependent and/or medically complex child would receive appropriate services outweighs the transportation costs and necessity to provide appropriate staffing at the PMDC facility. Therefore, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-5.3 Initial Assessment and Initial Plan of Care

52. COMMENT: A commenter requests that the Department change proposed new N.J.A.C. 8:43J-5.3(b) to mirror *N.J.A.C. 8:43F-5.3(b)* and to allow five, rather than two, business days after admission within which a facility is to develop an initial plan of care. (17)

RESPONSE: Proposed new N.J.A.C. 8:43J responds to the work carried out by the Department's Pediatric Study Team to assure that eligible children receive appropriate services. One of the Pediatric Study Team's recommendations, as expressed through proposed new N.J.A.C. 8:43J, is that the Department change PMDC from its then-status as a subprogram of the adult day health services program and make it a separate program. The commenter's suggestion that PMDC continue to mirror adult day health services would be inappropriate in light of the work of the Pediatric Study Team. The admission criteria at proposed new *N.J.A.C. 8:87* would limit eligibility for PMDC to children with much higher care needs than adults who were eligible for adult day health services pursuant to *N.J.A.C. 8:86*. It would be inappropriate to provide services to medically complex or technology-dependent children for up to five days without a care plan. The Department expects that the development of care plans would be a major function of the nursing director. Therefore, the Department will make no change on adoption in response to the comment.

53. COMMENT: Several commenters state that they lack the authority to require a primary care provider to perform a physical examination within 30 days prior to child's PMDC admission as proposed new N.J.A.C. 8:43J-5.3(c) would require. The commenters state that this requirement "presents an undue burden on parents in that the parent may be unable to secure an appointment with the child's primary healthcare provider for a well-child visit within 30 days of admission. When a child reaches age [two], well-child visits are annual. Also, Medicaid will not provide reimbursement for an additional well-child visit." The commenters suggest the Department change this requirement to require an examination "60 days prior to or upon admission to" the facility, or to require that the facility obtain a copy of a progress note from any visit the child's primary health care provider performed more recently than 60 days prior to admission. (3, 5, 7, 8, 15, 16 and 18)

54. COMMENT: A commenter states that the requirement for a physical within 30 days of admission at proposed new N.J.A.C. 8:43J-5.3(c) would be difficult "since the ability to comply with this provision is contingent upon a primary health care provider over which a facility has no control or authority as well as the ability of

parents to secure an appointment with a provider in a timely manner." The commenter suggests that the time "be extended from 'within 30 days prior' to 'within 60 days prior' to or upon admission" along with a copy of more recent progress notes. (9)

RESPONSE TO COMMENTS 53 AND 54: Children who would be clinically eligible to participate in PMDC would be medically complex and/or technology-dependent. They generally would have compromised health and would routinely see physicians and other health care providers. Thus, the Department does not anticipate that the proposed requirement of a medical visit during the specified time would pose a hardship to parents or providers. Upon admission of a child to a PMDC facility, it is essential that medical findings and orders be as current as possible to ensure appropriate care. Therefore, the Department will make no change on adoption in response to the comments. However, the Department will monitor the impact of this rule as to whether it would impose an undue burden on the regulated community, with a view toward determining whether revision would be appropriate.

55. COMMENT: With respect to proposed new N.J.A.C. 8:43J-5.3(c), a commenter states, "a recent physical examination performed by a nurse practitioner should be permitted to meet the time constraints of developing an initial assessment and initial plan of care." The commenter states, "sometimes children are admitted more than 30 days after they have their physicals. It is often difficult to get the physician to perform another one, and difficult to get the cooperation of parents to have it done again. Part of the problem is that Medicaid will cover one physical per year. Again, the regulations do not take into consideration how the conflicting requirements of different government agencies impact poor children."

The commenter further states that the nurse practitioner in the facility on behalf of which the commenter comments performs "follow-up physicals upon admission and every two months afterward. In order to avoid delaying needed care to children, [the commenter requests] that physicals be performed by either the child's primary health care provider and/or advanced practice nurses." (2)

RESPONSE: Proposed new N.J.A.C. 8:43J would establish a model for pediatric medical day care that would recognize the child's primary health care

provider, and not the PMDC facility, as the child's "medical home." The child's primary health care provider is the appropriate party to direct the child's care, not the facility. Because of this, proposed new N.J.A.C. 8:43J-5.3(c), which would require a child's primary health care provider to perform a physical examination within 30 days prior to the date of admission, would establish an appropriate standard to implement this model. Therefore, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-5.4 Development and Implementation of Interdisciplinary Plan of Care and Discharge Planning

56. COMMENT: A commenter requests that the Department change proposed new N.J.A.C. 8:43J-5.4(a) to mirror existing *N.J.A.C. 8:43F-5.4(a)* and allow a facility up to 30 rather than 15 business days of admission within which to develop an interdisciplinary plan of care and to allow a member of the interdisciplinary care team, instead of a registered professional nurse, to prepare the interdisciplinary plan of care. (17)

RESPONSE: As stated more fully in response to a previous comment, the Department does not view the proposed new rules as establishing a program for children that mirrors the program for adults in adult day health services. It would be inappropriate for a medically complex or technology-dependent child to receive services for up to 30 days pursuant to an initial care plan. The Department anticipates that the development of care plans would be a major function of the nursing director. A prior authorization typically would be valid for as long as six months. It would be inappropriate for a child to receive services pursuant to only an initial plan of care and without an interdisciplinary care plan for 25 percent or more of the authorized period of care. Therefore, the Department will make no change on adoption in response to the comment.

57. COMMENT: The commenter requests that the Department reconsider proposed new N.J.A.C. 8:43J-5.4(f), which would make the implementation of the interdisciplinary plan of care "contingent upon the approval of the child's primary health care provider," because this would be very difficult for some facilities to implement. The commenter states this "may result in unnecessary delays in the

provision of services because primary care providers will not review and approve a plan of care in a timely manner [and the commenter requests] the rules require PMDC facilities to use best efforts in obtaining approval of the interdisciplinary plan of care by a child's primary health care provider." (17)

RESPONSE: It would be essential for a primary health care provider to approve a child's interdisciplinary plan of care, as proposed new N.J.A.C. 8:43J-5.4(f) would require. Children eligible to receive services at PMDC facilities face challenging health conditions. Each child's primary health care provider would need to remain apprised of the child's care plan to maintain proper medical supervision of the services the PMDC facility would be providing. The child's primary health care provider, not the child's PMDC facility, would be the child's "medical home" and the guide for the child's medical care. Therefore, the Department will make no change on adoption in response to the comment.

58. COMMENT: The commenter asks that if appropriate, the interdisciplinary plan of care address the needs and preferences of "the child himself." (1)

RESPONSE: Proposed new N.J.A.C. 8:43J-5.4(a)5 would require facilities to address the needs and preferences of a child as identified by the child's parent in the development of a plan of care. As children receiving services in PMDC facilities are younger than the age of six, the Department does not believe that it would be appropriate to require a facility to address the needs and preferences as expressed by the child in the development of a plan of care. Facility staff may elect to inquire of a child's preferences but would need to exercise professional judgment in allocating the weight to accord the child's stated preferences. The Department declines to mandate expressly that facilities accord deference to children's expressed preferences. Therefore, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-6.1 General Services Provided

59. COMMENT: With respect to proposed new N.J.A.C. 8:43J-6.1(a), a commenter states, "children often have medical appointments, become sick during the day or have an emergency situation in the facility that requires treatment outside the facility. A provider should not be required to provide up to six hours of care for

free. No other states have this draconian requirement. [The commenter] would suggest hourly reimbursement for all time in the facility if the child is present for more than one hour [and] would also eliminate the 'consecutive' requirement, as parents may pick up a child for a medical appointment and return them to the center after the appointment."

The commenter suggests the following amendments if the Department were to decline to rescind the six-hour minimum: "(i) require that a child be able to attend the facility for at least six hours on a regular basis for initial approval of services, and (ii) provide explicit authority and guidelines for the facility to discharge children who fail to attend for a minimum of six hours. In addition, [the commenter recommends] that transportation time be included in the hours because a facility is liable for the continuing care of the children while they are being transported to and from the facility." (6)

RESPONSE: The Department anticipates that parents would not permit their children to attend PMDC when they have offsite appointments, as this would involve multiple time-consuming transports of the child that would prove too physically taxing for this population. Moreover, the time spent out of the facility would make it nearly impossible for the child to receive minimum mandated onsite services.

N.J.A.C. 8:43J would establish licensure standards and would not address reimbursement issues. Proposed new N.J.A.C. 8:43J-6.1(a) would require facilities to offer services for at least six consecutive hours per day, exclusive of transportation time. Proposed new N.J.A.C. 8:87-5.1 would require as a condition of reimbursement that each child receive a unit of service, that is, six consecutive hours of services per day.

The commenter raises similar issues respecting transportation and discharge as they affect reimbursement in comments on the notice of proposal of proposed new *N.J.A.C. 8:87*. The Department responds to those comments in the context of the notice of adoption of proposed new *N.J.A.C. 8:87*, which appears elsewhere in this issue of the New Jersey Register.

60. COMMENT: With respect to proposed new N.J.A.C. 8:43J-6.2(b), a commenter "believes that a nursing director, in addition to the administrator and two

extra registered nurses is not appropriate as a minimum. We believe that administrator should be interchangeable with the nursing director, and that on a non-routine basis the administrator/nursing director should be counted towards staffing." (6)

RESPONSE: Proposed new N.J.A.C. 8:43J-3.3 and 7.3 would require the administrator to oversee the administrative aspects of a PMDC facility and the director of nursing to oversee the clinical aspects of the facility. These are two distinct, non-interchangeable positions. In light of the care needs of children receiving services in a PMDC facility, two individuals need to perform the functions of these positions.

N.J.A.C. 8:43J-6.2 General Staffing Requirements

61. COMMENT: Several commenters state that proposed new N.J.A.C. 8:43J-6.2(a) would not permit the director of nursing to count toward a facility's staffing level and that "the director of nursing in a PMDC [facility] is a hands-on member of the staff and should [count toward] the staffing level." (3, 5, 7, 8, 9, 15, 16 and 18)

RESPONSE: The role of a nursing director is distinct from the role of nurses providing direct care. Proposed new N.J.A.C. 8:43J-7.3 would prescribe these distinct roles. That rule would not prohibit a nursing director from providing direct care. However, the primary role of the nursing director would not be the provision of direct care, but performance of the responsibilities that proposed new N.J.A.C. 8:43J-7.3 would establish, that is, supervision and oversight. Thus, it would be inappropriate to count a nursing director toward the minimum facility staffing level or personnel required to perform direct care. Therefore, the Department will make no change on adoption in response to the comments.

62. COMMENT: With respect to the requirements at proposed new N.J.A.C. 8:43J-6.2(b), which would require two professional nurses, in addition to the nursing director, to be on site when children are present, and proposed new N.J.A.C. 8:43J-3.1(c), which would require the administrator to be on site at all times, several commenters state that because "children typically arrive and leave the program at scattered times, requiring this level of staffing during all hours children are present

would significantly increase the operational costs of the program, without providing added benefit to the children."

The commenters suggest as an alternative that "the provision apply only to a six-hour program day, as defined by the center's policy and procedures" and recommend "that the term 'registered professional nurses' be replaced with the term 'licensed nurses.'" (3, 5, 7, 8, 9, 15, 16 and 18)

63. COMMENT: A commenter states that proposed new N.J.A.C. 8:43J-6.2(b), which would require two registered professional nurses, the nursing director and the administrator, to be on-site at all times children were present "would make the program unaffordable" at her centers. The commenter states that the proposed rule and statements have not articulated any discernable increase in health benefits for PMDC participants and "requests that the [Department] maintain the same standards . . . contained in existing N.J.A.C. 8:43F-19." (17)

RESPONSE TO COMMENTS 62 AND 63: The commenters appear to view the requirement at proposed new N.J.A.C. 8:43J-6.2(b) as primarily a safety and care needs issue. Children who would receive services at a PMDC facility are medically complex and/or technology dependent, so one-to-one contact may be necessary, particularly in the event of an emergency. At a hospital, one could draw staff from other units within the hospital to respond in an emergency. A PMDC facility would not have that advantage.

The use of the term, "licensed nurses," would be insufficiently specific, because one could construe the term to include licensed practical nurses. The respective scopes of practice of registered professional nurses and licensed practical nurses are different and establish that a licensed practical nurse's provision of care, such as intervention in an emergency, needs to be under the direction of a registered professional nurse. N.J.S.A. 45:11-23b.

Moreover, as stated above in response to previous comments, while there are some consistencies between them, it would be inappropriate to view the proposed new rules as a mirror image of the existing adult day health services rules at *N.J.A.C. 8:43F*, given the differences in care needs of the respective populations.

Therefore, the Department will make no change on adoption in response to the comments.

64. COMMENT: A commenter asks whether the two registered nurses that proposed new N.J.A.C. 8:43J-6.2(b) would require could apply toward satisfying the six-to-one staffing ratio that proposed new N.J.A.C. 8:43J-6.2(d) would require and the three-to-one staffing ratio that proposed new N.J.A.C. 8:43J-6.2(c) would require. (2)

RESPONSE: A facility could count the two registered nurses that proposed new N.J.A.C. 8:43J-6.2(b) would require towards satisfying both the six-to-one staffing ratio that proposed new N.J.A.C. 8:43J-6.2(d) would require and the three-to-one staffing ratio that proposed new N.J.A.C. 8:43J-6.2(c) would require.

65. COMMENT: A commenter states that proposed new N.J.A.C. 8:43J-6.2 would require a daycare with 27 participants to have six RNs on staff. The commenter has "worked in acute care settings in several hospitals in New Jersey and Pennsylvania and would often have five to seven acutely ill children under [the commenter's] care. Additionally, in the acute care hospitals, LPNs can also have a full patient work load under the supervision of an RN with [the RN's] own caseload. This would be forbidden in [PMDC facilities] under the new proposed rules. Not only is a one-to-six ratio unnecessary for chronically ill children, but . . . there is a terrible nursing shortage and the hospitals and nursing homes do not need added competition for the few available nurses. [The facility of behalf of which the commenter comments is] licensed for 20 patients and would be required to have a total of [five] RNs. This would be an untenable burden on a small facility . . ."

The commenter does "not understand what precipitated the need for these new regulations, but [feels] that under [existing *N.J.A.C. 8:43F* that the facility on behalf of which the commenter comments] has been running effectively, efficiently and safely. A ratio of [one] RN or [one] LPN for 10 participants would be more reasonable and allow [the facility] to provide care for many chronically ill children and their families. If the [proposed new rules] take effect, [the facility] will not be able to remain open providing this very necessary service." (13)

66. COMMENT: A commenter states, "[proposed new N.J.A.C. 8:43J-6.2(d)] and related summary statements have not articulated any discernable increase in health benefits for PMDC beneficiaries . . . that would be facilitated by the proposed change [and] requests that the Department maintain the . . . staffing ratio" at existing N.J.A.C. 8:43F-19. (17)

RESPONSE TO COMMENTS 65 AND 66: As stated above in response to previous comments, the proposed new rules envision caring for a population that is medically complex and/or technology-dependent. This population would be different from the one currently receiving care in pediatric day health services facilities pursuant to existing *N.J.A.C. 8:86*, given the more stringent clinical eligibility standards at proposed new *N.J.A.C. 8:87*.

One cannot compare staffing requirements in PMDC facilities to hospitals. While a registered professional nurse might have more children under his or her care in a hospital than he or she would in a PMDC facility under the proposed new rules, the registered professional nurse in a hospital could draw staff from outside the unit, including physicians, to respond to an emergency, whereas PMDC facility staff would need to rely on staff on hand.

Based on the foregoing, the Department will make no change on adoption in response to the comments.

67. COMMENT: With respect to proposed new N.J.A.C. 8:43J-6.2(b), a commenter states, "that one registered nurse (as a staff position) should be the minimum at all times when children are present [and agrees] with the three-to-one staffing ratio required, but [disagrees] with the top heavy staffing requirements." (6)

RESPONSE: Pursuant to the proposed new rules, there might be as many as 30 children in a PMDC facility at one time. With only one registered professional nurse present, it would be impossible to meet the care needs of children receiving services in a PMDC facility, there would be insufficient supervision of other caregivers, and, in an emergency, insufficient staff would be present to provide care at the same time for the child in acute need and the other children present. Therefore, the Department will make no change on adoption in response to the comment.

68. COMMENT: With respect to proposed new N.J.A.C. 8:43J-6.2(i)1, which would require at least one on-site staff member to maintain pediatric advanced life support (PALS) certification, several commenters state, "only the assessment skills portion of the PALS training would be relevant in the PMDC [facility] environment. This training in assessment is already being conducted for PMDC staff outside of the PALS certification by qualified personnel. In emergency situations, the PMDC staff currently use these assessment skills and call 911 simultaneously, per their facility policy. Without clear evidence demonstrating the need for full PALS certification, [the commenters recommend] that the Department remove this provision from" proposed new N.J.A.C. 8:43J-6.2. (3, 5, 7, 8, 15, 16 and 18)

69. COMMENT: A commenter believes that proposed new N.J.A.C. 8:43J-6.2(i)1 and 2 "present obvious liability concerns. For special needs children, the American Academy of Pediatrics and the U.S. Department of Health and Human [Services] Maternal and Child Health Bureau have endorsed standards that require an emergency written plan that includes a first responder (paramedics) to transport the child to the nearest emergency center. At the facility, nurses should only initiate and maintain first aid and CPR on the child, and call the first responder. The facility does not maintain emergency drugs except as ordered by a child's physician. Nurses should not intubate or place interosseous lines in a child. Nurses can and do assist the paramedics, and the facility maintains any special information needed by the emergency responder to respond appropriately. PALS is not an appropriate certification in the [PMDC facility] setting." (6)

70. COMMENT: A commenter states that the requirement for at least one on-site staff member to have PALS certification is an economic burden and requests, without "clear evidence demonstrating the need for PALS that the Department remove this provision from the proposed regulation. (17)

RESPONSE TO COMMENTS 68 THROUGH 70: The assessment portions of PALS training and a call to 911 might not provide sufficient patient safety. Children receiving care at a PMDC facility are medically complex and/or technology-dependent. Nurses in a PMDC facility are the first to respond in the event of an emergency. With no guarantee that assistance may be available promptly, it would

be appropriate to require at least one on-site staff member with PALS certification when children are present, to assist in recognizing pediatric emergencies, accessing appropriate trauma and emergency response systems and providing appropriate immediate care within the staff member's scope of practice. Therefore, the Department will make no change on adoption in response to the comments. The Department will monitor medical literature to determine whether the requirement imposes an undue burden on the regulated community.

N.J.A.C. 8:43J-6.3 Personnel

71. COMMENT: Several commenters, while "recognizing the importance and necessity of training," request that the Department reduce the frequency of in-service training on emergency plans and procedures, infection prevention and control, and child rights and identification of child abuse from "upon hire and monthly thereafter," as proposed new N.J.A.C. 8:43J-6.3(e)1 would require, to "upon hire, annually, and as needed." The commenters state, if "the Department's intent was to require that the PMDC offer some form of in-service training on a monthly basis," then the Department should establish this as a separate requirement, and "the topics be determined by the PMDC based on the needs of the individual PMDC facility." (3, 5, 7, 8, 15, 16 and 18)

72. COMMENT: A commenter states that the frequency of training that proposed N.J.A.C. 8:43J-6.3(e)1 would require would be burdensome and would remove staff from their direct care duties. (9)

73. COMMENT: A commenter recommends that the Department change proposed new N.J.A.C. 8:43J-6.3(e)1 to require training upon hire and annually thereafter, and replace the requirement of monthly training with training "on an as-needed basis." (17)

RESPONSE TO COMMENTS 71, 72 AND 73: Proposed new N.J.A.C. 8:43J-6.3(e)1 would require monthly in-service training. In proposing this requirement, the Department intended facilities to provide monthly in-service training addressing the identified topics at least annually.

Standards governing emergency plans and procedures, infection prevention and control, child rights and identification of child abuse, while subject to evolution

and revision from time to time, do not change as frequently as monthly. In-service training addressing the listed topics would be appropriate when standards governing PMDC facilities change, and at least annually as a refresher for staff. The Department agrees with the commenters that it would be appropriate for a PMDC facility to satisfy the monthly in-service requirement by offering training on an individualized basis to staff in topics related to direct care duties. Thus, participation in training would not remove staff from their direct care duties.

For the reasons stated by the commenters, the Department will make a change on adoption at proposed new N.J.A.C. 43J-6.3(e) to require PMDC facilities to provide staff monthly in-service training on topics facilities identify at their discretion and to require facilities to provide staff in-service training at least annually that addresses the specific topics of emergency plans and procedures, infection prevention and control, child rights and identification of child abuse.

The change on adoption would not reduce the protection the rule as proposed would offer, because other provisions of the proposed new rules make staff knowledge of and adherence to standards addressing these topics inherent to PMDC facility operation. Specifically, proposed new N.J.A.C. 8:43J-15 would require facilities to meet infection control standards; proposed new N.J.A.C. 8:43J-3.4 would require facilities to comply with child abuse reporting standards; and proposed new N.J.A.C. 8:43J-13.16 would require facilities to have emergency plans and procedures in place, and in particular, proposed new N.J.A.C. 8:43J-13.16(e) would require PMDC facilities to conduct emergency drills at least four times each year.

This change on adoption would not increase the burdens the proposed new rules impose on the regulated community, and would provide a benefit to the regulated community. While proposed new N.J.A.C. 8:43J-6.3(e) would continue to require PMDC facilities to conduct monthly in-service training, facilities would have discretion to select topics relevant to the needs of the particular facility, its staff and the children and families the facility serves and to tailor the training accordingly.

74. COMMENT: With respect to proposed new N.J.A.C. 8:43J-6.3(g)4, several commenters request clarification as to the specific documents PMDC facilities are to place in employees' personnel files regarding a facility's policies as to overtime,

compensatory time, performance evaluations and termination of employment. The commenters inquire whether the Department's intends "to require each employee to acknowledge receipt of these policies, as opposed to requiring that a copy of the policies themselves be included in the employee's personnel file." The commenters suggest that the Department change proposed new N.J.A.C. 8:43J-6.3(g)4 by adding the phrase, "employee's signed acknowledgement of receipt of the," after the first word, "The." (3, 5, 7, 8, 15, 16 and 18)

RESPONSE: The Department did not intend proposed new N.J.A.C. 8:43J-6.3(g)4 to require facilities to place copies of all applicable policies and procedures in each employee's personnel file. The Department intended that employees receive copies of the policies and procedures. Placing copies of the policies and procedures in the employee's file would not serve this purpose, but placing an employee's signed acknowledgment of receipt of copies thereof would. Therefore, the Department will make a change upon adoption at new N.J.A.C. 8:43J-6.3(g)4 to reflect the commenters' suggestion. The change would reduce the recordkeeping burden on PMDC facilities while maintaining the intended protective purposes of the rule.

N.J.A.C. 8:43J-7.1 Designation of Nursing Director

75. COMMENT: Several commenters state that the responsibilities of a PMDC facility's nursing director are not exclusively administrative and include direct care responsibilities. They request that the Department delete proposed new N.J.A.C. 8:43J-7.1(c), which would prohibit a nursing director from performing the function of any other position and would preclude counting the nursing director toward a facility's minimum staffing level. The commenters likewise request that the Department delete proposed new N.J.A.C. 8:43J-7.1(c)1, which would prohibit a registered professional nurse acting in the nursing director's absence from performing the function of any other position and would preclude counting a registered professional nurse acting in the nursing director's absence toward a facility's minimum staffing level. (3, 5, 7, 8, 9, 15, 16 and 18)

76. COMMENT: A commenter states that proposed new N.J.A.C. 8:43J-7.1(c) would "state the Director of Nursing is not to be involved in the direct care of children and is to act only in an administrative capacity. [The commenter has] taken the time

over the last few months to keep a diary of the time [the commenter spends] on administrative and supervisory duties as director. With only 20 participants, [the commenter spends] approximately [one and one-half] hours a day on administrative duties and paperwork. The commenter states, "as a nurse [the commenter needs] to keep [the commenter's] skills current by participating in the children's care and therapies. This participation allows [the commenter] to supervise and intervene to keep the daycare working to provide the best quality care for the children." The commenter asks, "If as Director [the commenter is] not involved in the direct patient care, how can [the commenter] effectively assist in the writing of care plans and the assessment of the progress of children in [the facility's] care?" (13)

77. COMMENT: With respect to proposed new N.J.A.C. 8:43J-7.1(c), a commenter states, "the nursing director should be available to count towards staffing level on a non-routine basis." (6)

78. COMMENT: A commenter states that in the facility at which she works, the nursing director "has administrative and direct care responsibilities." The commenter requests that the Department change proposed new N.J.A.C. 8:43J-7.1 to count the nursing director toward the facility's required minimum staffing level. (17)

RESPONSE TO COMMENTS 75 THROUGH 78: The proposed new rules would not prohibit a director of nursing, or a registered professional nurse acting in the nursing director's absence, from providing hands-on care. However, administration and supervision, and not the provision of direct care, are the primary functions of a PMDC facility's nursing director. Proposed new N.J.A.C. 8:43J-7.3 would specify the responsibilities of a nursing director, the performance of which the Department anticipates would consume the majority of the nursing director's day. As a nursing director would need to spend most of the day on these administrative duties, it would be inappropriate to count a nursing director toward the number of staffers who are to provide full-time direct care. Therefore, the Department will make no change on adoption in response to the comments.

N.J.A.C. 8:43J-7.2 Qualifications of Nursing Director

79. COMMENT: Several commenters suggest that the Department change proposed new N.J.A.C. 8:43J-7.2(a)1 to add "inpatient pediatric rehabilitation

hospital" to the list of the types of facilities at which a nursing director could obtain experience to satisfy the requirement of full-time pediatric nursing experience. (3, 5, 7, 8, 9, 15, 16 and 18)

RESPONSE: The experience a nurse would obtain at an "in-patient pediatric rehabilitation hospital" is similar to the experience that a nurse would obtain at the types of facilities proposed new N.J.A.C. 8:43J-7.2(a)1 identifies. Therefore, the Department will make a change on adoption at proposed new N.J.A.C. 8:43J-7.2(a)1 to add "in-patient pediatric rehabilitation hospital" to the list of facilities at which a nurse can gain the required experience.

80. COMMENT: A commenter states that proposed new N.J.A.C. 8:43J-7.2(a), which would establish the experience requirements for nursing directors, is not justified in light of "the proposed rule and the Department's related summary statements." The commenter asks that the Department change proposed new N.J.A.C. 8:43J-7.2(a) to contain the same standards as at existing N.J.A.C. 8:43F-19 proposed for repeal. (17)

RESPONSE: As stated in response to previous comments, the proposed new rules would establish licensure standards for a population of medically complex and/or technology-dependent children, consistent with the more stringent clinical eligibility standards at proposed new *N.J.A.C. 8:87*, adopted elsewhere in this issue of the New Jersey Register. This population generally would have greater care needs than children participating in pediatric day health services pursuant to the eligibility standards at existing *N.J.A.C. 8:86*. Therefore, the particular needs of the population services warrants the greater experiential requirements that proposed new N.J.A.C. 8:43J-7.2(a) would impose for nursing directors at PMDCs. Therefore, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-7.3 Responsibilities of the Nursing Director

81. COMMENT: A commenter states that the requirement at proposed new N.J.A.C. 8:43J-7.3, "that the nursing director document contact with the child's physician every two months, or as needed, would create excessive paperwork. Such contact with physicians may occur on a daily basis, in some circumstances. Documenting every single contact is unnecessary." (2)

RESPONSE: The Department disagrees with the commenter's assertion that contacting a child's primary healthcare provider every two months would create excessive paperwork, as this standard would impose a minimal burden. This contact is important, and the Department anticipates that this activity would be a large part of the nursing director's duties. If a nursing director determines that contacting a child's primary health care provider is necessary, then that contact is important enough to warrant documentation in the child's medical record. Therefore, the Department will make no change on adoption in response to the comment.

82. COMMENT: Proposed new N.J.A.C. 8:43J-7.3(b) would require the nursing director to maintain contact with each child's primary healthcare provider at least every 60 days and more often, as needed. While several commenters support this requirement, they state that a facility lacks the authority to enforce cooperation by a potentially unresponsive primary health care provider. The commenters request that the Department delete proposed new N.J.A.C. 8:43J-7.3(b), because proposed new N.J.A.C. 8:43J-3.4(e)10 would require a facility to maintain contact with a primary healthcare provider every two months for review of changes made in the child's interdisciplinary plan of care. (3, 5, 7, 8, 9, 15, 16 and 18)

83. COMMENT: A commenter states that the requirement at proposed new N.J.A.C. 8:43J-7.3(b) should be "modified to permit the PMDC facility nursing director to obtain the required information and maintain contact with the primary health care provider on a best efforts basis." (17)

RESPONSE TO COMMENTS 82 AND 83: Proposed new N.J.A.C. 8:43J-8.1(a)1 and 3 would require facility medical directors and administrators to establish policies for the provision of medical services and to coordinate the provision of medical services through a child's primary health care provider. Proposed new N.J.A.C. 8:43J-3.4(e)10 would require the review of the interdisciplinary plan of care with the child's primary health care provider at least every 60 days. Nursing directors could coordinate the contact that proposed new N.J.A.C. 8:43J-7.3(b) would require every 60 days with the review of the interdisciplinary plan of care that proposed N.J.A.C. 8:43J-3.4(e)10 would require every 60 days.

If a nursing director were unable to make contact with a child's primary health care provider, proposed new N.J.A.C. 8:43J-7.3(b) would require the nursing director to document the repeated attempts at contact. Proposed new N.J.A.C. 8:43J-8.3(a)2 would require the facility medical director to liaise with the child's primary health care provider to facilitate compliance with the facility's policies and procedures.

Therefore, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-7.4 Qualifications of Nursing Staff

84. COMMENT: Several commenters request that the Department change proposed new N.J.A.C. 8:43J-7.4 to delete the phrase "working with medically complex children," because of the nursing shortage. (3, 5, 7, 8, 9, 15, 16 and 18)

85. COMMENT: With respect to proposed new N.J.A.C. 8:43J-7.4, a commenter states, "there are few settings in which LPNs are able to gain experience in the care of medically complex infants and toddlers. Not many RN's have this experience either, unless they have worked on pediatric hospital floors, specialized children's hospitals, or home care with ventilator patients. Because of the shortage of nursing professionals with this type of experience, costs of maintaining a nursing staff of 100 [percent] with a year or more experience would be astronomical. While the desirability of having nurses with experience caring for medically complex children is reasonable, there must be some flexibility for some nurses to obtain the needed experience on-the-job." (2)

RESPONSE TO COMMENTS 84 AND 85: The Department appreciates the commenters' concerns regarding application of the experiential requirements for pediatric nurses at proposed new N.J.A.C. 8:43J-7.4. However, PMDC is a unique program serving medically complex and/or technology-dependent children and prior experience with this population is essential to working in a PMDC. Therefore, the Department will make no change on adoption in response to the comments.

86. COMMENT: A commenter states that proposed new N.J.A.C. 8:43J-7.4, which would require registered professional nurses and licensed practical nurses to have one year of full-time pediatric experience working with "medically complex children . . . is a departure from current standards and that nurses in pediatric acute

care settings are not required to have one year of full-time pediatric experience. In light of these considerations and inasmuch as the proposed rule and the Department's related summary statements thereof have not articulated any discernable increase in health benefits for PMDC beneficiaries that would be facilitated by the proposed change[, the commenter] requests that the Department maintain the same standards . . . contained in existing *N.J.A.C. 8:43F-19.5*." (17)

RESPONSE: As stated in response to previous comments, the proposed new rules would establish licensure standards for a population of medically complex and/or technology-dependent children, consistent with the more stringent clinical eligibility standards at proposed new *N.J.A.C. 8:87*, adopted elsewhere in this issue of the New Jersey Register. This population generally would have greater care needs than children participating in pediatric day health services pursuant to the eligibility standards at existing *N.J.A.C. 8:86*. Therefore, the particular needs of the population services warrants the greater experiential requirements that proposed new *N.J.A.C. 8:43J-7.4* would impose for nursing staff at PMDCs. Therefore, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-8.1 Provision of Medical Services

87. COMMENT: A commenter requests that the Department change proposed new *N.J.A.C. 8:43J-8.1* "to provide that, as in existing *N.J.A.C. 8:43F-8.1*, the medical director can serve as the child's primary care physician, subject to the limitations and contingencies of this dual role as set forth in *N.J.A.C. 8:43F-8* . . . consistent with the requirements of proposed *N.J.A.C. 8:87*." (17)

RESPONSE: The commenter appears to have read a prohibition in proposed new *N.J.A.C. 8:43J-8.1* that does not exist. The proposed new rule would not prohibit a facility's medical director from also serving as a child primary health care provider. Any service by the medical director as a child's primary health care provider would need to comport with proposed new *N.J.A.C. 8:87*, adopted elsewhere in this issue of the New Jersey Register, particularly at *N.J.A.C. 8:87-4.1(c)1*. Therefore, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-8.4 Role of Primary Health Care Providers

88. COMMENT: The commenter states that "requiring facilities to obtain documentation from non-compliant physicians [as required by proposed new N.J.A.C. 8:43J-8.4(b)] is not enforceable by the facility. Documentation of needs in our centers is supported by written physician orders." The commenter requests "that the proposed rules be amended to permit PMDC facilities to use their best efforts in obtaining completed forms and reviews of interdisciplinary plans as required by this section." (17)

RESPONSE: It would be essential for the primary care provider to approve a child's interdisciplinary plan of care as children who would receive services at PMDC facilities would be medically complex and/or technology-complex and each child's primary care provider would need to remain apprised of the child's care plan to maintain proper medical supervision of the services the PMDC facility would be providing. The child's primary health care provider is the child's "medical home" and as such, is the guide for the child's medical care, not the PMDC. The Department does not understand how the commenter can think it would be appropriate to provide services to a medically complex or technology-dependent child without a health record, an immunization record, orders, specifications as to mobility and assistance devices and verification that the child is free of acute infectious disease, all requirements of proposed new N.J.A.C. 8:43J-8.4(b). Providing services to a child without this information places not only that child at risk, but also all children in the PMDC. Therefore, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-8.5 Medical Equipment

89. COMMENT: Proposed new N.J.A.C. 8:43J-8.5(b)4 would require facilities to maintain "airway" among their emergency equipment. Several commenters request "a clarification of 'airway' as required equipment as [PMD] facilities do not intubate children [and no] object [is] placed in a child's mouth in the event of a seizure." (3, 5, 7, 8, 15, 16 and 18)

RESPONSE: The term "airway" at proposed new N.J.A.C. 8:43J-8.5(b)4 would refer to a medical device that addresses an obstructed airway. It would not mean

intubation. PMDC facilities would use such a device, and it is important that airways be on hand, because responding EMTs might not have properly sized equipment.

N.J.A.C. 8:43J-8.6 Agreement with Emergency Medical Providers

90. COMMENT: A commenter states, "it is unnecessary to require, under proposed [new N.J.A.C.] 8:43J-8.6, a facility to have an agreement with a local pre-hospital emergency provider because all hospitals are required to provide emergency care without a written agreement." (2)

RESPONSE: The commenter appears to have misinterpreted the intended meaning of proposed new N.J.A.C. 8:43J-8.6. Proposed new N.J.A.C. 8:43J-8.6 would require the establishment of an agreement with pre-hospital emergency services providers, that is, basic and advanced life support services, to respond to emergencies. This would ensure that PMDC facilities have made emergency response providers aware of their locations and potential service needs.

N.J.A.C. 8:43J-8.7 Medical Emergencies

91. COMMENT: A commenter states that proposed new N.J.A.C. 8:43J-8.7, which addresses procedures to be followed by staff in the event of a medical emergency, "should include Danielle's Law." (1)

RESPONSE: A facility providing services to a child covered by Danielle's Law, *N.J.S.A. 30:6D-5.1 et seq.*, is already required by Danielle's Law to comply with that law. Therefore, the Department will make no change on adoption in response to the comment.

92. COMMENT: A commenter describes proposed new N.J.A.C. 8:43J-8.7(b), which would require staff to receive training in the use of medical equipment, as being "essential for the safety of children and scheduling arrangements must ensure consistent shift coverage of appropriately trained personnel." (1)

RESPONSE: The Department agrees. Accordingly, proposed new N.J.A.C. 8:43J-8.7(b) would require facilities to have staff trained in the use of the required medical equipment.

93. COMMENT: A commenter states that proposed new N.J.A.C. 8:43J-8.7(c) should require facilities to use the Emergency Information Form for Children with

Special Needs developed by the American Academy of Pediatric "for consistency."
(1)

RESPONSE: The Department is without jurisdiction to require a physician not affiliated with a licensed healthcare facility to comply with this chapter. Physicians could use the Emergency Information Form for Children with Special Needs to which the rule refers at proposed new N.J.A.C. 8:43J-8.7(c), or could elect to provide a PMDC facility with the information the form requires in any form that the physician prefers. Therefore, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-9.1 Designation and Responsibilities of Consultant Pharmacist

94. COMMENT: With respect to proposed new N.J.A.C. 8:43J-9.1, a commenter states that PMDC facilities "do not prescribe or dispense drugs. They administer drugs. Only one other State with [PMDC facility] laws and regulations requires a consultant pharmacist, and that is only on an 'as needed' basis." The commenter states that a "child's physician coordinates all care of the child and is aware of all drugs prescribed to the child. [An] outside pharmacist should [not] be required to routinely second[-]guess the physician's orders and the dispensing pharmacist's advice. [The Department should change proposed new N.J.A.C. 8:43J-9.1 to require] that pharmaceutical consulting services be available as needed in case a second opinion is needed. In [the facilities on behalf of which the commenter comments,] medications are ADMINISTERED by a Licensed Nurse in accordance with the Nurse Practice Act. All medications are documented on a Medication Administration Record. [The] primary caregiver is administering these medications during the hours when the child is not in attendance at the [facility]." (6)

RESPONSE: A consultant pharmacist is necessary because children served in PMDC facilities typically take multiple medications and see multiple specialists. PMDC facilities administer these medications to children and provide a location at which a Medication Administration Record is in use and is reviewed. Therefore, the Department will make no change on adoption in response to the comment.

95. COMMENT: A commenter states that proposed new N.J.A.C. 8:43J-9.1(b) would "depart from the existing standards," which require record review every 60, as

opposed to 90, days. "Absent a clinically necessary requirement for such review[, the commenter] requests that the current 90-day review standard . . . be incorporated."
(17)

RESPONSE: The commenter is incorrect in her assertion that the current rules require a quarterly records review. *N.J.A.C. 8:43F-19.1(f)* clearly requires that a pharmaceutical records review for a pediatric participant occur "at least every 60 days." Therefore, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-9.2 Medication Administration Policies and Procedures

96. COMMENT: Proposed new N.J.A.C. 8:43J-9.2 would permit only registered professional nurses to administer medication. A commenter "recommends that licensed practical nurses also be permitted to administer medications," and suggests that the Department change proposed new N.J.A.C. 8:43J-9.2 on adoption to delete the phrase "registered professional," and to add in its stead the term, "licensed." (7)

97. COMMENT: A commenter "believes that licensed nurses, not just registered professional nurses, are qualified to perform this function," and request that the Department change proposed new N.J.A.C. 8:43J-9.2 on adoption "to permit them to do so." (9) Another commenter requests that the Department change proposed new N.J.A.C. 8:43J-9.2 on adoption "to permit medication administration by licensed professional nurses[,] as well as registered professional nurses." (17)

98. COMMENT: A commenter requests that the Department change proposed new N.J.A.C. 8:43J-9.2(a) "to permit medication administration by licensed professional nurses[,] as well as registered professional nurses." (17)

RESPONSE TO COMMENTS 96, 97 AND 98: A licensed practical nurse can administer medication under the direction of a registered professional nurse. *N.J.S.A. 45:11-23b*; *N.J.A.C. 13:37-6.2*. Therefore, the Department will change proposed new N.J.A.C. 8:43J-9.2(a) upon adoption to reflect that licensed practical nurses can administer medication pursuant to a delegation by a registered professional nurse.

99. COMMENT: A commenter requests that the Department change proposed new N.J.A.C. 8:43J-9.2(a)2 to "provide that orders may also be securely transmitted

as electronic copies in PDF or other secured format for electronic data transmission."
(17)

RESPONSE: Proposed new N.J.A.C. 8:43J-9.2(a) would require PMDC facilities to ensure that within 72 hours of a prescriber's issuance of a verbal order, the child's PMDC medical record either reflects the prescriber's countersignature of the PMDC staff member's written memorialization of the verbal order, or contains either the original written order or a plain paper telefacsimile thereof.

N.J.A.C. 8:43G-16.2(a) requires hospital medical staff to adopt policies and procedures for the verification of verbal orders. As PMDC facilities do not have "medical staff" comparable to hospitals through which to develop required policies and procedures, the proposed new rules would be more prescriptive to specify the required procedure.

For the reasons stated more fully above in response to previous comments, the establishment of electronic medical records standards would exceed the scope of this rulemaking.

100. COMMENT: A commenter suggests using "NJ Poison Control Guidelines, 'Right dose, right route, right child'" for proposed new N.J.A.C. 8:43J-9.2(b)4. (1)

RESPONSE: Proposed new N.J.A.C. 8:43J-9.2(a) would require that "the right medication is administered to the right child in the right dose through the right route of administration at the right time." The Department believes this standard would provide more specific direction to PMDC facilities than the slogan the commenter suggests. Therefore, the Department will make no change on adoption in response to the comment.

101. COMMENT: A commenter states that it is essential to record the required information in proposed new N.J.A.C. 8:43J-9.2(b)5 in writing. (1)

RESPONSE: Proposed new N.J.A.C. 8:43J-9.2(b)5 would require a facility to record the required information during medication administration. To specify the method of recordation would unduly restrict PMDC facilities from taking advantage of innovations in recordkeeping methods, such as by means of digital storage devices. The method of recordation would not be critical, provided the PMDC facility records

the medication administered, including the method of administration, and the record is retrievable for review, as necessary. Therefore, the Department will make no change on adoption in response to the comment.

102. COMMENT: A commenter strongly supports the notification of parents in the event of a medication error that is included in proposed new N.J.A.C. 8:43J-9.2 and suggests "[Statewide] tracking and public reporting of medication errors." (1)

RESPONSE: The Department acknowledges the commenter's support of proposed new N.J.A.C. 8:43J-9.2.

The New Jersey Patient Safety Act, P.L. 2004, c. 9, was enacted in 2004. That statute was designed to improve patient safety in hospitals and other health care facilities by establishing a medical error reporting system. The Department's Office of Health Care Quality Assessment publishes a number of Patient Safety Newsletters, Alerts and Reports concerning patient safety. This information is available to all licensed facilities and the public at <http://www.state.nj.us/health/ps/newsletter.shtml>.

Subject to the foregoing, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-10.1 General Requirements for Dietary Services

103. COMMENT: With respect to proposed new N.J.A.C. 8:43J-10.1, a commenter states, a "dietician is an unnecessary expense and is not needed on a regular basis" and that that most "medically needy" children are "managed by [a medical doctor who is a gastrointestinal specialist (MD/GI)] in consultation with a dietician or nutritionist in their office. Many times feeding plans are also ordered by the speech therapist, in consultation with the MD/GI specialist, based on the results of a swallow study. Medically complex children often have feeding issues that require the consultation and/or services of the speech and/or occupational therapist but may not require a dietician. Before any child enters a facility, a written history of any special nutrition or feeding needs of the child are recorded, and a physician or nutritionist plan meals accordingly. A dietician should be available for consulting as needed only." (6)

RESPONSE: Proposed new N.J.A.C. 8:43J-10.1 would not require a facility to have a dietitian as a full-time employee, but would require the facility to have a

dietitian assess each child upon admission, at least every 60 days thereafter, and as otherwise needed, to ensure that the child's nutritional needs are being met. Therefore, the Department will make no change on adoption in response to the comment.

104. COMMENT: With respect to proposed new N.J.A.C. 8:43J-10.1(d), a commenter inquires whether "the statement that the facility shall provide special diets and supplemental feedings when ordered by the child's primary health care provider mean that the facility is responsible for the purchase of these items? Parents should provide all formula/[PediaSure(R)], etc." The commenter further states that proposed new N.J.A.C. 8:43J-10.1(e) "should have an exception for the parent's provision of formula/[PediaSure(R) and needs] clarification with regard to the parents' provision of food versus formula." (6)

RESPONSE: Facilities would be responsible to provide all care to children participating in PMDC, and this care would include meeting their nutritional needs. Proposed new N.J.A.C. 8:43J-10.1(d) would require facilities to provide items necessary for a special diet and supplemental feedings. Therefore, the Department will make no change on adoption in response to the comment.

105. COMMENT: A commenter states that since not "all children in a PMDC have eating disorders [that] require direct observation by the nursing director," the Department should change proposed new N.J.A.C. 8:43J-10.1(f) to require food and formula to be served under the supervision of nursing staff if required by the child's interdisciplinary plan of care. (17)

RESPONSE: The commenter appears to have misread proposed new N.J.A.C. 8:43J-10.1(f), which would not require "direct observation" but "supervision," thereby making the nursing director ultimately responsible to oversee the provision of food and formula to children, to ensure that the facility serves the appropriate food and formula to the appropriate child. Therefore, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-11.1 Developmental Services

106. COMMENT: With respect to proposed new N.J.A.C. 8:43J-11.1(a), which would require PMDC facilities to employ child life specialists, a commenter

"advocates for . . . [Certified] Therapeutic Recreation Specialists [CTRSs and states that the PMDC facility] environment requires a professional to provide program planning and assessments, along with developmentally appropriate activities. A CTRS organizes a more structured environment for the child, which is important in a PMDC facility." (11)

107. COMMENT: A commenter requests that the Department include therapeutic recreation specialists in the licensing rules, as well as the already included child life specialists. The commenter states, "including both professional positions is crucial to the welfare of the children being served" and that "while the two professional positions may occasionally overlap, they are vital for a child's stability and development."

The commenter states, "Therapeutic recreation specialists contribute to a child's welfare by possessing skill sets that enable them to provide both rehabilitation (therapy) and recreation services. Therapeutic recreation specialists can be both generalists and specialists, and both perspectives are needed in the various healthcare environments. Recreation therapists add value in a medical setting by not being a medical professional." The commenter states that recreation therapists reduce stress and confusion in a medical environment. (19)

108. COMMENT: A commenter states, "Certified Therapeutic Recreation Specialists should be the qualified professional in the medical day care setting." The commenter states that Certified Therapeutic Recreation Specialists (CTRSs) provide both treatment services and recreational services, using "a wide range of activity and community-based interventions and techniques to improve the physical, cognitive, emotional, social and leisure needs of the people they serve. Recreational therapists assist clients to develop skills, knowledge and behaviors for daily living and community involvement. The therapist works with the client and their family to incorporate specific interests and community services into therapy to achieve optimal outcomes that transfer to their real life situation."

The commenter states that there are a "number of positive health outcomes resulting from therapeutic recreation/recreational therapy programs." The commenter states that recreation therapy interventions in the pediatric population focus on

"developmentally appropriate activities, social skills, developmental play skills, and gross and fine motor skills."

The commenter states that certification for recreation therapists is provided by the National Council for Therapeutic Recreation Certification, "which requires a bachelors degree or higher from an accredited university, a formal internship, and the passing of a national certification examination."

The commenter states, "The two distinct disciplines of Child Life and Therapeutic Recreation vary in their professional definitions, professional preparation/education, philosophical base, and operational strengths" and that "therapeutic recreation and child life are not interchangeable professions and cannot substitute for each other."

The commenter states that a "Recreation Therapist provides therapeutic activities to promote developmental milestones[,] provides social, play and cognitive skills[, and] designs and facilitates educational and recreational programming within the medical day care setting." The commenter states, "thorough initial evaluation and ongoing assessments to determine recreation, social and cognitive skills guide the Recreation Therapist to develop individual and group therapeutic goals."

The commenter states that child life professionals serve children and families under stress "or who are experiencing hospitalization or a medical procedure," and that the "child life specialist focuses on the strengths and sense of well-being of children while promoting their optimal development potential and minimizing the adverse effects of children's experiences in a hospital setting."

The commenter states that it is challenging to determine which professional is best suited for a specific setting, and "given the nature of [a PMDC facility], the Certified Therapeutic Recreation Specialist is a more appropriate professional to hold the position required. The [PMDC] environment needs professionals whose strengths are program planning, assessment, and developmental play facilitation--those services provided by the Certified Therapeutic Recreation Specialist."

The commenter concludes, "Therapeutic Recreation and Certified Therapeutic Recreation Specialists should be included in the proposed amendments, repeals, and new rules for the licensure of [PMDC] facilities." (12)

RESPONSE TO COMMENTS 106, 107 AND 108: The Department acknowledges the commenters' description of the scope of practice of Certified Therapeutic Recreation Specialists.

The Department considered several factors in proposing to require certified child life specialists to coordinate developmental services in PMDC facilities at proposed new N.J.A.C. 8:43J-11.1.

First, proposed new N.J.A.C. 8:43J-11.1 would be consistent with existing *N.J.A.C. 8:43G-22.16(d)*, which requires hospitals to have child life specialists available as members of treatment teams for pediatric patients hospitalized in pediatric intensive care units. PMDC facilities would likewise serve technology-dependent and medically complex children, many of whom have been and/or would be at risk of hospitalization and PMDC generally would serve as an alternative to extended hospitalization of these children. Thus, having a child life specialist as a member of the PMDC developmental services team would ensure the continuity of this beneficial approach to pediatric care in the PMDC venue.

Second, in developing proposed new N.J.A.C. 8:43J-11.1, the Department considered model standards for providing services to medically complex and technology-dependent children in an out-patient setting known as prescribed pediatric extended care developed pursuant to Grant MCJ-123490 administered by the Maternal and Child Health Bureau of the United States Department of Health and Human Services. Patricia M. Pierce and Steve A. Freedman, Prescribed Pediatric Extended Care (PPEC). Medical Day Care. A Cost-Effective Alternative for Families of Medically Dependent Children - Final Report, Maternal and Child Health Bureau, Health Resources and Services Administration, United States Department of Health and Human Services, Rockville, MD, 1989 ("PPEC" standards), available from the National Technical Information Service, www.ntis.gov, as NTIS Order Number PB92-103423. These standards recommend the retention of child life specialists to direct the administration of developmental services in medical day care facilities.

The Department also considered national certification requirements for the Certified Child Life Specialist credential, administered by the Child Life Counsel, Inc, which established the Certified Child Life Specialist credential in 1985. Child Life

Counsel, Inc., Certified Child Life Specialist Candidate Manual (January 2008 edition), available from the Child Life Council, Inc., 11820 Parklawn Dr., Suite 240, Rockville, MD 20852-2529, (301) 881-7090, Telefacsimile: (301) 881-7092, and available at <http://www.childlife.org/files/CandidateManual2008FINAL.pdf>. To obtain the Certified Child Life Specialist credential, a candidate must possess a bachelor's degree, complete 10 college-level courses in the subject of child life or a related subject, obtain 480 hours of child life clinical experience under the direct supervision of a Certified Child Life Specialist, and obtain a passing score on the Child Life Professional Certification Examination. *Id.* at 2 through 5.

The National Council for Therapeutic Recreation Certification publication, Certification Standards Part I: Information for New Applicants at 6 through 17 (January 2009), available at <http://www.nctrc.org/documents/1NewAp.pdf>, describes the academic and experiential requirements for certification as therapeutic recreation specialists. These requirements are not equivalent to experiential requirements for certification as a Child Life Specialist, because the focus for certification as a Therapeutic Recreation Specialist in academic preparation and clinical experience is primarily on adult populations and training and work with children appear to be elective, that is, optional, instead of mandatory requirements. Indeed, it is possible that some Certified Therapeutic Recreation Specialists enter professional practice without ever having had direct clinical experience with children.

Further, while persons holding the Certified Therapeutic Recreation Specialist credential may meet the educational requirements for a Certified Child Life Specialist certification, they neither typically nor necessarily have clinical experience with children comparable to that of child life specialists, as they appear more typically to provide services to adult and disabled populations. See, for example, this description by the United States Department of Labor: "Recreational therapists held about 25,000 jobs in 2006. About 70 percent were in nursing and residential care facilities and hospitals. Others worked in State and local government agencies and in community care facilities for the elderly, including assisted-living facilities. The rest worked primarily in residential mental retardation, mental health, and substance abuse facilities; individual and family services; Federal Government agencies;

educational services; and outpatient care centers. Only a small number of therapists were self-employed, generally contracting with long-term care facilities or community agencies to develop and oversee programs." Bureau of Labor Statistics, United States Department of Labor, Occupational Outlook Handbook, 2008-2009, available at <http://www.bls.gov/oco> (the Occupational Outlook Handbook uses the terms "recreational therapist" and "therapeutic recreational therapist" interchangeably). In contrast, child life specialists' training and experiential requirements focus specifically on the developmental needs of children and families. See generally the Certified Child Life Specialist Candidate Manual, above.

For these reasons, the Department declines to authorize PMDC facilities to retain certified therapeutic recreational therapists to coordinate developmental services in PMDC facilities instead of, or in addition to, certified child life specialists. Therefore, the Department will make no change on adoption in response to the comments.

109. COMMENT: Several commenters support proposed new N.J.A.C. 8:43J-11.1(a), which would require the employment of a full-time child life specialist, and recommend that the Department authorize PMDC facilities to satisfy this requirement "on a consultancy basis as required by the children's needs." The commenters state that the role of a child life specialist would be limited in a PMDC facility and a full-time child life specialist would be costly. The commenters suggest that the Department change proposed new N.J.A.C. 8:43J-11.1(a) to permit a facility to contract with a child life specialist on an as-needed basis. (3, 5, 7, 8, 9, 15, 16, 17 and 18)

RESPONSE: A PMDC facility would need a full-time child life specialist to perform the services that proposed new N.J.A.C. 8:43J-11.1 would require and to serve as a PMDC facility's coordinator of all developmental and rehabilitative services that a facility would provide. Therefore, the Department will make no change on adoption in response to the comment.

110. COMMENT: A commenter supports the inclusion of a full-time child life specialist as required by proposed new N.J.A.C. 8:43J-11.1 "so that the 'whole child' is considered." (1)

RESPONSE: The Department agrees with the commenter and thanks her for her support.

111. COMMENT: In response to the requirements at proposed new N.J.A.C. 8:43J-11.1(e)1, which would require a child's parent to be included in care-related conferences, a commenter states that parents "must be informed of all aspects of their child's care." (1)

RESPONSE: The Department agrees, which is why the requirement for a child's parent inclusion in care-related conferences is included in proposed new N.J.A.C. 8:43J-11.1(e)1.

112. COMMENT: A commenter states, "Social workers and nurse practitioners have responsibilities, education, and experience overlapping that and exceeding those of newly mandated child-life specialists. [Therefore,] proposed N.J.A.C. 8:43J-11.1, requiring the employment of a full-time child-life specialist, is redundant and unnecessary."

The commenter states that the assessment functions are performed by the facility's licensed social worker and nurse practitioner, whose assessments are reviewed in each child's interdisciplinary review and that "Based upon these reviews, the Center's nurse practitioner prescribes medications, physical therapy, occupational therapy and/or speech therapy, where appropriate, in consultation with each child's primary care physician."

The commenter states that the social worker in the facility on behalf of which the commenter comments would not be permitted to sit for the child-life specialist certification exam "until after completing yet another 480 hours of child life clinical experience under the direct supervision of a Certified Child Life Specialist, an expensive, time-consuming, unnecessary and redundant process."

The commenter urges "the Department to allow the assessments that would be conducted by a child-life specialist to be performed by other competent professionals." (2)

RESPONSE: The child life specialist's position is not redundant. It appears that the facility the commenter represents is providing services that the proposed new rules would not require. Pursuant to the proposed new rules, a facility's nurse

practitioner would not prescribe medications, physical therapy, occupational therapy and/or speech therapy. These would be the responsibilities and functions of the child's primary health care provider, which would be neither the facility nor its staff.

113. COMMENT: Several commenters recommend that the Department change proposed new N.J.A.C. 8:43J-11.1(b) to delete the requirement that a child life specialist perform the assessment; change proposed new N.J.A.C. 8:43J-11.1(c) to require that the interdisciplinary team, instead of the child life specialist, consult with each child's rehabilitation therapist, if indicated, on recommendations for the activities and goals that are to be included in the interdisciplinary plan of care and assert that a child life specialist is necessary only as needed; and change proposed new N.J.A.C. 8:43J-11.1(d) to indicate that the child life specialist is an as-needed consultant. (3, 5, 7, 8, 9, 15, 16 and 18)

RESPONSE: The role of a child life specialist in a PMDC facility would be to coordinate rehabilitative and developmental services. Assessments are within the scope of a child life specialist's training. The professionals the commenters identify as potential substitutes to perform this function do not have the breadth of practice of a child life specialist. Child life specialists have the training necessary to coordinate across a spectrum that the other professionals do not, because performance of the responsibilities at proposed new N.J.A.C. 8:43J-12.1 is not within the respective scopes of practice of the other professionals the commenters identify. Therefore, the Department will make no change on adoption in response to the comments.

N.J.A.C. 8:43J-11.2 Rehabilitation Services

114. COMMENT: Several commenters have "a serious concern" regarding proposed new N.J.A.C. 8:43J-11.2, which would require PMDC facilities "to provide on-site rehabilitation services particularly since this mandated service, according to proposed *N.J.A.C. 8:87*, will be included in the facility's per diem rate and not billable as a separate service." The commenters "support the intent that a primary healthcare provider should be permitted to write an order for whatever rehabilitation services he or she believes the child requires, but it is unreasonable to require the facility to absorb the cost of providing these services within the established per diem rate for

PMDC services." The commenters state that since these costs "are unpredictable and based on the children's needs," a center will not be able to plan its budget.

The commenters state, "therapists are in great demand, and recruitment can take many months given that there is a well-recognized shortage of rehabilitation professionals. Under this [notice of] proposal, if an on-site therapist resigns or takes extended leave, the facility's license will be in constant jeopardy during the recruitment period, and the children will not be receiving the care they need. In addition, a facility will not be able to admit children who have a need for rehabilitation services even if they otherwise meet all the admission criteria, demonstrating this proposed provision's unintended effect of limiting children's access to services."

The commenters recommend "that the Department continue to permit separate billing for prescribed therapies as a way to ensure that children receive the care they need to achieve their optimal functional status and quality of life [and] that the Department work to implement appropriate oversight and audit strategies and plans to address any vulnerabilities it has identified or to identify vulnerabilities under the Medicaid program going forward."

The commenters suggest that the Department change proposed new N.J.A.C. 8:43J-11.2(a) to authorize "rehabilitation services either on-site or off-site under arrangement with another provider." (3, 5, 7, 8, 15, 16 and 18)

115. COMMENT: A commenter "objects to the mandate that rehabilitation services be provided on-site, especially since proposed *N.J.A.C. 8:87* would require that these services be included in a facility's per diem rate rather than be billed separately when these services are required." The commenter requests that the Department change proposed new N.J.A.C. 8:43J-11.2(a) "to permit these services to be provided either on-site or off-site with a rehabilitation services provider under contract with the facility." (9)

116. COMMENT: A commenter states that it would like to "ensure that the full range of rehabilitative services is made available to the children who need them in a way that does not financially penalize programs which take the more complicated cases." (19)

117. COMMENT: With respect to proposed new N.J.A.C. 8:43J-11.2(a), a commenter states, "therapies are included in the daily rate with no limitations on the number of therapies. Florida, Massachusetts, Pennsylvania and Florida all reimburse for therapies separately. In Georgia, Low Tech children get [one to two] physical or speech therapies per week included in the rate, and High Tech children get [three to five] physical or speech therapies per week. Occupational therapy is reimbursed separately. [The commenter] would recommend that physical and speech therapies be provided in limited amounts, and occupational therapy be provided as a separately reimbursed item." (6)

118. COMMENT: A commenter expresses a "deep concern" regarding proposed new N.J.A.C. 8:43J-11.2, which would require PMDC facilities "to provide on-site rehabilitation services as this mandated service, according to proposed *N.J.A.C. 8:87*, will be included in the facility's per diem rate and not billable as a separate service." The commenter asks for regulatory language limiting the amount of services the facility is required to provide, or access will be limited to these services as the "facility cannot afford to forego reimbursement outside of the per diem rate." The commenter recommends that the requirement for on-site services be deleted and only that access to speech language pathology, physical therapy and/or occupational therapy be provided. (17)

RESPONSE TO COMMENTS 115 THROUGH 118: The proposed new rules at N.J.A.C. 8:43J establish facility licensure standards. The issues the commenters raise relate to Medicaid reimbursement for PMDC services and therefore exceed the scope of the notice of proposal. The commenters raise similar comments on the proposed new rules at *N.J.A.C. 8:87*, which address Medicaid reimbursement. The Department responds to those comments in the notice of adoption of *N.J.A.C. 8:87* that appears elsewhere in this issue of the New Jersey Register.

119. COMMENT: A commenter requests "that proposed N.J.A.C. 8:43J-11.2(b) be clarified to explicitly permit speech-language pathology, physical therapy and/or occupational therapy evaluation to be provided either on-site or off-site with a service provider under contract with the facility [and that proposed new N.J.A.C. 8:43J-11.3(a)] apply only when these services are provided on-site." (8)

120. COMMENT: Several commenters suggest that the Department change proposed new N.J.A.C. 8:43J-11.2(b) to authorize the provision of speech-language pathology, physical therapy and/or occupational therapy "either on-site or off-site under arrangement with another provider." (3, 5, 7, 8, 15, 16 and 18)

RESPONSE TO COMMENTS 119 AND 120: Providing rehabilitation services on-site in the context of a PMDC program would be more desirable because it would be less disruptive to PMDC beneficiaries' overall programs, would assure better integration with other disciplines, and would obviate the need for transporting a child to an outlying facility, thus minimizing safety risks and personnel needs related to transportation. Therefore, the Department will make no change on adoption in response to the comments.

121. COMMENT: A commenter asks that the Department change proposed new N.J.A.C. 8:43J-11.2(d) to provide that "written progress notes on each therapy session be obtained from treating therapists and maintained not by therapists, but rather, by the facility." (9)

122. COMMENT: Several commenters suggest that the Department change proposed new N.J.A.C. 8:43J-11.2(d) to add the phrase "obtained from the treating therapists" and to delete the phrase "by the therapists." (3, 5, 7, 8, 15, 16 and 18)

RESPONSE TO COMMENTS 121 AND 122: The Department agrees with the commenters' suggestion that it would be appropriate to require PMDC facilities to maintain accurate and complete records of therapy sessions as part of children's medical records at the facility and not in potentially separate records. This is because therapies would be part of the services proposed new N.J.A.C. 8:43J would require PMDC facilities to provide to children at the facility. This would also be consistent with proposed new N.J.A.C. 8:43J-14.1(a) and (c), which would require facilities to document all services provided to a child participating in PMDC and to maintain the documentation of those services in a complete medical record as one unit in one location in a PMDC facility. Moreover, this would simplify the recordkeeping burden of the proposed new rules while minimizing the risk that records could be lost if they leave the facility. Finally, this would ensure that in developing an interdisciplinary plan of care, the interdisciplinary team would be sure to have all records at their disposal

as needed. Therefore, the Department will make a change upon adoption at proposed new N.J.A.C. 8:43J-11.2(d) to require therapists to enter the written progress notes they create during therapy sessions into the child's medical record kept at the facility, rather than to maintain them as a separate record.

123. COMMENT: A commenter asks that the Department change proposed new N.J.A.C. 8:43J-11.2(d) to require that "physical therapists, occupational therapists and speech-language pathologists collaborate as needed with the child life specialist under contract with the facility." (9)

124. COMMENT: Several commenters suggest that the Department change proposed new N.J.A.C. 8:43J-11.2(e) to provide that collaboration would be required "as needed with the consultant child life specialist." (3, 5, 7, 8, 15, 16 and 18)

RESPONSE TO COMMENTS 123 AND 124: Proposed new N.J.A.C. 8:43J-11.1(c) would require child life specialists to coordinate developmental and rehabilitative services provided to PMDC beneficiaries. As part of this function, child life specialists must collaborate with physical therapists, occupational therapists and speech-language pathologists. Therefore, the Department will make no change on adoption in response to the comments.

N.J.A.C. 8:43J-11.3 Rehabilitation Supplies and Equipment

125. COMMENT: Several commenters recommend that the Department change proposed new N.J.A.C. 8:43J-11.3, which would establish requirements relating to the provision of rehabilitative therapy at a PMDC facility, "to be applicable only when the PMDC will provide rehabilitation services on-site." (3, 5, 7, 8, 15, 16 and 18)

126. COMMENT: A commenter requests, "in light of [the commenter's] request that rehabilitation services can be provided off-site," that proposed new N.J.A.C. 8:43J-11.3 "apply only when these services are provided on-site." (9)

127. COMMENT: With respect to proposed new N.J.A.C. 8:43J-11.3, a commenter asks if "it is necessary to mandate specific rehabilitative equipment and supplies to be kept at the facility." The commenter states, "it utilizes the therapy services of independent contractors, who bring the needed equipment with them.

Thus, to the extent the [proposed new N.J.A.C. 8:43J-11.3 would] require specific items to be kept at the facility, such requirements are unnecessary." (2)

RESPONSE TO COMMENTS 125 THROUGH 127: Proposed N.J.A.C. 8:43J-11.2(a) would require PMDC facilities to provide rehabilitation therapy services on-site. Accordingly, PMDC facilities would need to maintain equipment on-site to facilitate the provision of these services. Nurses could provide therapy throughout the day using the equipment that proposed new N.J.A.C. 8:43J-11.3 would require. Therefore, the Department will make no change on adoption in response to the comments.

128. COMMENT: Several commenters inquire as to the purpose of the requirement at proposed new N.J.A.C. 8:43J-11.3(b) that a facility have an inflatable mattress. The commenters state, "an air mattress could be unsafe as it poses a possible suffocation hazard, and . . . recommend its removal from the list of required equipment." The commenters recommend, "a pediatric therapy table with mat be included" instead. (3, 5, 7, 8, 15, 16 and 18)

RESPONSE: For the reason the commenters state, the Department will change proposed new N.J.A.C. 8:43J-11.3(b) on adoption to delete "air mattress" from the list of required equipment and to add "pediatric therapy table with mat" to the list of required equipment.

129. COMMENT: With respect to proposed new N.J.A.C. 8:43J-11.3 a commenter states, "therapy equipment specific to the individual child should be provided by the child's [durable medical equipment] company (example: standers, feeding chairs, [ankle and/or foot orthotics,] etc.) The [p]roposed [r]ules need to clarify this distinction." (6)

RESPONSE: Proposed new N.J.A.C. 8:43J-11.3 would require PMDC facilities to provide the specified equipment and any other medically indicated equipment necessary to meet the needs of a specific child. The Department perceives no lack of clarity in this requirement. Therefore, the Department will make no change on adoption in response to the comment.

130. COMMENT: A commenter states that the requirement for "other medically indicated equipment" at proposed new N.J.A.C. 8:43J-11.3(b)10 was "a good addition so as to not limit the list of required equipment. (1)

RESPONSE: The Department agrees with the commenter, which is why it included the provision at proposed new N.J.A.C. 8:43J-11.3(b)10 that a facility provide medically indicated equipment, which may be necessary to meet the rehabilitation needs of a specific child.

N.J.A.C. 8:43J-12.2 Provision of Social Work Services

131. COMMENT: With respect to proposed new N.J.A.C. 8:43J-12.2(c), a commenter states, "social work services are not usually provided directly at facilities in Georgia, Florida and Pennsylvania, but facilities do refer children for social work services if needed and these services are paid for separately. Facilities in those states also have availability on a consulting basis, if needed. [Institutions,] such as hospitals and nursing homes use social work services on a regular basis, but you would not expect to see this type of utilization in a day care setting. Not all children require social work services, and to require that a social worker spend at least 30 minutes per child per week is unnecessary. In [PMDC facilities] operated by [the company on behalf of which the commenter comments], the primary nurse for the child and/or clinical coordinator should make referrals as necessary and appropriate, and [the company] maintains both a local and [S]tate resource guide on site." (6)

RESPONSE: In the Department's experience with pediatric day health services facilities, children in these facilities need the services of a social worker for 30 minutes per week, on average. The 30-minute requirement is not for each child, but is an average time requirement for all children receiving services in the facility. In the Department's experience, some children may require much more than 30 minutes of social work services a week, while others may require less. Therefore, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-13.1 Physical Plant

132. COMMENT: With respect to proposed new N.J.A.C. 8:43J-13.1(g), a commenter "questions why facilities licensed before these [p]roposed [r]ules are

exempt from the physical requirements if the physical requirements are an integral part of the rules." (6)

RESPONSE: There are times when a facility may be forced to upgrade or close. The Department generally exempts existing facilities that are compliant with existing physical plant standards from compliance with new physical plant standards in conformity with the New Jersey Uniform Construction Code (UCC) at *N.J.A.C. 5:23-6.2(f)*, addressing "Pre-Existing Buildings." That rule states, "Buildings or structures legally in existence at the time of the adoption or subsequent amendment of [the UCC] may continue in use and nothing herein shall be interpreted as requiring the repair, renovation, alteration or reconstruction of such building, except as provided at *N.J.A.C. 5:23-2.32*, Unsafe Structures." The Department incorporates the UCC by reference at *N.J.A.C. 8:43J-13.1(a)*.

The exemption at proposed new *N.J.A.C. 8:43J-13.1(g)* would apply only to the extent that earlier physical plant standards with which the licensee previously complied addressed the specific physical plant requirements in the proposed new rules that the licensee contends would require repair, renovation, alteration or reconstruction for the licensee to comply. The exemption would not be available with respect to physical plant standards that the earlier standards did not address. Compliance with the later standard would be necessary unless it were technically infeasible to comply or the Department were to issue a waiver or modification pursuant to proposed new *N.J.A.C. 8:43J-2.13*. Similarly, new facilities that would have difficulty meeting physical plant standards might elect to apply to the Department for a waiver pursuant to *N.J.A.C. 8:43J-2.13*.

Based on the foregoing, the Department will make no change on adoption in response to the comment.

133. COMMENT: With respect to proposed new *N.J.A.C. 8:43J-13.1(g)*, which would exempt existing facilities from the new physical plant requirements unless facilities were to renovate or construct additions to their existing physical plants, several commenters request clarification of the meaning of the terms, "renovation" and "construct additions." (3, 5, 7, 8, 15, 16, 17 and 18)

RESPONSE: The Department agrees that the undefined terms "renovation" and "construct additions" are unclear and potentially subject to differing interpretations. Rather than attempting to define these terms and risk establishing a meaning that potentially conflicts with the UCC, which the Department incorporates by reference at N.J.A.C. 8:43J-13.1(a), the Department will make a change on adoption at proposed new N.J.A.C. 8:43J-13.1(g) to delete the phrase, "and until a facility renovates or constructs additions to the existing physical plant," and to add the phrase, "subject to N.J.A.C. 5:23-6 with respect to a rehabilitation project," to establish that the exemption must conform to existing UCC requirements.

N.J.A.C. 8:43J-13.2 Functional Service Areas

134. COMMENT: With respect to proposed new N.J.A.C. 8:43J-13.2(a)2, a commenter suggests "than an employees' lounge can be the kitchen area." (6)

RESPONSE: It would be grossly inappropriate and violate *N.J.A.C. 8:24 Sanitation In Retail Food Establishments and Food and Beverage Vending Machines* to place an employees' lounge in a health care facility's food preparation area. Therefore, the Department will make no change on adoption in response to the comment.

135. COMMENT: With respect to proposed new N.J.A.C. 8:43J-13.2(a)7, a commenter states, "[the facility on behalf of which the commenter comments does] not dispense drugs on-site ([it] ADMINISTER[S] drugs) and, therefore, no functional area for pharmaceutical services is necessary." (6)

RESPONSE: Proposed new N.J.A.C. 8:43J-13.2(a)7 would not require facilities to have an area from which drugs are dispensed, but rather would require facilities to have an area at which pharmaceuticals can be properly and securely stored, that is, a functional area for pharmaceutical services. Therefore, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-13.3 Toilet Facilities

136. COMMENT: Several commenters object to proposed new N.J.A.C. 8:43J-13.3(b), which would require PMDC facilities to maintain a ratio of one toilet and sink for every 10 children, instead of one toilet and sink for every 15 children, as existing *N.J.A.C. 8:43F-14.3(b)3* provides. The commenters state that many of the children

attending PMDC facilities are in diapers, making the stricter ratio unnecessary, and request that the Department maintain the existing standard. (3, 5, 7, 8, 9, 15, 16 and 18)

137. COMMENT: A commenter states that retrofitting PMDC facilities to meet the new standard at proposed new N.J.A.C. 8:43J-13.3(b) would be costly. (9)

138. COMMENT: With respect to proposed new N.J.A.C. 8:43J-13.3(b), a commenter requests that the requirement of one toilet and one sink for every 10 children "be based upon those children old enough to make use of a bathroom." (2)

139. COMMENT: A commenter states that many children in a PMDC are in diapers, making the stricter "ratio of toilet facilities unnecessary. In the absence of any issue relative to care or participant rights," the commenter recommends "maintaining the current ratio." (17)

RESPONSE TO COMMENTS 136 THROUGH 139: Pursuant to the definition of "child" at proposed new N.J.A.C. 8:43J-1.2, children would be eligible to attend PMDC until the sixth birthday. Pursuant to proposed new N.J.A.C. 8:43J-2.3(b) and 8:87-2.1(a)3, a facility could have up to 30 children attending on a particular date. Depending on the functional capabilities and age of the children at a particular facility, it is possible that all 30 of these children could be toilet-trained and require access to toilet facilities on a given day. Thus, it is appropriate for the proposed new rules to operate from the premise that facilities must provide toilet facilities that would accommodate as many as 30 children.

There is ongoing turnover of children attending PMDC facilities. It would be inappropriate to develop a standard for fixtures based on the number of toilet-trained children attending a facility at a particular moment, as one commenter recommends. This standard would require facilities to add toilet facilities as their population turns over, and could lead to some facilities being unwilling or unable to accept older children into their programs rather than to trigger the need for construction of additional toilet facilities.

In developing the standard requiring one toilet and sink for every 10 children at proposed new N.J.A.C. 8:43J-13.3(b) would require, the Department took into consideration the recommendations of the American Academy of Pediatrics, the

American Public Health Association, the National Resource Center for Health and Safety in Child Care of the University of Colorado, and the Maternal and Child Health Bureau of the Health Resources and Services Administration of the United States Department of Health and Human Services, as expressed in their publication, *Caring for Our Children: National Health and Safety Performance Standards: Guidelines for Out-of-Home Child Care, Second Edition* at 238 (Child Care Performance Standards) (American Academy of Pediatrics, American Public Health Association, and National Resources Center for Health and Safety in Child Care, 2002). This publication is available for purchase from the American Academy of Pediatrics, PO Box 747, Elk Grove Village, IL 60009-0747, (888) 227-1770, Telefacsimile: (847) 228-1281, <http://www.aap.org>, Order # MA0191, and from the American Public Health Association, Publications Sales, PO Box 933019, Atlanta, GA 31193-3019, (888) 320-2742, Telefacsimile: (301) 843-0159 <http://secure.apha.org/source/orders/index.cfm>. It is also downloadable at <http://nrc.uchsc.edu/CFOC/>.

Child Care Performance Standard 5.122 at 248 recommends a ratio of one toilet and sink for up to 10 toddlers and preschool-age children. In comparison, it recommends a ratio of one to 15 for school-age children. As their rationale for recommending a greater number of toilets for toddlers and preschoolers than for school-age children, the authors note, "Young children use the toilet frequently and cannot wait long when they have to use the toilet. The ratio of [one to 10] is based on best professional experience of early childhood educators who are facility operators. This ratio also limits the group that will be sharing facilities (and infections)." *Id.*

Indeed, the authors would recommend an even greater number of toilets in certain circumstances: "A ratio of [one] toilet to every 10 children may not be sufficient if only one toilet is accessible to each group of 10, so a minimum of [two] toilets per group is preferable when the group size approaches 10. However, a large toilet room with many toilets used by several groups is less desirable than several small toilet rooms assigned to specific groups, because of the opportunities such a large room offers for transmitting infectious disease agents." *Id.*

Thus, the ratio at proposed new N.J.A.C. 8:43J-13.3(b) would establish a conservative minimum standard that would meet but not exceed the Child Care

Performance Standard. At the same time, in not requiring two toilets per 10 children, as the authors suggest in their commentary, described above, proposed new N.J.A.C. 8:43J-13.3(b) would reflect the possibility that the number of toilet-trained children attending PMDC may be smaller than the number of toilet-trained children attending a regular childcare facility. There may be more children in diapers attending PMDC due to the possibility that their medical complexity and/or technology-dependency may cause them to have less functional ability than children attending PMDC, and more may be in diapers.

Pursuant to proposed new N.J.A.C. 8:43J-13.1(g), proposed new N.J.A.C. 8:43J-13.3(b) would apply to new licensees. Facilities licensed in accordance with existing or prior standards would not need to retrofit their facilities to accommodate the ratio of one to 10.

Based on the foregoing, the Department will make no change on adoption in response to the comments.

N.J.A.C. 8:43J-13.4 Administration Areas

140. COMMENT: With respect to proposed new N.J.A.C. 8:43J-13.4 (a)2, a commenter states, "wheelchair storage should not have to be located in the reception area." (6)

RESPONSE: The reception area would be the appropriate wheelchair storage area because it is accessible when one is entering or exiting a facility. Therefore, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-13.8 Child Care Areas

141. COMMENT: With respect to proposed new N.J.A.C. 8:43J-13.8(a) a commenter states, "developmentally appropriate care means that children should be grouped according to chronological and developmental age" and that the proposed new rules would not require "the separation of children into appropriate groups." (6)

142. COMMENT: Several commenters state that proposed new N.J.A.C. 8:43J-13.8(a) "does not include pre-school-aged children and . . . that PMDC facilities currently already group children based on developmental status, not ambulatory status because this is more appropriate with regard to fulfilling their overall interdisciplinary care plan goals." The commenters ask that the Department change

proposed new N.J.A.C. 8:43J-13.8 by deleting proposed paragraphs (a)1 and 3; adding as new paragraph (a)1, "1. Infants"; and adding as new paragraphs (a)3 and 4, "3. Pre-school aged children; and 4. Children whose medical condition precludes integration based on developmental stage." (3, 5, 7, 8, 15, 16 and 18)

RESPONSE TO COMMENTS 141 AND 142: Proposed new N.J.A.C. 8:43J-13.8 would require PMDC facilities to provide the child care areas specified therein because medical issues would often preclude grouping children in a PMDC facility based on chronological or developmental age. Grouping children by ambulatory status would be appropriate because it would pose less risk of injury to one child from another child in the grouping. Proposed new N.J.A.C. 8:43J-13.8 would not prohibit a facility from grouping children into subsets based on chronological or developmental age within the specified child care areas. As the regulated community and the Department develop experience with the proposed new rules, the Department will revisit this issue.

Based on the foregoing, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-13.9 Cribs and Mats

143. COMMENT: With respect to proposed new N.J.A.C. 8:43J-13.9(a)1, several commenters inquire as to the rationale for the requirement of three feet of space between cribs and/or sleeping mats. The commenters request the Department to reconsider whether there must be three feet on all sides of the cribs and/or sleeping mats. The commenters state that if three feet of space is necessary to allow PMDC staff to provide care to a child, perhaps requiring the mandated space to be on at least one side would be sufficient. The commenters state that three feet of space on all sides would be a burden for facilities. The commenters recommend that the Department change proposed new N.J.A.C. 8:43J-13.9(a)1 to allow a minimum of three feet on at least one side of, rather than between cribs or sleeping mats. (2, 3, 5, 7, 8, 9, 15, 16 and 18)

RESPONSE: The requirement at proposed new N.J.A.C. 8:43J-13.9(a)1 of three feet of space on each side between cribs and sleeping mats would be necessary to ensure that staff have ready access to a child, especially in an

emergency. Therefore, the Department will make no change on adoption in response to the comment.

144. COMMENT: With respect to proposed new N.J.A.C. 8:43J-13.9(b)1, a commenter states, "in the experience of [the facility on behalf of which the commenter comments,] there have been no health or safety issues arising from the use of stackable cribs," and requests, "unless such an arrangement had a specific impact on a child's health, [for example,] interfered with medical equipment in a particular case, there would be no reason to implement such a restriction." The commenter requests the Department to reconsider the proposed new rule. (2)

RESPONSE: In an emergency and/or for purposes of administering routine medical care, stackable cribs would not provide ready access to a child. Thus, stackable cribs would be particularly inappropriate for the medically complex and/or technology-dependent children that PMDC facilities would serve. Therefore, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-13.11 Nursing Services, Pharmaceutical Services and Examination Room or Private Treatment Space

145. COMMENT: Several commenters state that the Department should delete proposed new N.J.A.C. 8:43J-13.11(a), which would require an office with a minimum of 100 square feet for the nursing staff, and should require instead a "nursing area" with a minimum of 100 square feet. (3, 5, 7, 8, 9, 15, 16 and 18)

RESPONSE: Facilities must have a secure office for nursing staff to ensure that sensitive information pertaining to facility clients and their families to which nurses have access, communicated by spoken word and in writing, is protected from unnecessary disclosure and that records that nurses work with are secure from tampering, loss or destruction by children and others entering a facility. Moreover, applicable State and Federal standards governing the privacy of health information, such as the Health Insurance Portability and Accountability Act of 1996, *42 U.S.C. §§1301 et seq.* (HIPAA), and the Federal regulations promulgated pursuant thereto by the United States Department of Health and Human Services at 45 CFR Parts 160, 162, and 164, oblige healthcare facilities to ensure that facility employees have access to the minimum amount of a client's health information necessary to perform

their designated functions. Proposed new N.J.A.C. 8:43J-13.11(a) would facilitate adherence to applicable privacy protection standards by providing space for nursing staff to make telephone calls and conduct charting activities in confidence, by limiting staff and public access to sensitive information and establishing a "gatekeeper" process. For the Department to authorize PMDC facilities to establish an unsecured "area," rather than to provide a locked room, within which nursing staff are to work, would not cultivate an environment that values privacy protection and could jeopardize confidentiality. Therefore, the Department will make no change on adoption in response to the comment.

146. COMMENT: Several commenters state that proposed new N.J.A.C. 8:43J-13.11(b), which would require 120 square feet of space if the nursing staff office will also serve as the pharmaceutical area, is unnecessary because PMDC facilities use a secured medication cart or a locked box in a medication refrigerator. (3, 5, 7, 8, 9, 15, 16 and 18)

RESPONSE: Proposed new N.J.A.C. 8:43J-13.11(b) would not require PMDC facilities to combine the nursing staff office with the pharmaceutical area. However, if PMDC facilities were to elect to combine the nursing staff office with the pharmaceutical area, the additional 20 square feet would provide the minimum area necessary to include a sink in the dispensing area and space to store the medication cart and the medication refrigerator. Therefore, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-13.16 Emergency Plans

147. COMMENT: A commenter suggests that the Department change proposed new N.J.A.C. 8:43J-13.16(a) to refer to Danielle's Law, and to require emergency generators for technology-dependent children and training on emergency preparedness for children with special needs. (1)

RESPONSE: As stated in response to a previous comment, the Department declines to add reference to Danielle's Law because if that law applies to PMDC facilities, then they are subject to the law regardless of whether the Department provides a reference thereto in the proposed new rules at N.J.A.C. 8:43J.

Proposed new N.J.A.C. 8:43J-8.7(b) and (c) would address the commenter's other concerns by, respectively, requiring staff to be trained in the use of emergency equipment and requiring facilities to develop an emergency plan for each child. In addition, proposed new N.J.A.C. 8:43J-13.1(f) would address the commenter's concerns by requiring PMDC facilities to have an emergency generator available. Therefore, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-14.1 Maintenance of Medical Records

148. COMMENT: A commenter suggests that proposed new N.J.A.C. 8:43J-14.1(d) include a reference to HIPAA and Family Educational Rights and Privacy Act (FERPA). (1)

RESPONSE: The Federal laws known as HIPAA and FERPA, to the extent they might apply to PMDC facilities, would apply regardless of whether proposed new N.J.A.C. 8:43J refers to them. Moreover, proposed new N.J.A.C. 8:43J-3.4(b) requires PMDC facilities to comply with all applicable laws. Therefore, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-14.3 Contents of Medical Records

149. COMMENT: A commenter "would eliminate the requirement for a preadmission assessment of the child's home environment" at proposed new N.J.A.C. 8:43J-5.1 and would make a corresponding deletion to the medical record retention requirement relating to this assessment at proposed new N.J.A.C. 8:43J-14.3(a)3. The commenter states, "no other States with [PMDC facility] legislation require a home assessment for medical day care" and suggests, "if New Jersey insists on a home visit, that it is reimbursed separately." (6)

RESPONSE: A home assessment would be a necessary component of assessing a child's care needs and would provide a facility with an opportunity to determine if other services are necessary for a child and/or the child's family. The Department declines to authorize separate reimbursement for the conduct of a preadmission assessment because this service is part of the facility's determination of clinical eligibility that must occur before the facility submits a prior authorization

request to the Department. Therefore, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-14.4 Medical Records Policies and Procedures

150. COMMENT: A commenter suggests that the Department change proposed new N.J.A.C. 8:43J-14.4(c) to require a PMDC facility to determine "legal parental status, such as in cases of divorce" prior to a record release to a child's parent. (1)

RESPONSE: Facilities are not in a position to determine whether the parental rights of someone identified as a child's parent have been terminated. The custodial parent would need to provide a facility with the applicable legal documents if the custodial parent were to want to limit the access to the child's medical records of the parent whose legal rights had been terminated. Therefore, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-15.2 Admission Procedure

151. COMMENT: Several commenters recognize the importance of proposed new N.J.A.C. 8:43J-15.2, which would require every child to be immunized in accordance with *N.J.A.C. 8:57*, but state that a child may not be current in the specified immunization schedule because of illness or parental noncompliance. The commenters request that the Department change the rule to require facilities to make only reasonable efforts to ensure each child's compliance with immunization requirements. (3, 5, 7, 8, 9, 15, 16 and 18)

152. COMMENT: A commenter states that it is essential that every child be immunized in this medically fragile population but asks for flexibility in proposed new N.J.A.C. 8:43J-15.2 as "there may be situations where particular immunizations may be counter-indicated due to a child's specific health status." (1)

RESPONSE TO COMMENTS 151 AND 152: It is of paramount importance to the safety of all children in a PMDC facility that each child maintains optimum childhood immunization levels to prevent the spread of disease. *N.J.A.C. 8:57* establishes the only available exemptions from compliance, and allows for medical contraindications. It would be inappropriate for a child who has not received all required immunizations pursuant to N.J.A.C. 8:57-4 to receive services at a PMDC

facility, because that child could expose the medically complex and/or technology-dependent children who attend PMDC and their caregivers to infectious disease. Therefore, the Department will make no change on adoption in response to the comments.

N.J.A.C. 8:43J-15.5 Employee Health History and Examinations

153. COMMENT: Proposed new N.J.A.C. 8:43J-15.5(a) would require a PMDC facility to have new employees undergo physical examination by an outside healthcare practitioner prior to commencing work at a PMDC facility. Proposed new N.J.A.C. 8:43J-15.5(a)1 would permit a PMDC facility to allow new employees to commence work and to defer the physical examination for up to 30 days if the PMDC facility's nursing director performs a nursing assessment on the new employee. Several commenters believe that it is inappropriate for the nursing director to perform a health assessment on the new employee as this may be "construed as a violation of the employee's right to confidentiality." The commenters recommend that the Department delete this provision. (3, 5, 7, 8, 15, 16 and 18)

RESPONSE: Proposed new N.J.A.C. 8:43J-15.5(a)1 would not require a PMDC facility to have new employees undergo a nursing assessment by the facility nursing director. PMDC facilities could elect not to exercise this alternative to the requirement at proposed new N.J.A.C. 8:43J-15.5(a) that new employees undergo physical examination prior to commencing work at a PMDC. In addition, PMDC facilities could elect to authorize new employees to decline to exercise this option and to defer the commencement of work until they undergo the required physical examination. Facilities might elect to consult legal counsel as to the privacy and confidentiality ramifications of exercising the option at proposed new N.J.A.C. 8:43J-15.5(a)1. Based on the foregoing, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-16.1 Transportation Services

154. COMMENT: Several commenters recommend that the Department change proposed new N.J.A.C. 8:43J-16.1, which would establish that the child's total transportation time is not to exceed one hour one way, and is not to exceed two hours a day, by deleting the words "not exceed one hour one way." The commenters

state, "Providers already prepare routes with the one-hour timeframe each way as the benchmark, and make accommodations with respect to the order in which children are picked up or dropped off at their homes to ensure that the total two-hour timeframe is met." (3, 5, 7, 8, 15, 16 and 18)

RESPONSE: Proposed new N.J.A.C. 8:43J-16.1 would ensure that the time a child attending PMDC spends traveling to and from a PMDC facility is limited and would establish a standard that is more specific than the language the commenters suggest. It would not be appropriate to transport a child with the care needs necessary for clinical eligibility for PMDC for longer than one hour each way. Therefore, the Department will make no change on adoption in response to the comment.

155. COMMENT: A commenter states that the one hour each way transportation maximum in proposed new N.J.A.C. 8:43J-16.1(a)1 "seems excessive as medically fragile children would be subject to 10 hours/week of transportation" and suggests "clearance from the child's primary care physician regarding time/distance constraints based on a child's stamina." (1)

RESPONSE: The child's parent's, with input from the child's primary healthcare provider makes the determination on the appropriateness of placement. As such, the Department does not believe that it would be appropriate to second-guess this determination beyond the blanket prohibition on more than one hour of travel. Therefore, the Department will make no change on adoption in response to the comment.

156. COMMENT: A commenter states that proposed new N.J.A.C. 8:43J-16.1(b), requiring PMDC facilities to use mobility assistance vehicles (MAV), "would be enormously costly and, most importantly, not provide any additional health or safety benefit to a majority of PMDC children. The commenter asks that the Department maintain the same standards as at existing N.J.A.C. 8:43F-17. (17)

RESPONSE: As stated above in response to previous comments, children who would be eligible for PMDC under the proposed new rules generally would have greater care needs than those eligible under existing standards at *N.J.A.C. 8:43F* proposed for repeal or deletion. It would be inappropriate to permit a PMDC facility to

transport medically complex and/or technology-dependent children in an ordinary vehicle, such as a school bus. Use of an MAV ensures that these children are transported in a smaller vehicle, closer to adult supervision, with more safety features than the vehicles in use under existing standards proposed for deletion or repeal. Therefore, the Department will make no change on adoption in response to the comment.

N.J.A.C. 8:43J-16.2 Transportation Staffing Levels

157. COMMENT: With respect to proposed new N.J.A.C. 8:43J-16.2(a), a commenter "was surprised that the proposed rules have such a high level staffing requirement in the facility and yet have no requirements that a nurse ride the bus with children when they are at their most vulnerable. [The commenter suggests] that a nurse (LPN or RN) always accompany the children on the bus, and that the staffing levels in the facility should be adjusted accordingly when children leave the facility to board the bus." (6)

RESPONSE: Proposed N.J.A.C. 8:43J-16.2(a) would require the nursing director, in the exercise of licensed professional expertise, to establish staffing levels during the transportation of PMDC beneficiaries based on the particular care needs of each child, and would require, at minimum, a direct care staff member to be present on the vehicle during the transportation of a child. Proposed new N.J.A.C. 8:43J-16.1(b) would require vehicles used to transport children to conform to *N.J.A.C. 8:40*. Thus, facilities would not use school buses to transport children but rather would use specialized transportation vehicles specially equipped and staffed to provide health care transportation to sick, infirm or otherwise disabled persons. Therefore, the Department will make no change on adoption in response to the comment.

158. COMMENT: The commenter agrees that there must be another adult present with the with the driver when a child is being transported, as required by proposed new N.J.A.C. 8:43J-16.2(a)1, but states "based on the needs of medically fragile children, it may need to be a nurse or other specially trained personnel as appropriate." (1)

RESPONSE: The Department agrees with the commenter. Proposed new N.J.A.C. 8:43J-16.2(a) would require the nursing director of a PMDC facility to determine appropriate staffing levels, which would include using skilled staff on a vehicle when transporting a child, based on the particular needs of the child being transported.

N.J.A.C. 8:43J-17.2 Use of Restraints

159. COMMENT: A commenter strongly supports the requirement for a restraint-free environment at proposed new N.J.A.C. 8:43J-17.2(a) as "research has shown it has long lasting harmful psychological effects in children." (1)

RESPONSE: The Department acknowledges the commenter's support of the provision.

160. COMMENT: A commenter agrees with the requirement at proposed new N.J.A.C. 8:43J-17.2(b) that restraints be used only on an order by a child's primary healthcare provider and would like to add "only in the case of an emergency when the child is a danger to self or others and only to the extent and for the time period needed to stop the child from harming himself or others." (1)

RESPONSE: Proposed new N.J.A.C. 8:43J-17.2(d) would require PMDC facilities to use the least restrictive restraint in compliance with the order of a child's primary health care provider order, issued within the provider's licensed capacity and in the exercise of licensed professional judgment. The Department anticipates, given the nature of PMDC as a service for children with serious medical challenges due to their medical complexity and/or technology-dependency, professional staff designated by the Department performing prior authorization, upon a review of the totality of the circumstances, generally would find PMDC to be an inappropriate setting for children whose condition routinely would require a higher level of secure care to prevent harm to themselves or others through the use of restraints. The use of restraints would be indicated rarely, if ever, with respect to children attending PMDC as part of a child's routine plan of care. Thus, the Department anticipates that use of restraints might be indicated only in emergencies, and even then, only upon the order of the child's licensed healthcare provider. Therefore, the Department will make no change on adoption in response to the comment.

161. COMMENT: A commenter states that the Department should establish a special procedure for the use of restraints as governed by proposed new N.J.A.C. 8:43J-17.2(c), to be "done with the utmost caution as most injuries occur due to lack of trained personnel; 150 people die annually due to the use of restraints according to the Child Welfare League." (1)

RESPONSE: The Department agrees with the commenter that restraints be used with utmost caution; hence, the requirements limiting the use of restraints in proposed new N.J.A.C. 8:43J-17.2.

162. COMMENT: A commenter strongly supports "the elimination of use of restraints except in emergencies and the less restrictive the better." The commenter "suggests [Statewide] training in the use of Positive Behavioral Interventions." (1)

RESPONSE: Proposed new N.J.A.C. 8:43J-17.2(b) would prohibit the use of restraints in a PMDC facility, except by order by a child's primary healthcare provider. Proposed new N.J.A.C. 8:43J-17.2(d) would require PMDC facilities using a restraint to use the least restrictive restraint, subject to the order of a child's primary health care provider. Thus, the proposed new rules address the commenter's concerns by deferring to the guidance of the child's primary health care provider. To require Statewide training in the use of Positive Behavioral Interventions would impose an excessive burden on PMDC facilities because they would have no discretion in determining whether to use restraints. Therefore, the Department will make no change on adoption in response to the comment.

Summary of Agency-Initiated Change:

In a subsequently proposed rulemaking, the Department proposed to delete and replace *N.J.A.C. 8:82-5.2(g)*. Due to the delayed operative date of the instant rulemaking of April 1, 2010 and the Department's anticipated adoption of the deletion and replacement of subsection (g) prior to the delayed operative date, to adopt the instant amendments would have no legal effect. Therefore, the Department is not adopting the proposed amendments to *N.J.A.C. 8:82-5.2(g)*.

Federal Standards Statement

The adopted new rules, amendments and repeals are not subject to any Federal standards or requirements. Therefore, a Federal standards analysis is not required.

Full text of the adopted repeal may be found in the New Jersey Administrative Code at N.J.A.C. 8:43F-19.

Full text of the adopted amendments and new rules follows (additions to proposal indicated in boldface with asterisks ***thus***; deletions from proposal indicated in brackets with asterisks *[thus]*):

CHAPTER 43E

GENERAL LICENSURE PROCEDURES AND STANDARDS APPLICABLE TO ALL LICENSED FACILITIES

SUBCHAPTER 10. PATIENT OR RESIDENT SAFETY REQUIREMENTS AND REPORTABLE EVENTS

8:43E-10.2 Scope

(a) This subchapter shall apply to all health care facilities licensed pursuant to *N.J.S.A. 26:2H-1* et seq. and to State psychiatric hospitals operated by the Department of Human Services in accordance with the following:

1.-7. (No change.)

8. For adult day health services facilities licensed pursuant to *N.J.A.C. 8:43F* and pediatric medical day care facilities licensed pursuant to N.J.A.C. 8:43J, effective March 3, 2009;

9.-11. (No change.)

CHAPTER 43F

STANDARDS FOR LICENSURE OF ADULT DAY HEALTH SERVICES FACILITIES SUBCHAPTER 1. GENERAL PROVISIONS

8:43F-1.1 Scope and purpose

The rules in this chapter pertain to all facilities that provide adult day health services, regardless of the source of payment. These rules constitute the basis for the licensure of adult day health services facilities by the New Jersey Department of Health and Senior Services. The Medicaid rules for adult day health services are

contained in *N.J.A.C. 8:86*. Adult day health services facilities provide specialized, integrated care to participants in order to assist them in reaching the functional levels of which they are capable, as well as to protect their health and safety. The purpose of this chapter is to establish minimum rules to which an adult day health service facility must adhere to be licensed to operate in New Jersey. An adult day health services facility that is a Medicaid provider shall also comply with the rules at *N.J.A.C. 8:86*.

8:43F-1.2 Definitions

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise:

"Activities of daily living (ADL)" means the functions or tasks for self-care, which are performed either independently or with supervision or assistance. Activities of daily living include dressing, bathing, toilet use, transfer, locomotion, bed mobility and eating.

"Acuity" means the severity of the medical or healthcare needs of a participant.

"Administration-adult day health services facility" means an identifiable administrative unit within the adult day health services headed by a director/administrator, responsible for the overall conduct of all adult day health service program activities.

...

"Division" means the Division of Health Facilities Evaluation and Licensing within the New Jersey Department of Health and Senior Services.

...

"Medical consultant" means a facility's designated physician, who is licensed to practice medicine in the State of New Jersey, and who is responsible for assisting in and reviewing the provision of medical services to the participants of an adult day health services facility, in accordance with *N.J.A.C. 8:43F-8*.

...

"Participant" means a person who participates in a program of services from a licensed adult day health services facility.

...

"Prior authorization" means the approval process of eligible Medicaid participants by the Department prior to the provision of adult day health services in accordance with *N.J.A.C. 8:86-1.5* and *8:43F-2.8*.

...

SUBCHAPTER 2. LICENSURE PROCEDURES

8:43F-2.1 Licensure application procedures and requirements

(a) A person, organization, or corporation desiring to operate an adult day health services facility, or to expand or relocate an existing facility, shall submit an application for a license on forms prescribed by the Department. Such forms may be obtained from:

Director

Office of Certificate of Need and Healthcare Facility Licensure

Division of Health Facilities Evaluation and Licensing

New Jersey Department of Health and Senior Services

PO Box 358

Trenton, NJ 08625-0358

1. (No change.)

2. The Department shall charge a nonrefundable fee of \$1,500 plus \$10.00 per slot for the filing of an application to add services or program slots to an existing adult day health services facility.

3. The Department shall charge a nonrefundable fee of \$375.00 for the filing of an application to reduce services at an existing adult day health services facility.

4. The Department shall charge a nonrefundable fee of \$375.00 for the filing of an application for the relocation of an adult day health services facility.

5. The Department shall charge a nonrefundable fee of \$1,500 for the filing of an application for the transfer of ownership of an adult day health services facility.

6. Each adult day services facility shall be assessed a biennial inspection fee of \$450.00. This fee shall be assessed in the year the facility will be inspected along with the annual licensure fee for that year. The fee shall be added to the initial licensure fee for new facilities. Failure to pay the inspection fee shall result in non

renewal of the license for existing facilities and the refusal to issue an initial license for new facilities. This fee shall be imposed only every other year even if inspections occur more frequently and only for the inspection required to either issue an initial license or to renew an existing license.

7. Approval of a project proposal shall be contingent upon a review of the applicant's track record, in accordance with *N.J.A.C. 8:43E-5.1(b)*, and compliance with this chapter. All applicants shall demonstrate that they have the capacity to operate an adult day health services facility in accordance with the rules in this chapter. An application for a license or change in service shall be denied if that applicant cannot demonstrate that the premises, equipment, personnel, including principals and management, finances, rules and bylaws, and standards of health care are fit and adequate and that the health care facility will be operated in accordance with the standards required by these rules.

8. (No change in text.)

8:43F-2.3 Newly constructed or expanded facilities

(a) The licensure application for a newly constructed, renovated or expanded facility shall include written approval of final construction of the physical plant by:

Health Care Plan Review Unit

Division of Codes and Standards

New Jersey Department of Community Affairs

PO Box 815

Trenton, NJ 08625-0815

(609) 633-8151

1. Any existing or proposed adult day health services facility with a construction program shall submit plans to the Health Care Plan Review Unit, Division of Codes and Standards, New Jersey Department of Community Affairs, PO Box 815, Trenton, NJ 08625-0815, for review and approval prior to the initiation of construction.

2. (No change.)

8:43F-2.4 Preliminary conference

When a newly constructed facility is approximately 80 percent complete or when an applicant's estimated date of opening is within 30 days, the applicant shall schedule a preliminary conference with the Office of Certificate of Need and Healthcare Facility Licensure for review of the conditions for licensure and operation.

8:43F-2.5 Surveys

(a) When the written application for licensure is approved and the building is ready for occupancy, a survey of the facility by representatives of the Department shall be conducted at the Department's discretion to determine if the facility adheres to the rules in this chapter.

1. (No change.)

2. The facility shall notify the Office of Certificate of Need and Healthcare Facility Licensure of the Department when the deficiencies, if any, have been corrected, and the Assessment and Survey Program shall schedule one or more resurveys of the facility prior to occupancy.

3. (No change.)

(b) No facility shall admit participants to the facility until the Office of Certificate of Need and Healthcare Facility Licensure of the Department issues a license to operate the facility.

(c)-(e) (No change.)

8:43F-2.6 License

(a) The Department shall issue a license to the operator of the facility when all of the following conditions are met:

1. A project proposal has been submitted by the applicant and approved by the Office of Certificate of Need and Healthcare Facility Licensure, in writing;

i. The project proposal shall specify if there will be more than one shift of operation and shall provide the hours of operation for each shift. Any change in the hours of operation shall be reported in writing to the Office of Certificate of Need and Healthcare Facility Licensure; and

ii. (No change.)

2. (No change.)

3. A preliminary conference for review of conditions for licensure and operation has taken place between representatives of the facility and staff of the Division of Health Facilities Evaluation and Licensing;

4.-5. (No change.)

6. The applicant has submitted the following additional documents to the Office of Certificate of Need and Healthcare Facility Licensure:

i.-iii. (No change.)

7. A survey by Department staff indicates that the facility meets the standards set forth in the chapter and *N.J.S.A. 26:2H-1* et seq.

(b)-(g) (No change.)

8:43F-2.7 Surrender of license

The facility shall notify each participant, the participant's physician, advanced practice nurse, or physician assistant, and any guarantors of payment at least 30 days prior to the voluntary surrender of a license, or as directed under an order of revocation, refusal to renew, or suspension of license. In such cases, the license shall be returned to the Office of Certificate of Need and Healthcare Facility Licensure within seven working days after the voluntary surrender, revocation, non-renewal, or suspension of license.

8:43F-2.12 Transfer of ownership

(a) Any proposed change in ownership shall be reported to the Director of the Office of Certificate of Need and Healthcare Facility Licensure of the Department in writing at least 30 days prior to the change.

(b) Prior to transferring ownership of a facility, the prospective new owner shall submit an application to the Office of Certificate of Need and Healthcare Facility Licensure. The application shall include the following information:

1.-4. (No change.)

(c) (No change.)

(d) When a transfer of ownership application has been reviewed and deemed acceptable, an approval letter from the Office of Certificate of Need and Healthcare Facility Licensure shall be sent to the applicant along with licensure application forms.

(e) After the transaction has been completed, the applicant shall submit the following documents to the Office of Certificate of Need and Healthcare Facility Licensure:

1.-3. (No change.)

(f)-(g) (No change.)

SUBCHAPTER 3. ADMINISTRATION

8:43F-3.1 Appointment and responsibilities of the administrator

(a) (No change.)

(b) The administrator shall be responsible for, but not limited to, the following:

1.-6. (No change.)

7. Verifying that each Medicaid-eligible participant is eligible to receive services available at the adult day health services facility prior to the participant's entry into the program. For the purposes of this section, the administrator shall be entitled to rely on any prior authorization performed by the Department for the participant in accordance with *N.J.A.C. 8:86*.

8:43F-3.3 Administrative policies and procedures

(a)-(c) (No change.)

(d) A policy and procedure manual(s) for the organization and operation of the facility shall be developed, implemented, and reviewed at intervals specified in the manual(s). Each review of the manual(s) shall be documented, and the manual(s) shall be available in the facility to representatives of the Department at all times. The manual(s) shall include at least the following:

1.-7. (No change.)

8. Policies and procedures for complying with applicable statutes and protocols to report abuse or mistreatment of participants, elopement, sexual abuse, specified communicable disease, rabies, poisonings and unattended or suspicious deaths. These policies and procedures shall include, but not be limited to:

i. The notification of any suspected case of participant abuse or exploitation that occurs during the participant's participation in adult day health services to the Office of the Ombudsperson for the Institutionalized Elderly in the Division of Elder Advocacy of the New Jersey Department of the Public Advocate, pursuant to

N.J.S.A. 52:27G-7.1 et seq., if the participant is 60 years of age or older, and if less than 60 years of age, to the Assessment and Survey Unit in the Division of Health Facilities Evaluation and Licensing of the Department;

ii. The notification of any suspected case of participant abuse or exploitation that occurs outside of the participant's participation in adult day health services that is discovered by facility staff to Adult Protective Services, pursuant to *N.J.S.A. 52:27D-46* et seq., if the participant is 60 years of age or older;

iii. The notification of any suspected case of abuse or exploitation to the New Jersey Department of Children and Families, Division of Youth and Family Services of a participant who is 16 or 17 years of age;

iv. The development of written protocols for the identification and the treatment of participants who are abused and/or neglected;

v. The provision at least annually of education and/or training programs to appropriate persons regarding the identification and reporting of diagnosed and/or suspected cases of sexual abuse; domestic violence; abuse of participants and the facility's policies and procedures; and

vi. (No change in text.)

(e)-(f) (No change.)

8:43F-3.6 Participant care policies and procedures

(a) Written policies and procedures for the care of participants shall be established, implemented, and reviewed at intervals specified in the policies and procedures. Each review of the policies and procedures shall be documented. Policies and procedures shall include, but not be limited to, policies and procedures for the following:

1.-5. (No change.)

6. The prohibition of smoking in the facility in accordance with *N.J.S.A. 26:3D-55* et seq.;

7.-9. (No change.)

SUBCHAPTER 4. PARTICIPANT RIGHTS

8:43F-4.1 Policies and procedures regarding participant rights

(a)-(b) (No change.)

(c) The facility shall comply with all applicable State and Federal laws concerning participant rights.

8:43F-4.2 Rights of each participant

(a) (No change.)

(b) The administrator shall provide all participants and/or their families with the name, address, and telephone number of the following offices where complaints may be lodged:

Division of Health Facilities Evaluation and Licensing
New Jersey Department of Health and Senior Services
PO Box 367

Trenton, NJ 08625-0367

Telephone: (800) 792-9770

Office of the Ombudsperson for the Institutionalized Elderly

Division of Elder Advocacy

New Jersey Department of the Public Advocate

PO Box 852

Trenton, NJ 08625-0852

Telephone: (877) 582-6995

Division of Medical Assistance and Health Services

New Jersey Department of Human Services

PO Box 712

Trenton, NJ 08625-0712

Telephone: (609) 588-3828

Division of Youth and Family Services

New Jersey Department of Children and Families

PO Box 729

Trenton, NJ 08625-0729

Telephone: (609) 984-4500, or to report child abuse or neglect, 1-877-NJABUSE (652-2873)

(c) The administrator shall also provide all participants and/or their families with the telephone number of the local (county) agency of the Adult Protective

Services Program (APS), for adult participants, or the Division of Youth and Family Services Office of Child Abuse Control or District Office, for participants who are 16 or 17 years of age.

(d) (No change.)

SUBCHAPTER 6. GENERAL SERVICES

8:43F-6.1 General services provided

(a)-(b) (No change.)

(c) The facility shall provide or arrange for occupational therapy, physical therapy, and speech-language pathology services, either in the facility or outside of the facility. Habilitative services shall be provided or arranged for participants with developmental disabilities.

(d)-(f) (No change.)

8:43F-6.3 Personnel

(a) The facility shall make reasonable efforts to ensure that all staff providing direct care to participants in the facility are in good health, are concerned for the safety and well-being of participants, and have not been convicted of a crime relating adversely to the person's ability to provide care to participants, except when the applicant or employee with a criminal history has demonstrated his or her rehabilitation, in accordance with the standards set forth at *N.J.S.A. 2A:168A-1 et seq.*, and *N.J.A.C. 8:43F-2.1(a)8ii*, in order to qualify for employment at the facility.

1. "Reasonable efforts" shall include, but not be limited to, an inquiry on the employment application, reference checks, and/or criminal background checks when necessary for compliance with *N.J.A.C. 8:43F-2.1(a)8*.

i. Administrators and owners of adult day health services facilities shall have clearance from the Criminal Background Investigation in accordance with *N.J.A.C. 8:43F-2.1(a)8*.

(b)-(f) (No change.)

8:43F-10.1 Dietary services

The adult day health services facility shall provide a minimum of one meal per day to participants, as well as nutritionally appropriate snacks. The meal shall supply at least one-third of the daily caloric and protein requirements recommended by the

Nutrition Board of the National Academy of Sciences, National Research Council, and shall contain three or more menu items, one of which is or includes a high quality protein food such as meat, fish, eggs or cheese.

SUBCHAPTER 14. PHYSICAL PLANT REQUIREMENTS

8:43F-14.1 Physical plant

(a) Construction standards for freestanding facilities for new buildings and alterations, renovations, and additions to existing buildings for freestanding adult day health services facilities shall comply with *N.J.A.C. 5:23-3.2* of the New Jersey Uniform Construction Code; the New Jersey Uniform Fire Code, *N.J.A.C. 5:70*; and with *N.J.A.C. 5:23-7*, the Barrier-Free Subcode of the New Jersey Uniform Construction Code.

(b)-(d) (No change.)

8:43F-14.3 Functional service areas

(a) Each adult day health services facility shall provide the following service areas on-site:

1.-7. (No change.)

(b) Toilet facilities shall be provided to meet the needs of participants, staff and visitors.

1.-2. (No change.)

SUBCHAPTER 16. INFECTION CONTROL, SANITATION AND HOUSEKEEPING

8:43F-16.2 Infection control policies and procedures

(a)-(b) (No change.)

(c) The facility shall document evidence of annual vaccination against influenza for each participant, in accordance with the recommendations of the Advisory Committee on Immunization Practices of the Centers for Disease Control most recent to the time of vaccination, incorporated herein by reference, unless such vaccination is medically contraindicated or the participant has refused the vaccine, in accordance with *N.J.A.C. 8:43F-4.2(a)3*. Influenza vaccination for all participants accepting the vaccine shall be completed by November 30 of each year. Participants admitted after this date, during the flu season and up to February 1, shall, as

medically appropriate, receive influenza vaccination prior to or on admission unless refused by the participant.

(d) (No change.)

Recodify existing (f) through (h) as (e) through (g) (No change in text.)

(h) The facility shall retain copies of the results of all tuberculin testing of personnel in each employee's personnel file.

(i) Written infection control policies and procedures shall include, but not be limited to, policies and procedures for the following:

1. In accordance with *N.J.A.C. 8:57*, a system for investigating, reporting, and evaluating the occurrence of all infections or diseases, which are reportable or conditions, which may be related to activities and procedures of the facility and maintaining records for all participants or personnel having these infections, diseases or conditions;

2. Infection control in accordance with *29 CFR 1910.1030* Bloodborne pathogens, as amended and supplemented, incorporated herein by reference;

3.-8. (No change.)

Recodify existing (k) through (o) as (j) through (n) (No change in text.)

SUBCHAPTER 18. QUALITY IMPROVEMENT

8:43F-18.2 Use of restraints

(a)-(d) (No change.)

CHAPTER 43J

STANDARDS FOR LICENSURE OF PEDIATRIC MEDICAL DAY CARE FACILITIES

SUBCHAPTER 1. GENERAL PROVISIONS

8:43J-1.1 Purpose and scope

(a) The purpose of this chapter is to establish licensure standards for pediatric medical day care facilities.

(b) A pediatric medical day care facility provides health care services to medically complex or technology-dependent children whose medical condition requires treatment and services beyond the scope provided by day care centers to children with special health care needs.

(c) A pediatric medical day care facility provides a comprehensive program of services designed to meet the medical, developmental, educational, nutritional, and psycho-social needs of the children served.

8:43J-1.2 Definitions

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise:

"Advanced practice nurse" means an individual certified by the New Jersey State Board of Nursing in accordance with *N.J.S.A. 45:11-23 et seq.*

"American Academy of Pediatrics" means the entity by that name for which the contact information is American Academy of Pediatrics, 141 Northwest Point Boulevard, Elk Grove Village, IL 60007-1098, (847) 434-4000, www.aap.org.

"American College of Emergency Physicians" means the entity by that name for which the contact information is American College of Emergency Physicians, P.O. Box 619911, Dallas, TX 75261-9911, (800) 798-1822, www.acep.org.

"American Dietetic Association" means the entity by that name for which the contact information is American Dietetic Association, 120 South Riverside Plaza, Suite 2000, Chicago, Illinois 60606-6995, (800) 877-1600, www.eatright.org.

"American Heart Association" means the entity by that name for which the contact information is American Heart Association National Center, 7272 Greenville Avenue, Dallas, TX 75231, (800) AHA-USA-1, www.americanheart.org.

"Child" means an individual aged birth through the last day prior to his or her sixth birthday.

"Child life specialist" means:

1. An individual who holds the Certified Child Life Specialist credential issued by the Child Life Council, Inc., which can be contacted at 11820 Parklawn Dr., Suite 240, Rockville, MD 20852-2529, (301) 881-7090, www.childlife.org; or

2. Until *[(three years from the effective date of this chapter)]* ***November 16, 2012***, an individual who meets the educational eligibility requirements for certification as a Certified Child Life Specialist by the Child Life Council, Inc., and who has at least one year of full-time experience working with children in a health care or educational setting.

"Class III medical device" means a medical device that the FDA has categorized as "class III" as defined at *21 CFR 860.3*.

"Consultant pharmacist" means a pharmacist who has formalized his or her training in pediatric pharmacy through:

1. One year of experience in the full-time practice of pharmacy in a licensed pediatric healthcare facility; and
2. At least 10 hours of continuing education in pediatric pharmacy in his or her last renewal cycle for licensure as a pharmacist.

"Daily census" means the number of children who, during any calendar day, receive services in a facility.

"Department" means the New Jersey Department of Health and Senior Services.

"Device" means a device as that term is defined at Section 201(h) of the Federal Food, Drug and Cosmetic Act, *21 U.S.C. §321(h)*.

"Direct care staff" means employees of a facility who provide care to children in the facility under the supervision of the nursing director.

"Drug" or "medication" means a substance as defined in the New Jersey State Board of Pharmacy Rules, *N.J.A.C. 13:39-1.2*.

"Emergency Nurses Association" means the entity by that name for which the contact information is Emergency Nurses Association, 915 Lee Street, Des Plaines, IL 60016-6569, (800) 900-9659, www.ena.org.

"Facility" means a pediatric medical day care facility.

"Family" means individuals who are related by blood, marriage, civil union, domestic partnership or a legal process.

"Full-time equivalent" means any combination of staff who work part-time on any given day and together provide the same number of working hours as one full-time staff person.

"Initial plan of care" means a care plan based on an initial assessment completed prior to or the day of admission that guides a child's care until an interdisciplinary plan of care is completed.

"Interdisciplinary plan of care" means an individualized comprehensive plan of medical, nursing, psychosocial, developmental and educational therapies that specifies the goals to be achieved, discharge planning and the disposition to be followed in the event of emergency situations.

"Interdisciplinary team" means those individuals representing different professions, disciplines and services who work together to provide an integrated program of care to a child.

"Licensed nurse" means a registered professional nurse and/or a licensed practical nurse.

"Licensed nursing staff" means registered professional nurses and/or licensed practical nurses under the employ of a facility.

"Licensed practical nurse" or "LPN" means an individual who is licensed by the New Jersey State Board of Nursing pursuant to *N.J.S.A. 45:11-27*.

"Medicaid" means medical assistance provided under a State plan approved under Title XIX of the Social Security Act or otherwise authorized under Title XIX or Title XXI of the Social Security Act, including Medicaid Waiver programs authorized under §§11115 and/or 1915 of the Social Security Act.

"Medicaid beneficiary" means a child who has been determined by the County Board of Social Services to be financially eligible to participate in Medicaid.

"Medical director" means a physician certified by the American Board of Pediatrics who serves as liaison between a pediatric medical day care facility and the medical community, reviews the quality and appropriateness of pediatric medical day care facility policies and services, and is available for consultation to the pediatric medical day care facility staff.

"Medical record" means all records in a facility pertaining to a child and maintained in accordance with this chapter.

"Medically complex child" means a child who exhibits a severity of illness that requires ongoing skilled nursing intervention.

"Medication administration" means a procedure in which a prescribed medication is given to a child by an authorized person in accordance with all laws and rules governing such procedures.

"National Academy of Sciences" means the entity by that name for which the contact information is National Academy of Sciences, 500 Fifth St. NW, Washington, DC 20001, (202) 334-2000, www.nationalacademies.org.

"Neonatal intensive care unit" or "NICU" means a unit that provides "neonatal intensive care" as that term is defined at *N.J.A.C. 8:33C-1.2*.

"Occupational therapist" means an individual who is licensed by the New Jersey Occupational Therapy Advisory Council in accordance with *N.J.S.A. 45:9-37.51*.

"Office of Certificate of Need and Healthcare Facility Licensure" means the health care facility licensing unit within the Division of Health Facilities Evaluation and Licensing of the Senior Services and Health Systems Branch of the Department, for which the contact information is Office of Certificate of Need and Healthcare Facility Licensure, Division of Health Facilities Evaluation and Licensing, Department of Health and Senior Services, PO Box 358, Trenton, NJ 08625-0358, (609) 292-5960, website address for forms: www.nj.gov/health/forms.

"Ongoing" means 24 hours per day, seven days per week.

"Parent" means:

1. A biological or adoptive parent;
2. A foster parent of a child, pursuant to the definition of a "resource parent," as defined at *N.J.A.C. 10:121-1.1*;
3. A guardian generally authorized to act as the child's parent (but not the State if the child is a ward of the State);
4. An individual acting in the place of a biological or adoptive parent (including a grandparent, stepparent, or other relative) with whom the child lives, or an individual who is legally responsible for the child's welfare;
5. An individual appointed by a court having jurisdiction over the child, pursuant to *34 CFR 300.30(b)(2)*; or
6. A surrogate parent assigned pursuant to *N.J.A.C. 8:17-5*.

"Pediatric intensive care unit" means a unit licensed under *N.J.A.C. 8:43G-22*.

"Pediatric medical day care" or "PMDC" means a health care service designed to meet the medical, developmental, educational, nutritional and psycho-social needs

of medically complex and/or technology-dependent children whose medical condition requires treatment and services beyond the scope provided to children with special health care needs by day care centers or preschool programs.

"Pediatric medical day care facility" or "PMDC facility" means a pediatric day health care facility as specified at *N.J.S.A. 26:2H-7a*.

"Pharmacist" means an individual who is licensed by the New Jersey State Board of Pharmacy, pursuant to *N.J.A.C. 13:39-3*.

"Physical therapist" means an individual who is licensed by the New Jersey State Board of Physical Therapy Examiners, pursuant to *N.J.S.A. 45:9-37.11 et seq.*

"Physician" means an individual who is licensed by the New Jersey State Board of Medical Examiners to practice medicine in the State of New Jersey, pursuant to *N.J.S.A. 45:9-1 et seq.*

"Prescriber" means an individual who is authorized to write prescriptions in accordance with Federal and State laws.

"Primary health care provider" means a child's physician or advanced practice nurse who provides ongoing medical care, maintains responsibility for the child's overall therapeutic plan, and is available for consultation and collaboration with the pediatric medical day care facility staff.

"Progress note" means a written, signed, and dated notation or, if a computerized medical records system is used, an authenticated electronic notation, summarizing information about care provided and the child's response to it.

"Registered dietitian" means an individual so credentialed by the American Dietetic Association."

"Registered professional nurse" or "R.N." means a person who is licensed as such by the New Jersey State Board of Nursing, pursuant to *N.J.S.A. 45:11-26*.

"Rehabilitation services" means physical therapy, occupational therapy, and speech-language pathology services.

"Schedule II controlled substance" means a substance so defined pursuant to *N.J.S.A. 24:21-6*.

"Signature" means, at a minimum, the first initial and full surname and title (for example, R.N., A.P.N., P.A., L.P.N., D.D.S., M.D., D.O.) of a person, legibly written in his or her own hand, or by means of a controlled electronic signature system.

"Skilled nursing intervention" means care that requires the knowledge and experience of licensed nursing staff or a specially trained primary caregiver able to meet the specific needs of the child in the child's home.

"Slots" means the number of children for which a facility is licensed to provide services.

"Social worker" means an individual who is certified or licensed by the New Jersey State Board of Social Work Examiners, pursuant to *N.J.S.A. 45:15BB-1 et seq.*

"Speech-language pathologist" means an individual who holds a current New Jersey license issued by the Audiology and Speech-Language Pathology Advisory Committee of the Division of Consumer Affairs of the New Jersey Department of Law and Public Safety, pursuant to *N.J.S.A. 45:3B-1 et seq.*

"Technology-dependent child" means a child who requires a specific class III medical device to compensate for the loss of a vital body function to avert death or further disability and ongoing skilled nursing intervention in the use of the device.

"Toddler" means a child less than three years of age who has not mastered independent ambulation.

"Transportation services" means the conveying of children who require transportation between the facility and the child's home, either directly or through contractual arrangements, in accordance with N.J.A.C. 8:43J-16.

"Unlicensed assistive personnel" means unlicensed individuals to whom selected nursing tasks are delegated.

SUBCHAPTER 2. LICENSURE PROCEDURES

8:43J-2.1 Licensee

(a) The license holder shall have responsibility for the operation, management and financial viability of its facility.

(b) The licensee shall disclose in writing to the Department the ownership of entities that hold the license, any management company hired to operate the facility

and the ownership of the property on which the facility operates and shall make ownership information available in the facility on request to any party.

(c) Absent a finding by the Department that the individual is rehabilitated using the standards and procedures at N.J.A.C. 8:43J-2.5(a)2, an individual is ineligible to own or operate a facility in New Jersey if the individual:

1. Has a history of continuing or serious violations of N.J.A.C. 8 or 10;
2. Has engaged in conduct that would constitute continuing or serious violations of N.J.A.C. 8 or 10 if the conduct occurred in New Jersey; or
3. A forum of competent jurisdiction has made a finding of the individual's dishonesty or of unethical conduct in either a civil or a criminal matter.

8:43J-2.2 Licensure application procedures and requirements

(a) A person, organization or corporation desiring to operate a pediatric medical day care facility, or to expand or relocate an existing facility, shall submit a project proposal and a completed Application for a Long Term Care Facility License LCS-9, along with the appropriate licensure fee.

1. The application form can be obtained from the Department's forms website at nj.gov/health/forms, or upon request to the following:

Director, Office of Certificate of Need and Healthcare Facility Licensure
Division of Health Care Facilities Evaluation and Licensing
NJ Department of Health and Senior Services
PO Box 358
Trenton, NJ 08625-0358

2. The project proposal shall include scaled plans of the proposed facility, for preliminary review.

(b) A person, organization or corporation desiring to operate a pediatric medical day care facility, or to expand or relocate an existing facility, shall submit the following, on the licensure application form provided by the Department:

1. The name the facility shall be operating under;
2. The street address of the facility;
3. The number of slots sought;
4. The name and address of the applicant seeking licensure;

5. Type of business organization;
6. Identification of the ownership of the physical plant;
 - i. If the physical plant is to be leased, a signed copy of the lease;
7. Identification of any management company that will be operating the facility, including the entity's name and address and the name, title and telephone number of a contact person;
8. Identification of 100 percent of the proposed owners, including the names and addresses of all principals (that is, individuals and/or entities with a 10 percent or more interest);
9. Whether any person mentioned in the application has ever had any interest in any application for a health care facility in New Jersey or any other state, which was denied or revoked.
 - i. If yes, provide whom and the details;
10. Whether any of the principals have an ownership, management, or operational interest in a licensed health care facility in New Jersey, or any other state.
 - i. If yes, indicate whom and submit a listing of the licensed health care facilities;
11. Whether any person mentioned in the application is related to any person who now operates or has operated a health care facility in New Jersey or any other state.
 - i. If yes, indicate whom, the relationship, and a listing of the licensed health care facilities;
12. Whether any principals, owners, operators or managers of the facility have ever been found guilty of a criminal or administrative charge of fraud, abuse and/or neglect of a resident, participant and/or patient.
 - i. If yes, indicate whom and provide details;
13. Whether any principals, owners, operators or managers of the facility have ever been indicted for or convicted of a felony crime.
 - i. If yes, indicate whom and provide details;
14. The name and address of an agent in the State of New Jersey for service of process; and

15. A certification, signed by the applicant that states:

i. All the information submitted is true and correct to the best of the applicant's knowledge and belief and that willful misrepresentation of the facts contained in the application shall make the applicant subject to civil penalties;

ii. The governing body of the applicant has duly authorized the application;
and

iii. The applicant shall operate the facility in accordance with applicable licensing requirements.

(c) Approval of a project proposal is contingent upon a review of the applicant's track record, in accordance with *N.J.A.C. 8:43E-5.1(b)*, and compliance with this chapter.

(d) Any proposed pediatric medical day care facility shall submit plans to the Health Care Plan Review Unit, Division of Codes and Standards, New Jersey Department of Community Affairs, PO Box 815, Trenton, NJ 08625-0815, for review and approval prior to the initiation of construction, renovations or expansion.

1. Construction of freestanding facilities for new buildings and alterations, renovations, and additions to existing buildings for freestanding pediatric medical day care facilities shall comply with *N.J.A.C. 8:43J-13*.

2. Construction of facilities within long-term care facilities for new buildings and alterations, renovations, and additions for pediatric medical day care facilities in existing buildings, which are part of long-term care facilities shall comply with *N.J.A.C. 8:43J-13*.

(e) The Department recommends that applicants contact the Office of Certificate of Need and Healthcare Facility Licensure prior to the submission of construction plans to the Department of Community Affairs, as the Department of Community Affairs reviews construction plans for compliance with building code standards, and not for compliance with the physical plant standards contained in this chapter to schedule a functional review of their proposed projects, including, but not limited to:

1. Physical plant plans;
2. Policies and procedures;

3. Licensing protocols; and
4. Applicable rules and regulations.

(f) When a newly constructed facility is approximately 80 percent complete or when an applicant's estimated date of opening is within 30 days, the applicant shall schedule a preliminary conference with the Department's Assessment and Survey Program for review of the conditions for licensure and operation.

(g) In accordance with N.J.A.C. 8:43J-2.5, the Department shall not license a facility until the owners, administrators, volunteers and employees of the facility have clearance from the Department's Criminal Background Investigation Unit.

(h) An application for a license or change in service shall be denied if the applicant cannot demonstrate that the premises, equipment, personnel, including principals and management, finances, rules and bylaws and standards of health care are fit and adequate and that the facility will be operated in accordance with this chapter.

8:43J-2.3 License

(a) The Department shall issue a license to the operator of the facility when:

1. The applicant submits the following documents to the Office of Certificate of Need and Healthcare Facility Licensure:

- i. A copy of the certificate of occupancy from the local authority;
- ii. Documentation of a satisfactory fire safety inspection by the local fire authority; and
- iii. A copy of the written final release of the physical plant construction plans by the Health Care Plan Review Unit, Division of Codes and Standards, New Jersey Department of Community Affairs, if applicable; and

2. A survey by Department staff indicates that the facility complies with this chapter and *N.J.S.A. 26:2H-1 et seq.*

(b) A facility shall be licensed for a maximum of 27 slots.

(c) A facility shall exceed its licensed capacity only to the extent that a facility's on-site daily census may be three children more than the number of slots for which the facility is licensed for provided that:

1. The facility is appropriately staffed and meets the physical plant requirements for the number of children present; and

2. The facility maintains an on-site average daily census of the number of slots the facility is licensed for or fewer children.

i. Average daily census shall be calculated each calendar quarter beginning on January 1 of the calendar year.

(d) A facility shall provide only one session each calendar day.

(e) A license shall be granted for a period of one year.

(f) The license shall be conspicuously posted in the facility.

(g) A license is not assignable or transferable and shall be immediately void if the facility ceases to operate, if the facility's ownership changes, or if the facility is relocated to a different site.

8:43J-2.4 Fees

(a) The Department shall charge the following nonrefundable fees:

1. Application for licensure	\$1,500 plus \$10.00 per slot
2. Annual renewal fee	\$1,500 plus \$10.00 per slot
3. Addition of program slots.	\$1,500 plus \$10.00 per slot
4. Reduction of program slots	\$375.00
5. Relocation of existing facility	\$375.00
6. Transfer of ownership application	\$1,500
7. Inspection fee (initial)	\$450.00
8. Inspection fee (biennial)	\$450.00

(b) Failure to pay any of the applicable fees shall result in nonrenewal of the license for existing facilities and the refusal to issue an initial license for new facilities.

8:43J-2.5 Requirement for criminal background investigation

(a) The Department shall not issue or continue licensure for the operation of a pediatric medical day care facility unless, in accordance with *N.J.S.A. 30:5B-6.10* et seq., current or prospective staff members, administrators, and individuals seeking employment at or ownership of a pediatric medical day care facility, including volunteer staff, shall have obtained clearance from the Department's Criminal Background Investigation Unit, prior to respectively, owning, operating, administering, volunteering or working for a pediatric medical day care facility.

1. In accordance with *N.J.S.A. 30:5B-6.14*, the Department shall not issue clearance to own, operate, administer, volunteer or work for a pediatric medical day care facility to a person who has been convicted of any of the following crimes and offenses:

i. A crime against a child, including endangering the welfare of a child and child pornography, pursuant to *N.J.S.A. 2C:24-4*;

ii. Child molestation, pursuant to *N.J.S.A. 2C:14-1 et seq.*;

iii. Abuse, abandonment or neglect of a child, pursuant to *N.J.S.A. 9:6-3*;

iv. Endangering the welfare of an incompetent person, pursuant to *N.J.S.A. 2C:24-7*;

v. Sexual assault, criminal sexual contact or lewdness, pursuant to *N.J.S.A. 2C:14-2 through 2C:14-4*, inclusive;

vi. Murder, pursuant to *N.J.S.A. 2C:11-3* or manslaughter, pursuant to *N.J.S.A. 2C:11-4*;

vii. Stalking, pursuant to *N.J.S.A. 2C:12-10*;

viii. Kidnapping and related offenses, including criminal restraint, false imprisonment, interference with custody, criminal coercion or enticing a child into a motor vehicle, structure or isolated area, in violation of any crime established in Chapter 13 of Title 2C of the Revised Statutes of New Jersey (*N.J.S.A. 2C:13-1 et seq.*);

ix. Arson, pursuant to *N.J.S.A. 2C:17-1* or causing or risking widespread injury or damage that would constitute a crime of the second degree or higher, pursuant to *N.J.S.A. 2C:17-2*;

x. Terroristic threats, pursuant to *N.J.S.A. 2C:12-3*; and

xi. An attempt or conspiracy to commit any of the crimes or offenses listed in (a)1i through x above.

2. For convictions of crimes and offenses other than those listed in (a)1i through xi above, the Department shall issue clearance to own, operate, administer, work or volunteer to work for a pediatric medical day care facility to a person if the Department determines that the person has demonstrated clear and convincing

evidence of the person's rehabilitation, upon the Department's consideration of the following:

- i. The nature and responsibility of the position that the applicant would hold or currently holds at the facility, as the case may be;
- ii. The nature and seriousness of the offense;
- iii. The circumstances under which the offense occurred;
- iv. The date of the offense;
- v. The age of the person when the offense was committed;
- vi. Whether the offense was an isolated or repeat incident;
- vii. Any social conditions that may have contributed to the offense; and
- viii. Any evidence of rehabilitation, including good conduct in prison or in the community, counseling or psychiatric treatment received, acquisition of additional academic or vocational schooling, successful participation in correctional work-release programs or the recommendation of those who have had the person under their supervision.

3. For convictions occurring in any other state or jurisdiction, conduct that, if committed in New Jersey, would constitute any of the crimes or offenses described in (a)1 above.

(b) In accordance with the Administrative Procedure Act, *N.J.S.A. 52:14B-1 et seq.* and *52:14F-1 et seq.*, and the Uniform Administrative Procedure Rules, *N.J.A.C. 1:1*, the Department shall give any individual disqualified from owning, operating, administering, volunteering or working for a pediatric medical day care facility pursuant to (a)1 above an opportunity to challenge the accuracy of the disqualifying criminal history record prior to being permanently disqualified from participation.

(c) The Department shall give an individual disqualified from owning, operating, administering, volunteering or working for a pediatric medical day care facility pursuant to (a)1 above the opportunity to challenge the accuracy of the disqualifying criminal history record or the denial of a determination of rehabilitation pursuant to (a)1i through viii above.

(d) Pursuant to *N.J.S.A. 30:5B-6.13*, a staff member who has been fingerprinted and is awaiting the results of the criminal background investigation may begin employment, as long as the staff member is not left unsupervised with children.

1. A staff member awaiting the results of a criminal background investigation shall not count towards the facility's staffing level.

8:43J-2.6 Facility standards

(a) Any existing or proposed facility with a construction program shall submit plans to the Health Care Plan Review Unit, Division of Codes and Standards, New Jersey Department of Community Affairs, PO Box 815, Trenton, NJ 08625-0815, for review and approval prior to the initiation of construction, renovations or expansion.

1. Construction of freestanding facilities for new buildings and alterations, renovations, and additions to existing buildings for freestanding facilities shall comply with N.J.A.C. 8:43J-13.

2. Construction of facilities within long-term care facilities for new buildings and alterations, renovations and additions for facilities in existing buildings that are part of long-term care facilities shall comply with N.J.A.C. 8:43J-13.

3. The physical standards of an existing building that a facility intends to locate or relocate to shall comply with N.J.A.C. 8:43J-13.

8:43J-2.7 Surveys

(a) When the Department approves an initial licensure application and the facility is ready for occupancy, representatives of the Department shall conduct a survey of the facility to determine if the facility adheres to this chapter.

1. The Department shall notify the facility in writing of the findings of the survey, including any deficiencies found.

2. The facility shall notify the Division of Health Care Facilities Evaluation and Licensing when the deficiencies, if any, have been corrected, and the Department shall schedule one or more resurveys of the facility prior to occupancy of the facility.

3. The facility shall employ professional personnel in accordance with the staffing requirements in this chapter.

(b) No facility shall admit children to the facility until the Office of Certificate of Need and Healthcare Facility Licensure issues a license to operate the facility.

(c) Authorized representatives of the Department may make survey visits to a facility at any time.

1. Such visits may include, but not be limited to, the review of all facility documents and children's records and conferences with children and their parents and with staff.

(d) The Department shall conduct an ongoing evaluation of the pediatric medical day care facility by on-site visits and shall inform the facility, in writing, of the results of the on-site evaluation.

(e) The Department may request a plan of correction if the Department finds the facility to be in noncompliance with this chapter or otherwise violating any applicable laws, in which request the Department shall specify a date on which the facility's plan of correction is due to the Department.

1. The facility shall submit by the requested date a plan of correction that addresses deficiencies noted by the Department staff.

i. If a follow-up on-site visit by the Department reveals that the facility is not implementing the plan of correction, the Department shall take enforcement action in accordance with *N.J.A.C. 8:43E*, General Licensure Procedures and Standards Applicable to all Licensed Facilities.

ii. Non-compliance with this chapter may result in the Department's imposition of sanctions and remedies upon a facility in accordance with *N.J.A.C. 8:43E*, General Licensure Procedures and Standards Applicable to all Licensed Facilities.

2. Facilities wishing to contest decisions made by the Department pursuant to this section may request a hearing pursuant to the procedures set forth in *N.J.A.C. 8:43E*, General Licensure Procedures and Standards Applicable to all Licensed Facilities.

8:43J-2.8 Licensure renewal

(a) The Department shall issue to the facility a renewal application form pursuant to (c) below and a licensure fee request form requiring submission of the information in (c) and the renewal fee 30 days prior to the expiration of the facility license unless the Department has suspended or revoked the license.

(b) The Department shall not issue a renewed license until the Department receives a completed renewal application and the appropriate licensure renewal fee.

(c) A facility desiring to renew its license shall submit the following, on a licensure renewal application form that the Department provides pursuant to (a) above:

1. The name under which the facility has been operating;
2. The street address of the facility;
3. The number of slots;
4. The name and address of the applicant seeking renewal;
5. The type of business organization;
6. Identification of the ownership of the physical plant.
 - i. If the physical plant is to be leased, a signed copy of the lease;
7. Identification of any management company that will be operating the facility, including the entity's name and address and the name, title and telephone number of a contact person;
8. Identification of 100 percent of the proposed owners, including the names and addresses of all principals (that is, individuals and/or entities with a 10 percent or more interest);
9. Whether any person mentioned in the renewal application has ever had any interest in any application for a health care facility, in New Jersey or any other state, which was denied or revoked.
 - i. If yes, indicate whom and the details;
10. Whether any of the principals have an ownership, management or operational interest in a licensed health care facility in New Jersey or any other state.
 - i. If yes, indicate whom and provide a list of the licensed health care facilities;
11. Whether any person mentioned in the renewal application is related to any person who now operates or has operated a health care facility in New Jersey or any other state.
 - i. If yes, indicate whom, the relationship, and provide a list of the licensed health care facilities;

12. Whether any principals, owners, operators or managers of the facility have ever been found guilty of a criminal or administrative charge of fraud, abuse and/or neglect of a resident, a participant and/or a patient.

i. If yes, indicate whom and provide details;

13. Whether any principals, owners, operators or managers of the facility have ever been indicted for or convicted of a felony crime.

i. If yes, indicate whom and provide details;

14. The name and address of an agent in the State of New Jersey for service of process; and

15. A certification, signed by the applicant that states:

i. All the information submitted is true and correct, to the best of the applicant's knowledge and belief, and that willful misrepresentation of these facts may make the applicant subject to civil penalties;

ii. The application has been duly authorized by the governing body of the applicant; and

iii. The facility has been operated in accordance with applicable licensing requirements.

(d) The license shall not be renewed if local rules, regulations, and/or requirements are not met.

8:43J-2.9 Surrender of license

(a) The facility shall notify the Department, each child's parent, the child's primary health care provider and any guarantors of payment:

1. At least 30 days prior to the voluntary surrender of a license or relocation of a facility; or

2. As the Department directs in an order of revocation or suspension or in a notice of refusal to renew.

(b) The facility shall return the license to the Office of Certificate of Need and Healthcare Facility Licensure within seven working days after the voluntary surrender or the revocation, suspension or non-renewal of its license.

8:43J-2.10 Action against a licensee

(a) Pursuant to *N.J.S.A. 26:2H-1* et seq., the Commissioner or his or her designee may impose all enforcement actions permitted under *N.J.A.C. 8:43E* for violation of this chapter or other laws.

(b) Enforcement actions include civil monetary penalty, curtailment of admissions, appointment of a receiver, revocation of a license, order to cease and desist operation of an unlicensed health care facility and other remedies for violations of law.

8:43J-2.11 Hearings

[(a)] If the Department proposes to revoke, deny or refuse to renew a license, or to assess a monetary penalty pursuant to *N.J.A.C. 8:43E*, the licensee or applicant may request a hearing, which shall be conducted pursuant to the Administrative Procedure Act, *N.J.S.A. 52:14B-1* et seq. and *52:14F-1* et seq. and the Uniform Administrative Procedure Rules, *N.J.A.C. 1:1*.

8:43J-2.12 Transfer of ownership

(a) Prior to transferring ownership of a facility, the prospective owner shall apply to the Office of Certificate of Need and Healthcare Facilities Licensure for approval of the transfer by submitting the following:

1. A cover letter stating the proposed owner's intention to purchase the facility, identifying the facility by name, address and county and stating the licensed child capacity (that is, the number of licensed slots);
2. A written description of the proposed transaction, including:
 - i. Identification of the current owners of the facility;
 - ii. Identification of 100 percent of the proposed owners, including the names and addresses of all principals (that is, individuals and/or entities with a 10 percent or more interest); and
 - iii. If applicable, a copy of an organizational chart, including parent corporations and wholly owned subsidiaries of the proposed owner;
3. A copy of the agreement of sale and, if applicable, a copy of any lease; and
4. The names of any licensed health care facilities and states in which they are located that the proposed owner or any of the principals own, operate or manage in New Jersey or any other state.

i. If the proposed owner or any of its principals own, operate or manage facilities in other states, the proposed owner shall submit letters from the state health departments or applicable regulatory agencies in each of the respective states, verifying that the facilities have operated in substantial compliance during the last 12-month period and have had no enforcement actions imposed during that period of time.

(b) The Department shall review the request for authorization to transfer ownership, which review shall include an evaluation of the applicant's track record, in accordance with *N.J.A.C. 8:33-4.10* and *8:43E-5.1*, and clearance from the Criminal Background Investigation Unit.

(c) When the Department has reviewed the request for authorization to transfer ownership and deemed it acceptable, the Office of Certificate of Need and Healthcare Facility Licensure shall send a letter approving the transfer and licensure application forms to the proposed owner.

(d) After the transaction has been completed, the new owner shall submit the following documents to the Office of Certificate of Need and Healthcare Facilities Licensure:

1. A complete licensure application and the annual licensure fee;
2. A notarized letter stating the date on which the transaction occurred; and
3. A copy of a certificate of continuing occupancy from the local municipality or a letter from the municipality verifying a policy of not issuing any such document for changes of ownership.

(e) The Department shall not issue a license to the new owner until the Department receives the items required pursuant to (d) above.

(f) For Medicaid provider enrollment, the new owner shall contact Unisys for an application for Medicaid participation at (609) 588-6036 or access the application on the Internet at www.njmmis.com.

8:43J-2.13 Waiver of licensing standards

(a) The Commissioner or his or her designee, in accordance with the general purposes and intent of *N.J.S.A. 26:2H-1* et seq. and this chapter, may waive provisions of this chapter if, in his or her opinion, such waiver would not render the

premises, equipment, personnel, finances, rules and bylaws and standards of health care at a facility unfit or inadequate.

1. A facility seeking a waiver of these rules shall apply in writing to the Director of the Office of Certificate of Need and Healthcare Facility Licensure of the Department.

2. A written request for a waiver shall include the following:

i. A citation to the specific rule or part of the rule for which a waiver is requested;

ii. Reasons for requesting a waiver, including a statement of the type and degree of hardship that would result to the facility upon adherence;

iii. An alternative proposal that would ensure the care and safety of the children in the facility; and

iv. Documentation to support the request for a waiver.

3. The Department may request additional information before processing a request for waiver.

8:43J-2.14 Duty to update information

(a) Whenever any information included in a license or renewal application changes, the licensee shall provide that information to the Office of Certificate of Need and Healthcare Facility Licensure, in writing, within 10 calendar days of the change.

(b) Failure to comply with the requirements of this chapter may result in penalties being assessed against a facility pursuant to *N.J.A.C. 8:43E*.

SUBCHAPTER 3. ADMINISTRATION

8:43J-3.1 Appointment of the administrator

(a) The license holder shall appoint an administrator who is a full-time employee of the facility.

(b) A facility shall designate an alternate in writing to act in the absence of the administrator.

1. The designated alternate shall meet the qualification standards for an administrator at *N.J.A.C. 8:43J-3.2*.

(c) The administrator, or the designated alternate, shall be available on the premises of the facility during the hours when pediatric medical day care services are being provided.

(d) The administrator, or the designated alternate who is functioning as the administrator, shall not perform the duties of any other position at the facility.

8:43J-3.2 Qualifications of the administrator of a pediatric medical day care facility

(a) The administrator or designated alternate of a pediatric medical day care facility shall:

1. Have a master's degree from a college or university approved by a state department of education and at least one year of full-time administrative or supervisory experience in a licensed health care facility;

2. Have a baccalaureate degree from a college or university approved by a state department of education and three years of full-time experience in a licensed health care facility, at least one year of which shall have been in a full-time administrative or supervisory capacity; or

3. Have at least one year of full-time administrative or supervisory experience in a licensed health care facility and be:

i. A physician;

ii. A licensed social worker;

iii. A licensed clinical social worker;

iv. A registered professional nurse with either a Master of Science (MS) degree or a Bachelor of Science in Nursing (BSN) degree; or

v. An advanced practice nurse (APN).

(b) In addition to meeting the criteria in (a) above, the administrator of a pediatric medical day care facility shall have had at least one year of experience in the last five years in the care of children with special health care needs *[and be knowledgeable regarding their physical, social and medical health needs]*.

8:43J-3.3 Responsibilities of the administrator

(a) The administrator shall be responsible for, at minimum, the following:

1. Ensuring the development, implementation and enforcement of all policies and procedures, including child rights;

2. Planning and administering the operational, managerial, fiscal and reporting components of the facility;
3. Participating in the quality improvement program for child-care and staff performance;
4. Ensuring that all personnel are assigned duties based upon their education, training, competencies and job descriptions;
5. Ensuring the provision of staff orientation, staff education and ongoing staff training in accordance with this chapter;
6. Establishing and maintaining liaison relationships and communication between facility staff and services providers and with a child's parent; and
7. Ensuring that each child satisfies N.J.A.C. 8:43J-6.1(c) prior to admission.

i. For purposes of this paragraph, the administrator may rely on an authorization letter from the fiscal agent reflecting a determination of eligibility pursuant to N.J.A.C. 8:87-3.4(c)5i.

8:43J-3.4 Administrative policies and procedures

(a) If a health care facility licensed by the Department provides pediatric medical day care in addition to other health care services, the facility shall adhere to this chapter and to the applicable rules for licensure of facilities providing the other health care services.

(b) The facility shall adhere to applicable Federal, State and local laws.

(c) The facility shall develop, implement and review, at intervals specified therein, a policy and procedure manual for the organization and operation of the facility.

(d) Each review of the manual shall be documented and the manual(s) shall be available in the facility to representatives of the Department at all times.

(e) The manual shall address at least the following:

1. The program's philosophy and objectives and the services provided by the facility;
2. An organizational chart delineating the lines of authority, responsibility and accountability for the administration and child care services of the facility;

3. Specifications for each therapeutic intervention for use by all staff involved in the care of the children;

i. With respect to this requirement, the facility shall review the manual every six months to assure that the facilities procedures conform to prevailing and acceptable treatment practices.

4. The maintenance of an admission register listing children admitted by name with identifying information about each, the referral source, family contacts and emergency contacts;

5. The maintenance of a discharge register with final disposition and the discharge date;

6. The maintenance of a daily census record;

7. The maintenance of an accident and incident record;

8. The maintenance of an individual record for each child that contains:

i. Identifying data;

ii. All details of the referral and admission;

iii. Correspondence;

iv. Payer status; and

v. Medical history, *[prepared in ink and]* signed and dated ***in ink*** by the health professional providing the service, which contains allergies, special precautions, an immunization record, the initial plan for care and updates, physician's orders, progress notes and medications dispensed;

9. Referral procedure to other health care providers in a manner that ensures the provision of a continuum of care for the child;

10. The conduct of an interdisciplinary review of each child's interdisciplinary plan of care every two months, which requires, at a minimum, that the facility share the interdisciplinary plan of care summary and recommendations with the primary health care provider, who shall approve or modify any changes in writing, and which requires the facility to give a copy of the interdisciplinary plan of care summary and recommendations to the child's parent;

11. Discharge procedures that require, at a minimum, that the facility conduct a conference involving pediatric medical day care facility staff, the child's parent and

staff of other agencies involved in the child's care to discuss post-discharge care and follow-up and which require the facility to develop a written discharge summary and to enter it in the child's record within 10 business days following discharge;

12. A quality improvement program for child-care and staff performance;

13. Facility operation hours and days on which services are provided;

14. The maintenance of personnel records for each employee, which require, at a minimum, the employee's name, address, previous employment, educational background, credentials, license and/or certification and/or registration number, as applicable, with the effective date and date of expiration, and the results of the criminal background investigation;

15. The content and frequency of physical examinations, upon employment and subsequently, for employees and for other persons providing direct care services to children;

16. Procedures for follow-up of a child in the event that a child does not appear for services on scheduled days and for documentation of the follow-up in the child's medical record; and

17. *[Compliance]* ***Procedures for compliance*** with applicable statutes and protocols to report abuse or mistreatment of children, elopement, sexual abuse, specified communicable diseases, poisonings, birth defects and unattended or suspicious deaths, which shall address, at a minimum, the following:

i. The notification of any suspected case of child abuse or exploitation to the New Jersey Department of Children and Families, Division of Youth and Family Services;

ii. The development of written protocols for the identification and the treatment of children who are abused and/or neglected;

iii. The provision at least annually of education and/or training programs to appropriate persons regarding the identification and reporting of diagnosed and/or suspected cases of sexual abuse, domestic violence, child abuse and the facility's policies and procedures;

iv. Communicable disease reporting, in accordance with *N.J.A.C. 8:57*; and

v. Birth defect reporting, in accordance with *N.J.A.C. 8:20*.

(f) The policy and procedure manual shall be available and accessible to children's parents, staff and the public.

(g) The facility shall have a written agreement for services not directly provided by the facility.

1. The written agreement, or its equivalent, shall specify that the facility retain administrative responsibility for services rendered and shall require that services be provided in accordance with this chapter.

(h) Each facility shall maintain at least one bulletin board in a conspicuous location in the facility in an area accessible to the public upon which the facility shall place all notices this chapter requires to be posted.

8:43J-3.5 Childcare policies and procedures

(a) The facility shall develop, implement and review, at intervals specified in its policies and procedures, a manual of policies and procedures for the care of medically complex or technology-dependent children.

(b) Each review of the manual shall be documented and the manual shall be available in the facility to representatives of the Department at all times.

(c) The manual shall address at least the following:

1. Emergency care of children, which includes a disposition procedure to be followed in the event of a medical emergency, which includes notification of the child's parent;

2. Child instruction and health education, including the provision of printed and/or written instructions and information for a child's parent, with multilingual instructions, as indicated;

3. Advance directives, including, but not limited to, the following:

i. Routine inquiry, at the time of admission and at such other times as are appropriate under the circumstances, of a child's parent of the existence of an advanced directive;

ii. Requirements for provision of a written statement of a child's rights regarding advance directives, approved by the Commissioner or his or her designee, to such child's parent; and

iii. Requirements for documentation in the medical record;

4. The prohibition of smoking in the facility in accordance with *N.J.S.A. 26:3D-55 et seq.*;

5. Discharge, transfer, and readmission of children, including criteria for each; and

6. Exclusion of children and staff from the facility, and authorization to return to the facility, for children and staff with acute infectious diseases.

8:43J-3.6 Mandatory notification

(a) The facility shall notify the Department immediately by telephone at (609) 633-9034, or (609) 392-2020 after business hours, followed by written confirmation within 72 hours, of the following:

1. Termination of employment of the administrator and the name and qualifications of the administrator's replacement;

i. If a new administrator cannot be designated within 72 hours, the facility shall notify the Department in writing and the facility shall make arrangements, which are acceptable to the Department, for administrative supervision; and

ii. A new administrator shall be appointed within 30 days; and

2. Termination of employment of the nursing director and the name and qualifications of the nursing director's replacement;

i. If the facility cannot designate a new nursing director within 72 hours, the facility shall notify the Department in writing and the facility shall make arrangements that are acceptable to the Department for nursing supervision by a registered professional nurse; and

ii. The facility shall appoint a new nursing director within 30 days.

(b) The facility shall report in writing any change in the hours of operation to the Office of Certificate of Need and Healthcare Facility Licensure.

(c) The facility shall post on the bulletin board required in N.J.A.C. 8:43J-3.4(h) a notice that the following information is available in the facility to the public:

1. All waivers granted by the Department in accordance with N.J.A.C. 8:43J-2.2;

2. The list of deficiencies from the last annual licensure inspection and the list of deficiencies from any valid complaint investigation during the past 12 months;

3. The policies and procedures regarding child rights; and
4. An address and phone number at which the license holder may be contacted.

8:43J-3.7 Financial arrangements

(a) The facility shall:

1. Inform a child's parent in writing of the fees for services and supplies for which a fee is charged;
2. Maintain a written record of all financial arrangements with the child's parent and furnish a copy of the record to the child's parent;
3. Assess no additional charges, expenses or other financial liabilities in excess of the daily, weekly or monthly rate included in the admission agreement, except:
 - i. Upon written approval and authority of the child's parent, who shall be given a copy of the written approval;
 - ii. Upon written orders of the child's primary health care provider, specifying services and supplies not included in the admission agreement;
 - iii. Upon 15 days' prior written notice to the child's parent of additional charges, expenses or other financial liabilities due to the increased cost of maintenance and/or operation of the facility; and/or
 - iv. In the event of a health emergency involving the child and requiring immediate special services or supplies to be furnished during the period of the emergency.

8:43J-3.8 Denial of admission

If a facility denies admission to a child, the administrator shall give the child's parent the reason for such denial in writing, signed by the administrator, within 15 days of the denial determination.

8:43J-3.9 Involuntary discharge

(a) The administrator shall provide written notice to a child's parent of a decision to involuntarily discharge the child from the facility at least 30 days prior to the proposed discharge date.

1. The notice shall state the reason for discharge, the right to appeal the determination, and the procedure by which to make such an appeal.

2. A copy of the notice shall be entered in the child's medical record.

(b) The child's parent shall have the right to appeal to the administrator any involuntary discharge from the facility.

1. The appeal shall be in writing and a copy shall be included in the child's medical record with the disposition or resolution of the appeal.

(c) An involuntary discharge for reasons of the welfare of the child or other children shall comply with N.J.A.C. 8:43J-4.2(a)4.

1. A facility shall not retain a child who manifests a degree of behavioral disorder that causes the facility to reasonably believe that the child is a danger to himself or herself or others or whose behavior would interfere with the health or safety or well-being of other children.

8:43J-3.10 Interpretation services

The facility shall demonstrate the ability to provide a means to communicate with children and/or their parents who are non-English speaking and/or have communication disabilities, using available community or on-site resources.

8:43J-3.11 Notification of parent

The facility shall notify the child's parent in the event that the child sustains an injury, or an accident or incident occurs, immediately after the occurrence and shall document the notification in the child's medical record immediately following such notification.

8:43J-3.12 General record policies

(a) The facility shall maintain the following records:

1. A chronological listing of children admitted and discharged, including the destination of children who are discharged; and

2. Statistical data concerning use of program services and demographic information related to children.

8:43J-3.13 Required documents

(a) All facilities shall have the following documents on the premises and available to staff:

1. This chapter;
2. *N.J.A.C. 8:43E*;
3. *N.J.A.C. 8:87*;
4. *N.J.A.C. 10:122*; and
5. The facility's policy and procedure manual(s).

***(b) Information on ordering the New Jersey Administrative Code is available:**

- 1. On the Internet at lexisnexis.com;**
- 2. By writing to LexisNexis<(R)> Matthew Bender<(R)>, 744 Broad Street, Newark, NJ 07102; or**
- 3. By telephoning LexisNexis<(R)> at (973) 820-2000 or (800) 252-9257.***

SUBCHAPTER 4. CHILD RIGHTS

8:43J-4.1 Policies and procedures regarding the rights of children

(a) The facility shall establish and implement written policies and procedures regarding the rights of children, which shall be available to the child's parent, staff and the public and shall post them in a conspicuous location in the facility in English and the primary language(s) of the children's parents.

(b) The facility shall provide staff with in-service education concerning the implementation of policies and procedures regarding child rights.

(c) The facility shall notify the Department of Children and Families, Division of Youth and Family Services, of any suspected child abuse.

(d) The facility shall comply with all applicable laws concerning child rights.

8:43J-4.2 Rights of each child

(a) The facility shall establish policies and procedures to protect the rights of each child, that require, at a minimum, that children's parents:

1. Are informed of these rights, as evidenced by the execution of a written acknowledgement of receipt of this information prior to or upon admission, in terms that the child's parent understands;

2. Are informed of services available in the facility and of the names and professional status of the personnel providing and/or responsible for the child's care and receive a written statement of fees and related charges, including the payment,

fee, deposit and refund policy of the facility, any charges for services not covered by sources of third-party payment or by the facility's basic rate and any special payment plans established by the facility;

3. Are assured of the child's care in accordance with the interdisciplinary plan of care, is informed of the interdisciplinary plan of care, and have the opportunity to participate in the planning of the child's care;

4. Are advised that the facility shall transfer or discharge the child for medical reasons or for the welfare of the child or of other children only upon the written order of the child's primary health care provider, as documented in the child's medical record, except in an emergency situation, in which case the administrator shall notify the primary health care provider and the child's parent immediately following the transfer and document the reason for the transfer in the child's medical record.

i. If the facility requests a transfer or discharge on a non-emergency basis, including transfer or discharge for nonpayment for services (except as prohibited by sources of third-party payment), the child's parent shall be given at least 30 days advance written notice of such transfer or discharge;

5. Have access to and/or may obtain a copy of the child's medical record, in accordance with the facility's policies and procedures;

6. Are assured that the child shall be free from mental and physical abuse, exploitation and the use of chemical and physical restraints, unless the use of restraints are authorized by a written order from the child's primary health care provider and that medications shall not be used for punishment or for convenience of facility personnel;

7. Are assured that the child's records and disclosures shall receive confidential treatment and that the parent shall have the opportunity to approve or refuse their release to any individual in writing, except in the case of the child's transfer to another health care facility or as required by law or third-party payment contract;

8. Are advised that the child shall be treated with courtesy, consideration, respect and full recognition of the child's dignity, individuality and right to privacy, including, but not limited to, auditory and visual privacy and confidentiality concerning

treatment and disclosures and that the privacy of the child's body shall be maintained during toileting, bathing and other activities of personal hygiene;

9. Are advised that the child shall not be deprived of any constitutional, civil and/or legal rights;

10. Are informed that every parent 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 a result of such grievance or suggestion;

11. Are informed that, in the case of a Medicaid beneficiary, the determination of eligibility to receive services is not permanent and that redeterminations will be made on the basis of subsequent assessments pursuant to *N.J.A.C. 8:87*.

i. An acknowledgement of this shall be signed by the parent and retained in the child's permanent record; and

12. Are informed of the availability of regular day care or preschool if the child's condition improves sufficiently to no longer require pediatric medical day care facility services.

(b) The administrator shall provide the child's parent with the name, address and telephone number of the following offices with which complaints may be lodged:

Division of Health Care Facilities Evaluation and Licensing

New Jersey Department of Health and Senior Services

PO Box 367

Trenton, NJ 08625-0367

Telephone: (800) 792-9770

Division of Medical Assistance and Health Services

New Jersey Department of Human Services

PO Box 712

Trenton, NJ 08625-0712

Telephone: (609) 588-3828

Division of Youth and Family Services

New Jersey Department of Children and Families

PO Box 717

Trenton, NJ 08625-0717

Telephone: (609) 292-6920 or (800) 792-8610.

(c) The administrator shall provide the child's parent with the telephone number of the applicable local office of the Division of Youth and Family Services, Child Abuse Control Office.

(d) The telephone numbers in (b) and (c) above, shall be posted in the facility at every public telephone and on all bulletin boards used for posting public notices.

SUBCHAPTER 5. CHILD ASSESSMENT AND INTERDISCIPLINARY PLAN OF CARE

8:43J-5.1 Pre-admission assessment

(a) A facility shall conduct a pre-admission assessment to screen the child for PMDC clinical eligibility pursuant to N.J.A.C. 8:43J-6.1(c), which shall consist of a review of the child's medical records by the facility's nursing director and a home visit by a member of the interdisciplinary team and which shall address the child's:

1. Medical history;
2. Developmental status;
3. Nutritional status;
4. Use of assistive devices;
5. Treatment procedures; and
6. Medications.

(b) Based on the information obtained in the preadmission assessment, the administrator, in consultation with the nursing director and the medical director, shall:

1. For a Medicaid beneficiary who, based upon the preadmission assessment, meets the clinical eligibility requirements for PMDC, adhere to the procedure in N.J.A.C. 8:87-3 and either admit the child or deny admission; or

2. For a child whose participation at the facility would be paid from private funds, based upon the preadmission assessment, either admit the child if the child is clinically eligible for PMDC, or deny admission if the child is not clinically eligible for PMDC.

(c) A facility shall not admit a child who manifests a degree of behavioral disorder that causes the facility to reasonably believe that the child is a danger to

himself or herself or others, or whose behavior would interfere with the health or safety or well-being of other children.

8:43J-5.2 Admission procedure

(a) The administrator or his or her designee shall conduct an interview with the child's parent prior to or at the time of the child's admission that addresses, at a minimum, the matters in (a)1 through 5 below, and shall summarize the interview in the child's medical record:

1. An orientation of the facility's policies and services;
2. Hours and days on which services are provided;
3. The fee schedule;
4. The child's rights; and
5. Criteria for attendance, treatment and discharge.

(b) At the time of admission, the child's parent shall execute a PMDC facility consent form addressing the purpose of PMDC services, family responsibilities, authorized treatment, applicable liability releases and emergency disposition plans.

8:43J-5.3 Initial assessment and initial plan of care

(a) A registered professional nurse shall complete an initial assessment no earlier than five working days prior to, or upon, the day of admission for each child, which shall address, at minimum, the child's personal hygiene, immediate dietary needs, procedures, medications and diagnosis.

(b) A registered professional nurse shall develop a written initial plan of care that is based on the initial assessment within two business days of admission.

(c) The facility shall have a copy of a history taken and a report of a physical examination performed by the child's primary health care provider within 30 days prior to, or upon, admission to the facility.

(d) The facility shall have orders in place from a child's primary health care provider on the day of admission.

(e) The nursing, dietary, social work, developmental, rehabilitation, and/or pharmacy services, as applicable, and in accordance with professional standards of practice, shall execute each primary health care provider's order.

8:43J-5.4 Development and implementation of interdisciplinary plan of care and discharge planning

(a) A registered professional nurse shall develop a written interdisciplinary plan of care within 15 business days of the date of admission, which shall address, at a minimum:

1. The child's scheduled days of attendance;
2. The specific goals of care;
3. The time frames for achieving the goals and the schedule for evaluation of progress;
4. The interventions needed to accommodate the medical, nursing, psychosocial and educational needs of the child and family;
5. The child's needs and preferences as identified by the child's parent;
6. The orders for treatment, services, medications and diet;
7. The time intervals at which the facility shall review the child's response to treatment; and
8. Specific discharge criteria.

(b) In developing the written interdisciplinary plan of care the registered professional nurse shall base the written interdisciplinary plan of care on the assessments provided by nursing, dietary, child life specialist and social work staff, and, if ordered by the child's primary health care provider, other health professionals.

(c) The interdisciplinary plan of care shall contain measurable objectives with interventions based on the child's care needs and means of achieving each goal and shall address, as appropriate, rehabilitative and/or restorative measures, preventive intervention and training and teaching of personal care.

(d) The interdisciplinary plan of care shall contain discharge planning that takes into account the child's changing clinical and/or financial status as it may affect the child's continued eligibility for PMDC.

1. The facility shall involve, to the fullest extent possible, the child's parent in developing the discharge plan.

(e) The facility's interdisciplinary care team shall review the child's interdisciplinary plan of care at least every 60 days, or more often, if indicated by a change in the child's medical condition.

(f) The implementation of the interdisciplinary plan of care is contingent upon the approval of the child's primary health care provider.

(g) The facility shall give a copy of the interdisciplinary plan of care to the child's parent and shall maintain the parent's signed acknowledgment of receipt thereof in the child's medical record.

SUBCHAPTER 6. GENERAL SERVICES

8:43J-6.1 General services provided

(a) A facility shall provide, in accordance with this chapter, therapeutic, rehabilitative and developmental services to children for a minimum of six consecutive hours per day, each day the facility is open, exclusive of the transportation time referred to in N.J.A.C. 8:43J-16.1.

(b) Facilities shall comply with the requirements at *N.J.A.C. 10:122*, the Manual of Requirements for Child Care Centers.

1. Where the provisions of this chapter differ from those of *N.J.A.C. 10:122*, the requirements of this chapter shall govern.

(c) Regardless of the payer source, children attending pediatric medical day care shall be technology-dependent or medically complex.

1. For children who are Medicaid beneficiaries, the facility shall comply with *N.J.A.C. 8:87*.

(d) The facility shall maintain a daily record of child attendance for each day during which services are provided, in accordance with N.J.A.C. 8:87-2.1(a)4.

(e) Each facility shall have a system to ensure that each child's nutritional needs are met, based upon the child's interdisciplinary plan of care.

(f) A facility shall plan and implement a diversified program of activities for the child, based upon the child's interdisciplinary plan of care.

8:43J-6.2 General staffing requirements

(a) Only direct care staff members, excluding volunteers, of a facility shall count towards the staffing level.

(b) All facilities shall have, in addition to the nursing director, a minimum of two registered professional nurses on site at all times when children are present.

(c) The facility shall maintain a staffing ratio of one direct care staff member for every three children in attendance.

(d) As part of the staffing ratio in (c) ***above***, the facility shall also maintain a ratio of one licensed nurse for every six children in attendance.

(e) The nursing director shall increase the number of licensed nurses providing direct care when necessary based on the medical needs of the children being served.

(f) Transportation staff shall not count as direct care staff for purposes of satisfying the staffing ratio, except during any hours that they spend in the facility providing direct care to the children.

1. The time spent driving children to or from a facility shall not count as direct care staff hours.

(g) All direct care staff shall:

1. Have had pediatric care experience or shall receive training from the facility in the care, growth and development of children with special needs; and

2. Receive ongoing training from the facility regarding children with special needs.

(h) All direct care staff shall have current certification in pediatric cardio-pulmonary resuscitation (CPR) and the use of an automatic external defibrillator (AED).

(i) At all times when children are present in the facility, at least one staff member shall be on-site who:

1. Is certified by the American Heart Association in pediatric advanced life support;

2. Is certified by the American Academy of Pediatrics or American College of Emergency Physicians in advanced pediatric life support; or

3. Has completed the emergency nursing pediatric course offered by the Emergency Nurses Association.

8:43J-6.3 Personnel

(a) The facility shall make reasonable efforts to ensure that all staff providing direct care to children in the facility are in good health and are concerned for the safety and well-being of children;

1. A staff member who has been fingerprinted and is awaiting the results of the criminal background investigation may begin employment, as long as the staff member is not left unsupervised with children.

i. A staff member awaiting the results of a criminal background investigation shall not count toward a facility's staffing level.

(b) The facility shall develop written job descriptions and ensure that personnel are assigned duties based upon their education, training and competencies and in accordance with their job descriptions.

(c) The facility shall ensure that all personnel who require licensure, certification or authorization to provide care to children shall hold current licensure, certification or authorization, in good standing, under the appropriate laws or rules of the State of New Jersey.

(d) The facility shall maintain written staffing schedules that the facility shall implement in a manner that ensures continuity of care.

(e) The facility shall develop and implement a staff orientation plan and a staff training and education plan, including plans for each service and designation of person(s) responsible for providing ongoing training.

1. All staff shall receive orientation at the time of employment and a monthly ongoing in-service training *[that addresses, at a minimum,]**.*

i. At least once annually, the monthly in-service training shall address emergency plans and procedures, infection prevention and control, child rights and identification of child abuse.

[i.]* *ii. The facility shall document the orientation and ***the monthly*** ongoing in-service training of all staff.

(f) Facilities shall maintain employee health records for each employee in a confidential manner and separate from personnel records and shall ensure that the records contain documentation of the performance and the results of all required medical screening tests.

(g) The facility shall develop personnel policies and procedures that identify the minimum content of an employee's personnel file and that require each employee's personnel file to contain, at a minimum, an employee's:

1. Current licensure information as applicable;
2. Position description;
3. Clearance from the Department's Criminal Background Investigation Unit;

and

4. *[The]* **Signed acknowledgement of receipt of the*** applicable policies for the performance of overtime, compensatory time, performance evaluations and termination of employment.

SUBCHAPTER 7. NURSING SERVICES

8:43J-7.1 Designation of nursing director

(a) A facility shall designate in writing a nursing director, who shall be a registered professional nurse who meets the criteria at N.J.A.C. 8:43J-7.2.

1. The facility shall designate in writing a registered professional nurse to act in the event of the nursing director's absence.

(b) The nursing director shall be a full-time employee of the facility and on duty at all times when children are present in the facility.

(c) The nursing director shall not perform the functions of any other position and shall not count toward the facility's staffing level while functioning as the nursing director.

1. A registered professional nurse acting in the nursing director's absence shall not perform the functions of any other position and shall not count toward the facility's staffing level while functioning as the nursing director.

8:43J-7.2 Qualifications of nursing director

(a) The nursing director shall be a registered professional nurse who, in the five years prior to being named nursing director, has had:

1. At least three years of full-time pediatric nursing experience, of which at least one of those years shall have been in:

- i. A pediatric intensive care unit;
- ii. A neonatal intensive care unit;

- iii. A pediatric nursing home;
- iv. Pediatric home care; *[or]*
- v. A pediatric medical day care facility; *[and]**or*

vi. An in-patient pediatric rehabilitation hospital; and

2. One year of full-time experience in nursing supervision and/or administration in a licensed health care facility.

8:43J-7.3 Responsibilities of the nursing director

(a) The nursing director shall be responsible for:

- 1. The supervision of all nursing staff and unlicensed assistive personnel;
- 2. The direction, provision and quality of nursing services provided to children;
- 3. Overseeing the pre-admission and discharge planning processes; and
- 4. Overseeing the development of the interdisciplinary plan of care.

(b) The nursing director shall maintain contact with each child's primary health care provider at least every 60 days and more often, as needed, and shall document the contact in the child's medical record.

(c) The nursing director shall develop and implement written objectives, standards of practice, policies and procedures and an organizational plan for the nursing service.

1. The written policies and procedures shall address, at a minimum, the following:

- i. The assessment of the child's health service needs;
- ii. Monitoring the child's condition on a continuing basis;
- iii. The notification of the administrator if there is a significant change in the child's condition;
- iv. The assessment of the child's need for referral to the child's primary health care provider; and
- v. The maintenance of records as required by the facility.

8:43J-7.4 Qualifications of nursing staff

Registered professional nurses and licensed practical nurses shall have at least one year of full-time pediatric experience working with medically complex children.

8:43J-7.5 Provision of nursing services

(a) The facility shall provide nursing services to children directly in the facility.

(b) A registered professional nurse shall be responsible for, at a minimum, the following:

1. Maintaining the standards of nursing practice including, but not limited to:
 - i. Monitoring of identified medical conditions;
 - ii. Administering and/or supervising the administration of prescribed medications and treatments;
 - iii. Coordinating rehabilitative services;
 - iv. Monitoring clinical behavior and nutritional status;
 - v. Monitoring growth and development;
 - vi. Implementing infection control procedures;
 - vii. Conducting daily checks to assure that a child's parent is maintaining the child's personal hygiene and administering medications as prescribed; and
 - viii. Communicating findings to a child's primary health care provider;
2. Managing medical emergencies;
3. Documenting the nursing services provided to a child, including the initial assessment and evaluation of the child's health care needs, development of the nursing component of the interdisciplinary plan of care, coordinating the development of the interdisciplinary plan of care, evaluation of the child's progress in reaching established goals and defining the effectiveness of the nursing component of the individualized interdisciplinary plan of care;
4. Alerting the nursing director about changes in the child's medical status, the beneficial or untoward effects of therapeutic action and the need to change the individualized interdisciplinary plan of care in response to any changes;
5. Coordinating the services provided by other staff to meet the mutually identified health care and psychosocial needs of each child;
6. Providing health education to a child's parent;
7. Serving as an advocate to assist the child's parent to resolve problems;
8. Participating in interdisciplinary staff meetings regarding the child's progress; and

9. Instructing the child's parent how to implement provisions of the care plan required in the home that are appropriate for the child's parent to perform.

(c) Each nurse shall serve as a resource person and health educator to the child's parent, the facility administrator and the facility staff.

8:43J-7.6 Responsibilities of licensed nursing personnel

A registered professional nurse may delegate, in accordance with *N.J.A.C. 13:37*, selected nursing tasks in the implementation of the nursing regimen to licensed practical nurses and unlicensed assistive personnel.

SUBCHAPTER 8. MEDICAL SERVICES

8:43J-8.1 Provision of medical services

(a) Medical services shall be provided as follows:

1. The facility's medical director, with the administrator, shall establish written medical and administrative policies governing the provision of medical services to the children, which shall address, at a minimum:

- i. Emergency procedures; and
- ii. Standing orders;

2. The facility shall maintain an individual medical record for each child;

3. All medical services shall be coordinated through the child's primary health care provider; and

4. A child's primary health care provider shall provide medical orders for a child's treatment, which shall address, at a minimum:

i. Medication;

ii. Diet;

iii. Permitted activities;

iv. Therapies, such as physical therapy, occupational therapy and speech-language pathology services; and

v. Other services, as necessary.

8:43J-8.2 Designation of a medical director

A facility shall designate a physician who is board-certified in pediatrics to serve as the facility's medical director.

8:43J-8.3 Medical director's responsibilities

- (a) The medical director shall be responsible for, at a minimum, the following:
1. Assisting the facility in developing written objectives, policies, a procedure manual, an organizational plan and a quality improvement program for the medical service;
 2. Serving as a liaison between the facility and the child's primary health care provider to facilitate compliance with the facility's policies and procedures; and
 3. Reviewing the facility's written medical policies in cooperation with a child's primary health care provider for providing care to the child.

(b) The medical director and the administrator shall ensure compliance with *N.J.S.A. 45:9-22.5*.

8:43J-8.4 Role of primary health care providers

(a) The facility shall ensure that the parent identifies a primary health care provider for each child, who can be contacted when necessary, such as in a medical emergency, and who maintains responsibility for the overall medical therapeutic plan and is available for consultation and collaboration with the pediatric medical day care facility's medical and nursing directors and/or other staff, as appropriate.

(b) The facility shall obtain the following from the child's primary health care provider:

1. A completed Universal Child Health Record form, CH-14, which is available on the Department's forms webpage at <http://www.nj.gov/health/forms/ch-14.pdf> or by telephoning the Division of Family Health Services of the Department at (609) 292-5666, including the immunization record, which has been signed and dated within 30 days of admission;
2. Orders written within the last 60 days for the specific type and intensity of care that is to be provided, which orders are to be signed and dated by the child's primary health care provider;
3. Specification of the degree of child mobility and specification of any assistive devices that the child requires; and
4. Verification at the time of the pre-admission physical examination that the child is free of acute infectious disease.

(c) The facility shall have a mechanism to ensure that the child's primary health care provider reviews and approves the child's interdisciplinary plan of care.

8:43J-8.5 Medical equipment

(a) The medical director shall determine the quantity and types of pediatric medical equipment and supplies that the facility is to have on hand to meet the needs of the children.

(b) The facility shall maintain, on hand, in operable condition, safely store when not in use and make available as needed, emergency equipment suitable for pediatric use, including but not limited to:

1. Oxygen;
2. Suction machine;
3. Ambu bag;
4. Airway;
5. An automatic external defibrillator.

(c) The administrator shall ensure that the facility has on hand the pediatric medical equipment and supplies specified in (a) and (b) above, as well as any specific items required for individual children prescribed by the primary health care provider.

8:43J-8.6 Agreement with emergency medical providers

The facility shall have a current written agreement with local pre-hospital emergency medical providers, at both the basic and advanced life support levels.

8:43J-8.7 Medical emergencies

(a) A facility's medical policies shall address procedures to be followed by staff in the event of a medical emergency.

(b) Each facility shall ensure that staff are trained in the use of emergency equipment.

(c) Each child shall have an emergency plan developed by the child's primary care provider, which addresses the content of the Emergency Information Form for Children with Special Needs developed by the American Academy of Pediatrics, incorporated herein by reference, as amended and supplemented, available at <http://www.aap.org/advocacy/blankform.pdf>.

1. As appropriate, a child's medical record shall contain standing orders from each child's primary health care provider for the use of emergency medications, which orders shall conform to the rules of the New Jersey Board of Medical Examiners, the New Jersey Board of Nursing and a facility's medical policies.

(d) A facility shall have copies of the following reference sources on site:

1. "Childhood Emergencies in the Office, Hospital, and Community" (2000), as amended and supplemented, also known as "The Blue Book," published by The American Academy of Pediatrics; and

2. "The American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care" (2005), as amended and supplemented.

SUBCHAPTER 9. PHARMACEUTICAL SERVICES

8:43J-9.1 Designation and responsibilities of consultant pharmacist

(a) The facility shall designate a consultant pharmacist.

(b) The designated consultant pharmacist shall be responsible, in accordance with *N.J.A.C. 13:39*, for the following:

1. Establishing written policies and procedures to ensure the safe use, labeling, storage, integrity, administration, control and accountability of all medications stored or administered by the facility;

2. Reviewing the records of all children in the facility at least once every 60 days to assure that the medication records are accurate and up-to-date and indicate that medications are administered in accordance with the orders of the child's primary health care provider;

3. Reviewing a child's records at least every 60 days to assure that the facility is monitoring a child's medication regimens, laboratory tests, special dietary requirements and foods or natural or herbal medicines used and/or administered concomitantly with other medications to the same child for potential adverse reaction, allergies, medication interaction, contraindications, rationality, medication evaluation and test modification; and that the facility documents irregularities and/or changes the consultant pharmacist recommends in the child's record and reports these

irregularities and/or recommended changes to the nursing director and the child's primary health care provider; and

4. Providing and documenting in-service training and consulting with facility staff to assure pharmaceutical and utilization compliance.

8:43J-9.2 Medication administration policies and procedures

(a) Registered professional nurses ***or licensed practical nurses acting under direction pursuant to N.J.S.A. 45:23-11b and, as applicable, delegation in accordance with N.J.A.C. 13:37-6.2,*** shall accurately administer medications and shall ensure that the right medication is administered to the right child in the right dose through the right route of administration at the right time only upon a written order from the child's primary health care provider, except that verbal or telephone medication orders may be taken if:

1. The facility has defined in the facility's policies and procedures when verbal or telephone orders may be accepted by a registered professional nurse acting within his or her authorized scope of practice who shall write the order into the child's medical record; and

2. The facility ensures that, within 72 hours, the order is:

i. Countersigned by the prescriber; or

ii. Documented by the original written order or a plain-paper (non-thermal paper) faxed copy.

(b) The facility shall establish a system of medication administration, which includes:

1. Removing an individual dose from a previously dispensed, properly labeled container (including a unit dose container);

2. Verifying it with the prescriber's orders;

3. Giving the individual dose to the child;

4. Observing that the medication is taken; and

5. Recording the required information, including the method of administration.

(c) The facility shall establish a system to accurately identify a child before any medication is administered.

(d) Medication errors and adverse reactions shall be reported immediately upon discovery to the nursing director.

1. The nursing director shall:

i. Immediately notify the child's primary health care provider of the medication error or adverse reaction;

ii. Enter a description of the medication error or adverse reaction into the child's medical record;

iii. Notify the child's parent; and

iv. If the event was a medication error that originated in the pharmacy, notify the pharmacy.

8:43J-9.3 Pharmacy reporting policies and procedures

(a) The consultant pharmacist shall report any irregularities to the nursing director, who shall:

1. Report the irregularity to the administrator and the child's primary health care provider; and

2. Act on the report.

(b) A registered professional nurse shall document a child's medication allergies in the child's medical record and on its outside front cover.

(c) The administrator shall notify the Drug Control Division, New Jersey Department of Law and Public Safety of any theft or unexplained loss of any controlled substances, syringes, and/or needles within 48 hours of discovery of such loss or theft.

8:43J-9.4 Pharmacy control policies and procedures

(a) All prescription medication shall be supplied to the facility by the child's parent, in the original, labeled containers.

(b) Each child's individual medication container or package shall be labeled in accordance with *N.J.A.C. 13:39-5.9*.

(c) The facility may keep over-the-counter (OTC) medications as stock, as approved by the pharmacy consultant who is to monitor the OTC medications for accountability.

1. OTC medications labels are to include the medication name, strength, manufacturer's name, lot number, expiration date, recommended dosage for OTC use (if repackaged), and applicable cautionary and/or accessory labeling.

(d) The facility shall store all medications in a locked cabinet, located in or convenient to the nurse's station or center.

(e) The facility shall keep Schedule II controlled substances in separately locked, securely fixed boxes or drawers in the locked medication cabinet, that is, under two locks.

(f) The facility shall store medications intended for external use separately from other medications.

(g) The facility shall keep medications requiring refrigeration in a locked box in the refrigerator and separate from food.

SUBCHAPTER 10. DIETARY SERVICES

8:43J-10.1 General requirements for dietary services

(a) Dietary services shall be under the direction of a dietitian who meets the requirements in N.J.A.C. 8:43J-10.2.

(b) The dietitian shall assess the nutritional status and dietary needs of each child as part of the interdisciplinary plan of care and every 60 days thereafter, or more often, if medically necessary.

1. The assessment shall address the presence of:

- i. Food allergies;
- ii. Metabolic disorders; and
- iii. Any special needs related to feeding.

2. The dietitian shall document the results of each assessment in the child's medical record.

(c) Unless dictated otherwise by the child's interdisciplinary plan of care, the facility shall provide a minimum of one meal per day, as well as nutritionally appropriate snacks.

(d) The facility shall provide special diets and supplemental feedings when ordered by the child's primary health care provider.

(e) The facility shall not accept food provided by the child's parent, unless medically indicated and a current, signed agreement exists between the facility and the child's parent addressing the provision of food from sources other than the facility.

(f) The facility shall serve all food and formula under the supervision of the nursing director.

(g) The dietary service shall comply with *N.J.A.C. 8:24*.

(h) The facility shall make available a current diet manual to personnel in the facility and, if applicable, to the off-site food provider.

(i) The facility shall ensure that meals are planned, prepared and served in accordance with, but not limited to, the following:

1. Menus shall be prepared with regard for the nutritional and therapeutic needs, cultural backgrounds, food habits and personal food preferences of a child and his or her parent;

2. Written, dated menus shall be planned at least 14 days in advance for all diets.

i. The same menu shall not be used more than once in any continuous seven-day period;

3. Current menus with portion sizes and any changes in menus shall be posted in the food preparation and/or serving area and kept, with changes, on file in the dietary service for at least 30 days;

4. Diets served shall be consistent with the diet manual and shall be served in accordance with physicians' orders;

5. Food shall be prepared by cutting, chopping, grinding, or blending to meet the needs of each child;

6. Nutrients and calories shall be provided for each child, as ordered by a physician, based upon Recommended Dietary Allowances, 10th Edition (1989), incorporated herein by reference, as amended and supplemented, Food and Nutrition Board of the National Academy of Sciences, Commission on Life Sciences, National Research Council, adjusted for age, sex, weight, physical activity, and therapeutic needs of the child;

7. Designated staff shall observe meals refused and/or missed and shall document the name of the child and the meal refused and/or missed;
8. Designated staff shall provide assistance with eating, when necessary;
9. The facility shall provide self-help feeding devices;
10. All meals shall be attractive when served to children;
11. The facility shall maintain a record in the serving area for each child, identifying the child by name, and including diet order, known allergies and other information, such as meal patterns when on a calculated diet;
12. The facility shall ensure that all food served is stored and prepared in accordance with acceptable professional standards and at appropriate temperatures; and
13. The facility shall provide a speech-language pathologist to evaluate and monitor a child's ability to chew and swallow food when ordered by the child's primary health care provider.
 - (j) If food is prepared off-site, the facility shall have a system to inform the caterer each day of the number and types of meals required and any substitutions;
 1. Minimum supplies of food (for example, cereal, peanut butter, tuna, canned fruits and vegetables and juices) shall be maintained in facilities with an off-site food preparation system so that simple meals can be prepared in the event there are last-minute requests or emergency situations.

8:43J-10.2 Qualifications of the dietitian

The dietitian shall be a registered dietitian.

8:43J-10.3 Qualifications of the food service supervisor

(a) The food service supervisor shall:

1. Be a dietitian;
2. Be a graduate of a dietetic technician or dietetic assistant training program approved by the American Dietetic Association; or
3. Be a graduate of a New Jersey State-approved course in food service management and have at least one year of full-time, or full-time equivalent, experience as a food service supervisor in a licensed health care facility.

8:43J-10.4 Administrator's responsibilities for dietary services

(a) If meals are prepared in the facility, the administrator shall designate a food service supervisor who shall be present in the facility during food preparation and service.

1. If the food service supervisor is not a dietitian, then:

i. The food service supervisor shall have scheduled consultations with a dietitian; and

ii. The administrator shall designate a consultant dietitian who shall review the dietary services at a minimum, every 60 days, make recommendations, assess the nutritional needs of the children and provide nutritional counseling.

(b) If meals are prepared off-site or catered, the administrator shall be responsible for the direction, provision, and quality of the dietary services.

1. The administrator shall appoint a consultant dietitian who shall review the dietary services on a regularly scheduled basis, make recommendations, assess the nutritional needs of each child and provide nutritional counseling.

2. If the off-site catering service does not employ a food service supervisor who is qualified in accordance with N.J.A.C. 8:43J-10.2, the administrator shall specify the facility's needs, assess the quality of the services, and ensure that the services conform to the standards of this chapter.

3. If the off-site catering service employs a food service supervisor who is qualified in accordance with N.J.A.C. 8:43J-10.3, the administrator shall verify the credentials of the food service supervisor.

SUBCHAPTER 11. DEVELOPMENTAL AND REHABILITATION SERVICES

8:43J-11.1 Developmental services

(a) A facility shall employ full-time a child life specialist.

(b) A facility shall have each child assessed by a child life specialist to determine the child's present performance level in the following developmental domains:

1. Gross motor;
2. Fine motor;
3. Cognitive; and
4. Social.

(c) The child life specialist, in consultation with the rehabilitation specialist, shall make recommendations for developmentally appropriate activities and measurable goals in each developmental domain, which shall be included in the child's interdisciplinary plan of care and provided on-site.

(d) The child life specialist shall participate in regularly scheduled interdisciplinary staff meetings.

(e) The facility shall provide a program for parents to assist them in meeting the medical, developmental and psychosocial needs of their child at home.

1. To ensure continuity of care, the child's parent shall be included in care-related conferences.

8:43J-11.2 Rehabilitation services

(a) The facility shall provide rehabilitation services on-site to those children whose need for these services has been documented in the child's interdisciplinary plan of care and ordered by the child's primary health care provider.

(b) The facility shall provide a speech-language pathology, physical therapy and/or occupational therapy evaluation when ordered by the child's primary health care provider.

1. The facility shall transmit a report of evaluations and recommendations to the child's primary health care provider and a copy shall remain a part of the child's medical record.

(c) The orders of a child's primary health care provider for physical and occupational therapy and speech-language pathology services shall be specific as to goals and the frequency of treatment and shall be incorporated into the child's interdisciplinary plan of care.

[(d) Written progress notes on each therapy session shall be maintained by the therapists as part of the child's medical record.]

(d) Therapists shall make written progress notes that the facility shall maintain as part of the child's medical record.

(e) Physical therapists, occupational therapists and speech-language pathologists shall collaborate with nursing personnel and the certified child life specialists to integrate therapeutic interventions in daily activities, as appropriate.

(f) To the extent possible, a child's therapist(s) shall participate in the interdisciplinary review of the child's interdisciplinary plan of care.

1. The updated recommendations of the therapist(s) shall be incorporated in the child's interdisciplinary plan of care.

8:43J-11.3 Rehabilitation supplies and equipment

(a) When clinically indicated, the facility shall provide visual privacy and provisions for auditory privacy for children during evaluation and rehabilitation treatment.

(b) The facility shall ensure that the following therapy equipment, in a quantity appropriate to meet the needs of the children present, is available:

[1. Inflatable mattress with air compressor;]

1. Pediatric therapy table with mat;

2. Therapy rolls and half-rolls of varying sizes;

3. Nesting benches of varying heights;

4. A wooden weighted push cart;

5. A toddler's swing;

6. A floor mirror;

7. Therapy balls of varying sizes;

8. Steps;

9. Climbing equipment; and

10. Other medically indicated equipment.

SUBCHAPTER 12. SOCIAL WORK SERVICES

8:43J-12.1 Qualifications of social workers

(a) All social workers shall:

1. Be licensed or certified by the New Jersey State Board of Social Work Examiners, pursuant to *N.J.S.A. 45:15BB-1* et seq.; and

2. Have at least one-year of experience in providing social work services for children.

8:43J-12.2 Provision of social work services

(a) The facility shall arrange for the provision of social work services to children and their parents who require them, in accordance with *N.J.S.A. 45:15BB-1* et seq. and *N.J.A.C. 13:44G*.

(b) Social workers shall provide at least the following social services:

1. Interviewing the child's parent to obtain a social assessment and evaluation of needs and problems;

2. Providing, or arranging for the provision of individual, family and group counseling that addresses the psychological, social, financial, legal and educational needs of the child and where appropriate, the child's parent;

3. Assisting with obtaining social work services;

4. Referring the children and their parent to and/or developing support groups and educational programs;

5. Arranging and/or providing crisis intervention;

6. Coordinating the child's interdisciplinary plan of care with other community resources;

7. Providing in-service training to staff that addresses the psychosocial needs of the child, and the child's parent;

8. Participating in the facility's quality improvement program;

9. Participating in the child's pre- and post-admission case conferences;

10. Documenting assessments, treatment plans, evaluations and clinical notes; and

11. Coordinating discharge planning for the child, which shall include providing the child's parent information and assistance in accessing necessary and appropriate community services.

(c) A social worker shall provide social work services in the facility for at least 30 minutes per week per child equivalent, calculated on the basis of the daily census.

SUBCHAPTER 13. PHYSICAL PLANT REQUIREMENTS

8:43J-13.1 Physical plant

(a) Construction standards for new buildings and alterations, renovations and additions to existing buildings for freestanding pediatric medical day care facilities shall comply with *N.J.A.C. 5:23-3.2* and 7 (the Barrier-Free Subcode) of the New

Jersey Uniform Construction Code and *N.J.A.C. 5:70*, the New Jersey Uniform Fire Code.

(b) The facility shall have all direct care services located on one floor.

(c) Prior to any construction, the facility shall submit plans for review to the New Jersey Department of Community Affairs, Health Care Plan Review Services Unit for which the telephone number is (609) 633-8151.

(d) The facility shall install fire extinguishers in compliance with *N.J.A.C. 5:70*:

1. Fire extinguishers shall be examined at least annually and maintained in accordance with manufacturers' standards; and

2. Each fire extinguisher shall be labeled to show the date of such inspection and maintenance.

(e) The facility shall install smoke detectors in compliance with *N.J.A.C. 5:70*.

(f) An emergency generator, capable of powering medical equipment for a period of at least two hours, shall be available and on-site or to be provided through an agreement with a local pre-hospital emergency provider.

(g) **[The]* ***Subject to N.J.A.C. 5:23-6 with respect to rehabilitation projects, the*** Department shall not require facilities as to which the Department and the Department of Community Affairs have approved the physical plant under rules enacted prior to **[(the effective date of this chapter)]* *November 16, 2009**, to upgrade their physical plants to meet the requirements of this subchapter^{*}[, unless and until a facility renovates or constructs additions to the existing physical plant]^{*}.

(h) Each facility shall have a signed agreement with its utility provider stating that the utility provider will notify the facility in the event that there will be a disruption in service.

(i) Each facility shall notify the local fire department and emergency services unit that the facility is operating at its location.

8:43J-13.2 Functional service areas

(a) Each pediatric medical day care facility shall provide the following functional service areas on-site:

1. Administration services as required at *N.J.A.C. 8:43J-3.4*;

2. An employees' lounge as required at *N.J.A.C. 8:43J-13.5*;

3. Housekeeping services as required at N.J.A.C. 8:43J-13.6;
4. Social work services as required at N.J.A.C. 8:43J-13.7;
5. Child care areas as required at N.J.A.C. 8:43J-13.8;
6. Nursing services as required at N.J.A.C. 8:43J-13.11;
7. Pharmaceutical services as required at N.J.A.C. 8:43J-13.11;
8. An examination room or private treatment space as required at N.J.A.C. 8:43J-13.11;
9. Dietary services as required at N.J.A.C. 8:43J-13.12;
10. Physical therapy services as required at N.J.A.C. 8:43J-13.13;
11. Speech-language pathology services as required at N.J.A.C. 8:43J-13.14;
12. Laundry services as required at N.J.A.C. 8:43J-13.15; and
13. An outdoor play area as required at N.J.A.C. 8:43J-13.10.

8:43J-13.3 Toilet facilities

(a) Barrier-free toilet facilities shall be provided to meet the needs of the children, staff and visitors.

(b) Facilities shall have at least:

1. One toilet and one sink, of proper size and height for the use of children, for every 10 children;
2. Two adult, singular, unisex toilet rooms, one of which is to be barrier-free, for the use of visitors, volunteers and staff; and
3. Two diaper changing areas that are:
 - i. Separate from the toilet facilities;
 - ii. Located within five feet of a handwashing sink; and
 - iii. Privacy-screened.

8:43J-13.4 Administration areas

(a) The main entrance of the facility shall have a lobby and/or reception area, which shall contain space for:

1. Waiting for several persons; and
2. Wheelchair storage.

(b) The lobby and/or reception area shall be separated from any area used by children by a secure door.

(c) An office shall be provided for the administrator that may be shared with other staff and that shall be used for conducting private interviews.

(d) The facility shall conduct interviews related to credit and admission in a private area.

(e) The facility shall provide general or individual office(s) for business transactions, clerical work, filing, records, administrative and professional staff.

(f) The facility shall provide general storage facilities for supplies and equipment as needed for continuing operation.

8:43J-13.5 Employees' lounge

(a) The facility shall provide an employees' lounge for employees and volunteers.

1. The employees' lounge shall contain secure storage space, such as lockers, for the use of employees and volunteers.

8:43J-13.6 Housekeeping services area

(a) The facility shall provide a janitor's closet that contains a service sink and storage for housekeeping supplies and equipment.

(b) The facility shall ensure that the door to the janitor's closet is kept locked when not in use.

8:43J-13.7 Social work services area

(a) The facility shall provide office space for the social worker staff to conduct private interviewing and counseling.

(b) The facility shall provide a secure record storage area for the social worker staff.

8:43J-13.8 Child care areas

(a) Child care areas shall consist of an area for:

1. Ambulatory children, which may also be used by non-ambulatory children whose medical condition permits integration;

2. Toddlers; and

3. Non-ambulatory children whose medical condition precludes integration with ambulatory children or toddlers;

(b) Child care areas shall have two means of egress.

(c) Child care areas shall have a minimum of 35 square feet per child for activities and dining.

(d) The facility shall provide storage space for recreational equipment, cribs, mats and supplies.

8:43J-13.9 Cribs and mats

(a) The facility shall provide at least one crib or sleeping mat for each child in the program.

1. When in use, there shall be a minimum of three feet between cribs and/or sleeping mats.

(b) A crib is to be provided for each child under the age of one year, and for older children, as appropriate.

1. Stackable cribs are not permitted.

8:43J-13.10 Outdoor play area

(a) Each facility shall have an outdoor play area that can be used when weather permits.

(b) The appropriate staff-to-child ratio shall be maintained in the outdoor play area when the outdoor play area is in use.

(c) The outdoor play area shall comply with N.J.A.C. 5:23-11.

8:43J-13.11 Nursing services, pharmaceutical services and examination room or private treatment space

(a) The facility shall provide an office for nursing staff that has a minimum of 100 square feet.

(b) If the nurse's office will also serve as the pharmaceutical area, then the facility shall provide a minimum of 120 square feet of space for the combined use area.

(c) The facility shall provide the following for pharmaceutical services:

1. A dispensing area with a sink for handwashing;

2. A locked storage cart or locked cabinets; and

3. A separate lockable refrigerator or a locked box within a refrigerator for storage of medications.

(d) The facility shall provide a storage area for equipment and supplies.

(e) The facility shall provide an examination room or private treatment space that has a minimum floor area of 80 square feet, including an area for the storage of child charts, a sink for handwashing and a counter or shelf space for writing.

(f) If a facility combines the nursing office, pharmacy space and examination room, then the facility shall provide a minimum of 150 square feet for the combined use area.

8:43J-13.12 Dietary service area

(a) The construction, equipment and installation of food service facilities shall meet the requirements of the functional program.

(b) Services shall consist of an on-site conventional food preparation system, a convenience food service system, a catering service or an appropriate combination thereof.

(c) The facility shall provide the following to implement the food service selected:

1. If food is prepared on-site:

i. A conventional food preparation system with space and equipment for preparing, cooking, baking and serving meals; or

ii. A convenience food system, such as frozen prepared meals, bulk packaged entrees, individually packaged portions and contractual commissary services with space and equipment for thawing, portioning, cooking and/or baking; or

2. If food is prepared off-site and catered:

i. A control station for receiving food supplies.

(d) All facilities shall have the following:

1. Storage facilities for food supply, including cold storage items;

2. Handwashing sink(s) that are located in the food preparation area;

3. Warewashing space that is located in the kitchen or an alcove separate from the food preparation and serving area;

4. Waste storage facility(ies) that are located in a separate room easily accessible to the outside for direct waste pickup or disposal; and

5. Office or desk space for the dietitian or the food service manager.

(e) The provision of nutritional counseling shall occur in the dietitian's office or in a conference room, based on program requirements.

8:43J-13.13 Physical therapy service area

(a) The facility shall provide:

1. A designated area for the provision of physical therapy with a sink for handwashing.

i. The area may be within the child care areas;

2. Desk space for physical therapy staff; and

3. Storage space for physical therapy supplies and equipment.

8:43J-13.14 Speech-language pathology services area

(a) The facility shall provide:

1. A designated area for the provision of speech-language pathology services.

i. The area may be within the child care areas;

2. Desk space for therapy staff; and

3. Storage space for speech-language pathology supplies and equipment.

8:43J-13.15 Laundry service area

(a) If the facility provides laundry services on-site, the following areas shall be provided:

1. A laundry processing room;

2. Separate, clearly identified covered waste containers for soiled linens and/or soiled disposables in a designated area away from child activities and dining areas;

3. Storage for laundry supplies; and

4. A clean linen or disposables storage, issuing and holding room or area.

(b) If linen is processed off-site, the facility shall provide the following areas:

1. A receptacle for holding soiled linen; and

2. A clean linen and/or disposables receiving, holding, inspection, issuing and storage room(s) or area(s).

8:43J-13.16 Emergency plans and procedures

(a) The facility shall develop written emergency plans, policies and procedures to be followed in case of medical emergency, equipment breakdown, fire and other disasters, that address, at a minimum, the following:

1. Persons to be notified;
2. Process of notification and verification of notification;
3. Locations of emergency equipment and alarm signals;
4. Evacuation routes;
5. Procedures for evacuating children;
6. Procedures for reentry and recovery;
7. Frequency of fire drills; and
8. Tasks and responsibilities assigned to all personnel.

(b) The facility shall post emergency plans, including a written evacuation diagram specific to the unit that includes evacuation procedure, location of fire exits, alarm boxes and fire extinguishers and all emergency procedures in conspicuous locations throughout the facility.

(c) The facility shall train all employees as part of their initial orientation and at least annually thereafter in:

1. The procedures to be followed in the event of a fire, including evacuation; and
2. The instructions for the use of fire-fighting equipment.

(d) In the event that the facility is unable to provide services to children as scheduled due to the occurrence of an emergency, the facility shall immediately notify the children's parent of the change in schedule.

(e) The facility shall conduct drills of emergency plans at least four times a year and shall document the following in regard to each drill:

1. Date and hour;
2. Type;
3. Participating staff; and
4. Signature of the person in charge.

(f) Of the four drills, at least one drill shall address separately each of the following:

1. Fire; and
2. Emergencies due to another type of disaster, such as storm, flood, other natural disaster, bomb threat or nuclear accident.

(g) All staff shall participate in at least one drill annually and children may take part in drills.

SUBCHAPTER 14. MEDICAL RECORDS

8:43J-14.1 Maintenance of medical records

(a) The facility shall maintain a current, complete medical record for each child.

(b) The facility shall develop and implement written objectives, policies, a procedure manual, an organizational plan and a quality improvement program for medical record services.

(c) The facility shall maintain a record system in which the child's complete medical record is filed as one unit in one location within the facility.

(d) The facility shall protect the medical record from loss, destruction or unauthorized use.

(e) The facility shall retain medical records in accordance with *N.J.S.A. 26:8-5*.

8:43J-14.2 Assignment of responsibility

The facility shall assign responsibility for the medical record service to a full-time employee who, if not a medical record practitioner, functions in consultation with a person so qualified.

8:43J-14.3 Contents of medical records

(a) The child's complete medical record shall include, but not be limited to, the following:

1. Child identification data, including:
 - i. Name;
 - ii. Date of admission;
 - iii. Address;
 - iv. Date of birth;
 - v. Race;
 - vi. Religion (if parent elects to provide);

- vii. Sex;
 - viii. Referral source;
 - ix. Payment plan;
 - x. Travel directions to the child's home;
 - xi. Name, address and contact telephone number of the child's parent; and
 - xii. Name, address and contact telephone number of the person(s) to be notified in an emergency;
2. The parent's signed acknowledgment that the facility has informed them of, and given them a copy of, the child's rights pursuant to N.J.A.C. 8:43J-4;
 3. The preadmission assessment of the child's home environment pursuant to N.J.A.C. 8:43J-5.1;
 4. A summary of the admission interview pursuant to N.J.A.C. 8:43J-5.2;
 5. Documentation of the child's immunization record, medical history and physical examination, signed and dated by the child's primary health care provider;
 6. The information required pursuant to N.J.A.C. 8:43J-8.4(b);
 7. Advance directives and related documentation, as applicable, pursuant to N.J.A.C. 8:43J-3.5(c);
 8. Assessments developed by each service providing care to the child;
 9. Initial and interdisciplinary plans of care;
 10. Clinical notes, which shall be entered on the day service is rendered;
 11. Concise, accurate and initialed case notes reflecting progress toward goal achievement or reasons for lack of progress;
 12. A record of medications administered, including the name and strength of the medication, date and time of administration, dosage administered, method of administration and legible signature of the person who administered the medication;
 13. Documentation of allergies and any special precautions to be taken in the medical record and on its outside front cover;
 14. Any signed written informed consent forms;
 15. All orders for treatment, medication, therapy and diets, signed by the prescriber.

i. Orders for speech-language pathology, physical therapy and occupational therapy services shall include specific modalities and the frequency of treatment;

16. An attendance record listing all of the days on which the child was in the facility;

17. A current photograph of the child;

18. Documentation of Department determination of Medicaid clinical eligibility for PMDC services pursuant to *N.J.A.C. 8:87*, as applicable; and

19. The discharge summary, in accordance with *N.J.S.A. 26:8-5 et seq.*

8:43J-14.4 Medical records policies and procedures

(a) All orders for child-care shall be prescribed in writing and signed and dated by the prescriber.

1. All medication orders shall be in compliance with *N.J.A.C. 8:43J-9.2*.

(b) All entries in the child's medical record shall be written legibly in ink, dated and signed by the recording person or, if a computerized medical records system is used, authenticated.

1. If an identifier, such as a master sign-in sheet is used, initials may be used for signing documentation, in accordance with applicable professional standards of practice.

2. If computer-generated orders with an electronic signature are used, the facility shall develop a procedure to assure the confidentiality of each electronic signature and to prohibit the improper or unauthorized use of computer-generated signatures.

3. If a telefacsimile communications system is used, entries into the medical record shall be in accordance with the following procedures:

i. The prescriber shall sign the order, history and/or examination at an off-site location;

ii. The order or document shall be transmitted by telefacsimile to the facility for inclusion into the medical record;

iii. The prescriber shall submit the original order or document for inclusion into the medical record within seven days; and

iv. The original order or document shall replace the order or document transmitted by telefacsimile.

(1) If the order or document transmitted by telefacsimile is produced by a plain-paper telefacsimile process that produces a permanent copy, the plain-paper order or document may be used as part of the medical record, as an alternative to replacement of the original order or document.

(c) If a child's parent requests in writing a copy of the child's medical record, the facility shall provide a legible photocopy of the record within 30 days of request at a fee based on actual cost, which shall not exceed prevailing community rates for photocopying.

1. The facility shall establish a policy assuring access to copies of medical records for children whose parents do not have the ability to pay.

2. The facility shall establish a fee policy providing a means for use of abstracts or summaries of medical records, provided the child and/or his or her authorized representative shall have a right to receive a full copy of the medical record.

(d) The facility shall establish policies regarding the specific period of time within which the medical record shall be completed following child discharge and disciplinary action for non-compliance.

(e) The facility shall develop a procedure for the transfer of child information when the child is transferred to another health care facility.

(f) If the facility plans to cease operation, it shall notify the Department in writing, at least 14 days before cessation of operation, of the location at which medical records will be stored and of methods for their retrieval.

SUBCHAPTER 15. INFECTION CONTROL, SANITATION AND HOUSEKEEPING

8:43J-15.1 Administrator's responsibilities for infection control

(a) The administrator shall ensure the development and implementation of an infection prevention and control program.

(b) The administrator shall designate a person who shall be responsible for the direction, provision and quality of infection prevention and control services, and who shall:

1. Have education, training, experience and completed course work in infection control or epidemiology;
2. Be responsible for developing and maintaining written objectives for infection prevention and control services;
3. Be responsible for developing a policy and procedure manual for infection prevention and control services; and
4. Be responsible for developing an organizational plan and a quality improvement program for infection prevention and control services.

8:43J-15.2 Child immunization

Each facility shall ensure that each child is immunized in accordance with *N.J.A.C. 8:57*.

8:43J-15.3 Infection control policies and procedures

(a) The facility shall develop, implement and review, at least annually, written policies and procedures regarding infection prevention and control that are consistent with the following:

1. Guideline for Hand Hygiene in Health-Care Settings: Recommendation of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force, published in the Morbidity and Mortality Weekly Report at MMWR 2002; 51 (No. RR-16), incorporated herein by reference published by the Coordinating Center for Health Information and Service, available at <http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf> and at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5116a1.htm>; and

2. The standard precautions for Bloodborne Pathogens at *29 CFR 1910.1030*, incorporated herein by reference.

(b) The written infection control policies and procedures of the facility shall include, but not be limited to, policies and procedures for the following:

1. In accordance with *N.J.A.C. 8:57*, a system for investigating, reporting and evaluating the occurrence of all infections or diseases, which are reportable or conditions which may be related to activities and procedures of the facility and maintaining records for all children or personnel having these infections, diseases or conditions;

2. Exclusion from work, and authorization to return to work, for personnel with communicable diseases;

3. Surveillance techniques to minimize sources and transmission of infection;

4. Techniques to be used during each child contact, including handwashing before and after caring for a child;

5. Protocols for identification of children with communicable diseases and education of children regarding prevention and spread of communicable diseases;

6. The prevention of diaper rash; and

7. Cleaning, sterilization and disinfection practices and techniques to be used in the facility, that address, but are not limited to, the following:

i. Care of utensils, instruments, solutions, dressings, articles and surfaces;

ii. Selection, storage, use and disposition of disposable and nondisposable child care items and the fact that disposable items are not to be reused;

iii. Methods to ensure that sterilized materials are packaged, labeled, processed, transported and stored to maintain sterility and to permit identification of expiration dates; and

iv. Care of urinary catheters, intravenous catheters, respiratory therapy equipment and other devices and equipment that provide a portal of entry for pathogenic microorganisms.

(c) The facility shall use disinfection techniques for all reusable respiratory therapy equipment and instruments that touch mucous membranes consistent with the Centers for Disease Control requirements in the Guideline for Environmental Infection Control in Health-Care Facilities: Recommendation of the CDC Healthcare Infection Control Practices Advisory Committee (HICPAC), 2003, incorporated herein by reference, as amended and supplemented, available at http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Enviro_guide_03.pdf and manufacturer's specifications.

(d) The facility shall ensure that disinfection procedures for items that come in contact with bed pans, sinks and toilets conform with the Centers for Disease Control requirements in the Guideline for Environmental Infection Control in Health-Care

Facilities: Recommendation of the CDC Healthcare Infection Control Practices Advisory Committee (HICPAC), 2003, and manufacturer's specifications.

(e) Personnel who have had contact with a child's excretions, secretions or blood, whether directly or indirectly, in activities, such as performing a physical examination, providing catheter care or changing diapers, shall comply with the handwashing standards at N.J.A.C. 8:43J-15.2(a) immediately after such contact.

(f) The facility shall maintain equipment and supplies used for sterilization, disinfection and decontamination purposes according to manufacturers' specifications.

(g) The facility shall ensure that all needles and syringes are disposed of in compliance with *N.J.A.C. 8:43E*.

8:43J-15.4 Employee Mantoux testing

(a) Each new employee upon employment shall receive a two-step Mantoux tuberculin skin test with five tuberculin units of purified protein derivative.

1. The only exceptions shall be employees with documented negative two-step Mantoux skin test results (zero to nine millimeters of induration) within the last year, employees with a documented positive Mantoux skin test result (10 or more millimeters of induration), employees who have received appropriate medical treatment for tuberculosis, or when medically contraindicated.

(b) Results of the Mantoux tuberculin skin tests administered to new employees shall be acted upon as follows:

1. If the first step of the Mantoux tuberculin skin test result is less than 10 millimeters of induration, the second step of the two-step Mantoux test shall be administered one to three weeks later;

2. If the Mantoux test is significant (10 millimeters or more of induration), a chest x-ray shall be performed and, if necessary, followed by chemoprophylaxis or therapy; and

3. Any employee with positive results shall be referred to the employee's personal physician and if active tuberculosis is suspected or diagnosed shall be excluded from work until the physician provides written approval to return.

(c) The facility shall have written policies and procedures establishing timeframes, requiring annual Mantoux tuberculin skin tests for all employees except those exempted under (a)1 above.

(d) The facility shall assure that all employees have received the Mantoux test upon employment, except those exempted under (a)1 above.

(e) The facility shall retain the results of all tuberculin testing of personnel in each employee's file.

8:43J-15.5 Employee health history and examinations

(a) The facility shall require all new employees to complete a health history and to receive an examination performed by a physician or an advanced practice nurse within two weeks prior to the first day of employment or upon employment.

1. The examination may be deferred for up to 30 days if the nursing director performs a nursing assessment on the new employee upon employment.

(b) The facility shall establish criteria for determining the content and frequency of physical examinations for employees.

(c) The facility shall develop policies that specify the circumstances under which other persons providing direct child-care services shall receive physical examinations and Mantoux testing.

(d) The facility shall develop and implement policies and procedures to ensure that all volunteers and students who have contact with children on a routine basis provide documentation that they have received, at a minimum, a Mantoux tuberculin skin test and either a physical examination or a certification of health status from a physician.

(e) The facility shall offer yearly influenza immunization to employees at no charge to the employees.

1. Facilities shall obtain signed declination forms from employees who decline the influenza immunization and shall retain the forms in the employees' records.

8:43J-15.6 Regulated medical waste

(a) The facility shall ensure that regulated medical waste is collected, stored, handled and disposed of in accordance with applicable Federal and State laws.

(b) The facility shall comply with the *N.J.S.A. 13:1E-48.1* et seq., the Comprehensive Regulated Medical Waste Management Act, and all rules promulgated pursuant thereto, including N.J.A.C. 7:26-3A.

8:43J-15.7 Provision of housekeeping, sanitation and safety

(a) The facility shall provide and maintain a sanitary and safe environment for children.

(b) The facility shall be clean, orderly and free of offensive odors.

(c) The facility shall provide housekeeping and pest control services.

(d) The facility shall develop and implement written objectives, policies, a procedure manual, an organizational plan and a quality improvement program for housekeeping, sanitation and safety.

8:43J-15.8 Housekeeping

(a) The facility shall establish and implement a written work plan for housekeeping operations, with categorization of cleaning assignments as daily, weekly, monthly or annually within each area of the facility.

(b) The facility shall develop procedures for the selection and use of housekeeping and cleaning products and equipment.

(c) The facility shall train housekeeping personnel in cleaning procedures, including the use, cleaning and care of equipment.

8:43J-15.9 Pediatric medical day care facility environment

(a) The facility shall meet the following housekeeping, sanitation and safety conditions:

1. The facility and its contents shall be free of dirt, debris and insect and rodent harborages;
2. Nonskid wax shall be used on all waxed floors;
3. All rooms shall be ventilated to help prevent condensation, mold growth and noxious odors;
4. All child areas shall be free of noxious odors;
5. Throw rugs or scatter rugs shall not be used in the facility;
6. All furnishings are clean and in good repair and mechanical equipment is in working order.

- i. Equipment shall be kept covered to protect from contamination and accessible for cleaning and inspection; and
 - ii. Broken or worn items shall be repaired, replaced or removed promptly;
7. All equipment is provided unobstructed space for operation;
 8. All equipment and materials necessary for cleaning, disinfecting and sterilizing shall be provided;
 9. Thermometers, which are accurate to within three degrees Fahrenheit, shall be maintained in refrigerators, freezers and storerooms used for perishable and other items subject to deterioration;
 10. Pesticides shall be applied in accordance with *N.J.A.C. 7:30*;
 11. Articles in storage shall be elevated from the floor and away from walls;
 12. All poisonous and toxic materials shall be identified, labeled and stored in a locked cabinet or room that is used for no other purpose;
 13. Combustible materials shall not be stored in heater rooms or within 18 feet of any heater located in an open basement;
 14. Paints, varnishes, lacquers, thinners and all other flammable materials shall be stored in closed metal cabinets or containers;
 15. Unobstructed aisles shall be provided in storage areas;
 16. A program shall be maintained to keep rodents, flies, roaches and other vermin out of the facility;
 17. Toilet tissue, soap dispenser, paper towels or air dryers and waste receptacles shall be provided in each bathroom at all times;
 18. All solid or liquid waste that is not regulated medical waste, garbage and trash shall be collected, stored and disposed of in accordance with applicable rules of the New Jersey Department of Environmental Protection and the Department.
 - i. Solid waste shall be stored in insect-proof, rodent-proof and fire-proof, non-absorbent, watertight containers with tight-fitting covers and collected from storage areas regularly, so as to prevent nuisances, such as odors; and
 - ii. Procedures and schedules shall be established and implemented for the cleaning of storage areas and containers for solid or liquid waste, garbage and trash, in accordance with *N.J.A.C. 8:24*;

19. Garbage compactors shall be located on an impervious pad that is graded to a drain that is unobstructed and connected to the sanitary sewage disposal system;

20. Plastic bags shall be used for solid waste removal, which are of sufficient strength to safely contain waste from point of origin to point of disposal and are effectively closed prior to disposal;

21. Draperies, upholstery and other fabrics or decorations shall be fire-resistant and flameproof;

22. Wastebaskets shall be made of noncombustible materials;

23. Latex foam pillows are prohibited;

24. The temperature of the hot water used for bathing and handwashing shall be no less than 60 degrees Fahrenheit and shall not exceed 120 degrees Fahrenheit;

25. Equipment requiring drainage, such as ice machines, shall be drained to a sanitary connection; and

26. The temperature in the facility shall be kept at a minimum of 70 degrees Fahrenheit and a maximum of 85 degrees Fahrenheit when children are in the facility.

SUBCHAPTER 16. TRANSPORTATION SERVICES

8:43J-16.1 Transportation services

(a) The facility shall provide transportation services, either directly or through contractual arrangements, to all children who require transportation between the facility and the child's home.

1. No child's total transportation time between the facility and the child's home shall exceed one hour one way, and shall not exceed two hours a day.

2. The facility shall accommodate the special transportation needs of the child and the medical equipment used by the child.

(b) Vehicles used to transport children shall comply with the mobility assistance vehicle standards at *N.J.A.C. 8:40* and 8:43J-16.2.

8:43J-16.2 Transportation staffing levels

(a) The nursing director shall determine staffing levels to be met in a vehicle whenever a child is being transported, based on the particular needs of the child.

1. The facility shall ensure that at least one direct care staff member, in addition to the driver, is on duty in a vehicle whenever a child is being transported.

8:43J-16.3 Security and accountability during transportation

The facility shall establish and implement plans for security and accountability for the child and the child's personal possessions while transportation services are being provided.

SUBCHAPTER 17. QUALITY IMPROVEMENT

8:43J-17.1 Quality improvement program

(a) The facility shall establish and implement a written plan for a quality improvement program for child care, which shall specify a timetable and the person(s) responsible for the quality improvement program and shall provide for ongoing monitoring of staff and child-care services.

(b) The facility shall establish and implement a quality assurance committee whose members shall include:

1. A Board-certified pediatrician familiar with pediatric medical day care facility services and implementation of quality improvement programs;
2. A registered professional nurse with special expertise in the care of medically complex children; and
3. A certified child life specialist or a social worker with expertise in the care of medically complex children and their families.

(c) Quality improvement activities shall include, but not be limited to, the following:

1. Quarterly reviews by the quality improvement committee of the complete records for at least half of the children served by the pediatric medical day care facility at the time of the quality assurance review.

(d) At a minimum, each quarterly quality assurance committee review shall address:

1. The quality of care evidenced by review of a child's record for compliance with the requirements of N.J.A.C. 8:43J-14.3;
2. Parent involvement, which can be shown by involvement in the development of an interdisciplinary plan of care to be rendered in the pediatric

medical day care facility, attendance at interdisciplinary staffing conferences and participation in individual and/or group education sessions scheduled by the center, which include clearly written, practical and appropriately targeted training materials and scheduled individual and/or group education sessions for parent and other family members;

3. Formal discharge transition procedure, including:

i. Documentation that placement in the pediatric medical day care facility is no longer appropriate for the child;

ii. Evidence of pre-discharge conference involving the parent, representatives of the pediatric medical day care facility professional staff and agencies involved in child care after discharge to ensure a smooth transition; and

iii. A written discharge summary signed by the pediatric medical day care facility nursing director within two weeks of the child's discharge;

4. A review of the goals in each child's interdisciplinary plan of care, progress in achieving the goals, identification of unmet goals and correction plans;

5. At least annual review of:

i. Staff qualifications;

ii. Staff credentials;

iii. Staff orientation; and

iv. Staff education;

6. Evaluation of child care services, staffing, infection prevention and control, housekeeping, sanitation, safety, maintenance of physical plant and equipment, child care statistics and discharge planning services;

7. Evaluation by children and their families of care and services provided by the facility;

8. Review of medication errors and adverse medication reactions by the consultant pharmacist;

9. Audit of child medical records (including those of both active and discharged children) on an ongoing basis to determine if care provided conforms to criteria established by each child care service for the maintenance of quality of care; and

10. Establishment of objective criteria for evaluation of the child care provided by each service.

(e) The coordinator of the quality improvement committee shall submit the results of the quality improvement committee's review to the licensed operator, administrator, medical director and nursing director within 15 working days of its review.

1. The results shall include, at a minimum, the deficiencies found and recommendations for corrections or improvements.

i. The coordinator of the quality improvement program shall immediately report deficiencies that jeopardize child safety to the license holder.

ii. The administrator shall implement measures to ensure that corrections or improvements are made.

8:43J-17.2 Use of restraints

(a) The facility shall establish and implement policies and procedures that support a restraint-free environment for all children.

(b) A restraint shall be used only on an order from a child's primary health care provider.

(c) A specific procedure shall be established for the use of each type of restraint.

(d) The least restrictive restraint shall be used in compliance with the child's primary health care provider's order.

8:43J-17.3 Staff development

(a) The facility shall provide each new employee with an orientation to acquaint the employee with the philosophy, organization, program, practices and goals of the facility.

(b) The facility shall provide or arrange ongoing staff development and/or continuing education programs appropriate to the category of personnel to be conducted and documented to facilitate quality child-care.

(c) The facility shall provide staff development and/or continuing education programs to:

1. Facilitate the ability of the staff to function as a member of an interdisciplinary team, which includes health professionals and the parent;
2. Improve communication skills to facilitate a collaborative relationship between parent and staff;
3. Increase staff's understanding of the effects that childhood illness has on the child's development and the parent and family members;
4. Develop case management skills to assist the family in setting priorities, planning and implementing the child's care at home; and
5. Provide training in the implementation of new technology.

CHAPTER 82

STATEWIDE RESPITE CARE PROGRAM

SUBCHAPTER 5. SPONSORS AND PROVIDERS

8:82-5.2 Qualifications and requirements for provider agencies

(a)-(f) (No change.)

(g) All adult day health care facilities ~~*[used]*~~ ***utilized*** for the Statewide Respite Care Program shall be licensed to provide adult day health services in accordance with *N.J.A.C. 8:43F*-2**.

(h)-(i) (No change.)