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

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

Adopted Amendments: N.J.A.C. 8:43E-10.2, 8:43F, and 8:82-5.2

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

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

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

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

Filed: , 2009 as R. 2009, d. , <u>with substantive and technical changes</u> not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

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

Effective Date: , 2009.

Operative Date: , 2010.

Expiration Dates: N.J.A.C. 8:43E-10.2: August 18, 2011;

N.J.A.C. 8:43F: March 19, 2012;

N.J.A.C. 8:43J: , 2014; and

N.J.A.C. 8:82-5.2: January 2, 2010.

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, Pediatria 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 Román, 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.” (11)

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 Department disagrees with the commenter's implicit assertion that every asthma diagnosis of a child from an inner city should necessarily require a finding of clinical eligibility for PMDC, and that to provide otherwise renders the Department guilty of medical neglect. The commenter appears to suggest that a child's receipt of PMDC services for six hours a day would remedy situations where the child is at home for the other 18 hours of the day. For a PMDC facility to suggest that child abuse or neglect should make a child clinically eligible for Medicaid reimbursement of PMDC is inappropriate. Other systems and services are in place to address child abuse and neglect. N.J.S.A. 9:6-8.10 obliges PMDC facility staff to report suspected child abuse or neglect, including medical neglect, so that the appropriate authorities can secure the safety of a child at risk.

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 if 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/ucca.html.

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 9000 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, systems are in place to respond to the needs of children who are at risk of medical neglect or abuse that are more appropriate and comprehensive than PMDC services. 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 comments.

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, 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 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 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, 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, 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 or 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 to 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 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 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 facility-wide 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 facility-wide 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 N.J.A.C. 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 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 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 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, 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, 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 THROUGH 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, 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 N.J.A.C. 8:43J-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, 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, 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, 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 section 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, 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, 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 a 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 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 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, 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 use by competent adults, but not by children. (3, 4, 6, 7, 8, 9, 15, 16, 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 him or her self 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 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 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 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 comment 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, 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.

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 N.J.A.C. 8:43J-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, 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, 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, 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 excepts 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, 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 THROUGH 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 as 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. Thusly, 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 requires 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. 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, 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, 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, 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, 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, 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 [PMDC] 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, 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 to 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 it in 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 THROUGH 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®], 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® 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." (10)

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 can not 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 THROUGH 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 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, 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, 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 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, 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 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, 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, 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, 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, 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, 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 Proposed Rules 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 state 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 Proposed Rules 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, 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, 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 https://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 (a)1 and 3; adding as new (a)1, “1. Infants”; and adding as new (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, 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, 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, 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, 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 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, 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, 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, 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, "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 health care 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.

## 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]*):

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:

…

"Child life specialist" means:

1. (No change from proposal.)

2. Until *[(three years from the effective date of this chapter)]* *_____, 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.

8:43J-3.2 Qualifications of the administrator of a pediatric medical day care facility

(a) (No change from proposal.)

(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. – 6. (No change from proposal.)

7. Ensuring that each child satisfies N.J.A.C. 8:43J-6.1(c) prior to admission.

i. For purposes of this section, 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) – (d) (No change from proposal).

(e) The manual shall address at least the following:

1. – 7. (No change from proposal.)

8. The maintenance of an individual record for each child that contains:

i. -- iv. (No change from proposal.)

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. – 16. (No change from proposal.)

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. – v. (No change from proposal.)

(f) – (h) (No change from proposal.)

8:43J-3.13 Required documents

(a) (No change from proposal.)

*(b) Information on ordering the New Jersey Administrative Code is available:

1. On the Internet at lexisnexis.com;

2. By writing to LexisNexis® Matthew Bender®, 744 Broad Street, Newark, NJ 07102; or

3. By telephoning LexisNexis® at (973) 820-2000 or (800) 252-9257.*

8:43J-6.3 Personnel

(a) – (d) (No change from proposal.)

(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) (No change from proposal.)

(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. – 3. (No change from proposal.)

4. *[The]* *Signed acknowledgement of receipt of the* applicable policies for the performance of overtime, compensatory time, performance evaluations and termination of employment.

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. – iii. (No change from proposal.)

iv. Pediatric home care; *[or]*

v. A pediatric medical day care facility; *or

vi. An in-patient pediatric rehabilitation hospital;* and

2. (No change from proposal.)

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. – 2. (No change from proposal.)

(b) – (d) (No change from proposal.)

8:43J-11.2 Rehabilitation services

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

(d) *[Written progress notes on each therapy session shall be made by therapists as part of and be included in the child's medical record.]* *Therapists shall make written progress notes that the facility shall maintain as part of the child's medical record.*

(e) – (f) (No change from proposal.)

8:43J-11.3 Rehabilitation supplies and equipment

(a) (No change from proposal.)

(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]* *Pediatric therapy table with mat*;

2. - 10. (No change from proposal.)

8:43J-13.1 Physical plant

(a) – (f) (No change from proposal.)

(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)]* *_____, 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) – (i) (No change from proposal.)