Filed October 14, 2014

HUMAN SERVICES

DIVISION OF DEVELOPMENTAL DISABILITIES

Mechanical Restraints and Safeguarding Equipment

Readoption with Amendments: N.J.A.C. 10:42

Adopted New Rules: N.J.A.C. 10:42-2.3, 3.2, and 3.5

Proposed: June 2, 2014, at 46 N.J.R. 1302(a)

Adopted: September 24, 2014, by Jennifer Velez, Commissioner, Department of Human Services.

Filed: October 8, 2014, as R.2014 d.170, **with non-substantial changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 30:1-12 et seq., 30:4-6 et seq., and 30:6D-5

Effective Dates: October 8, 2014, Readoption;

November 3, 2014, Amendments and New Rules.

Expiration Date: October 8, 2021.

Summary of Public Comments and Agency Responses:

The following is a summary of the comments received from the public and the Division's responses. Each commenter is identified at the end of the comment by a number that corresponds to the following list:

1. Darren Blough, MSW, BCaBA, State Director, AdvoServ
2. Suzanne Buchanan, Psy.D., BCBA-D, Executive Director, Autism New Jersey
3. Jennifer DeLuca, Sr. Licensing-Accreditation Specialist, Bancroft
4. Kevin K. Walsh, Ph.D., Director of Quality Management and Research, Developmental Disabilities Health Alliance, Inc.

5. Jennifer M. Halper, Senior Staff Attorney, Disability Rights New Jersey
6. Carol Markowitz, M.A., M.Ed., Chief Program Officer, Eden Autism Services
7. Valerie Sellers, Chief Executive Officer, New Jersey Association of Community Providers
8. Richard A. Ridge, RN, MBA, PhD, NEA-BC, CENP, Chief Executive Officer, New Jersey State Nurses Association
9. Thomas Baffuto, Executive Director, The Arc of New Jersey

COMMENT: Two commenters asked questions about specific devices, one inquiring whether a specific device used by its agency would be considered as a prohibited device, and the other whether the use of a specific device used by its agency would be considered a mechanical restraint or safeguarding device. (1 and 6)

RESPONSE: Questions regarding specific devices are fact sensitive, operational questions, more appropriately addressed with the commenters directly. The Division thanks the commenters for their questions and looks forward to working with them on these issues.

COMMENT: Two commenters inquired whether the Division Human Rights Committee referred to in N.J.A.C. 10:42-3.4(a)14 and 15 could be the providers' internal Human Rights Committee that has been approved by the Division. (1 and 3)

RESPONSE: The purpose of these provisions is to allow for Division oversight when a mechanical restraint is used for an individual three times in a six-month period and such use is not included in the behavior support plan. Providers may develop their own internal human

rights committees, however the requirements outlined in N.J.A.C. 10:42-3.4(a)14 and 15 require the interdisciplinary team to report to a Division Human Rights Committee.

COMMENT: A commenter inquired whether the behavior support committee and human rights committee listed in N.J.A.C. 10:42-1.4(g)2 and 3, respectively, refer to the provider's internal behavior support committee and human rights committee. (3)

RESPONSE: The behavior support committee and human rights committee listed in N.J.A.C. 10:42-1.4(g)2 and 3 refer to the provider's internal committees. Division review of any special device sought to be developed is provided for in N.J.A.C. 10:42-1.4(g)5 and 6 through the required approval of the Behavior Policy Review Committee and the Assistant Commissioner.

COMMENT: Two commenters supported the Division's creation of a Behavior Policy Review Committee. One recommended that a sizeable number of the Committee's members be Board Certified Behavior Analysts with professional expertise in the assessment and treatment of severe behavior disorders and a minimum of five years in the field. This commenter also requested clarification of the specific responsibilities of this committee. The second inquired how appointees will be selected, how long they will serve, and whether the appointees will represent a broad base of stakeholder groups. (2 and 9)

RESPONSE: The Division thanks the commenters for their support and notes that the Division has been utilizing a Behavior Policy Review Committee for a number of years. This rule codifies that committee. The Division recognizes the importance of behavior analysts, but believes that it is appropriate for the Assistant Commissioner to appoint professionals with clinical expertise in behavior management, without strict adherence to a specific course of study,

to allow for flexibility. The Assistant Commissioner appoints members of the committee who have the required expertise, and appointees will serve at the discretion of the Assistant Commissioner. The specific duties of the Behavior Policy Review Committee are outlined in N.J.A.C. 10:42-1.4(g)5, 3.1(a), and 3.2(a). Its functions are to review and approve agency procedures for the use of restraints, training materials, and any special devices that an agency may seek to develop.

COMMENT: A commenter recommended that Board Certified Behavior Analysts be required to sit on the provider's or Division's Behavior Support Committees and that Board Certified Behavior Analysts be involved in the reviews outlined in N.J.A.C. 10:42-3.1(b) and 3.5(a). (2)

RESPONSE: The Division recognizes the importance of Behavior Analysts in the field, but believes it is appropriate for the Assistant Commissioner, Chief Executive Officer, Executive Director, or Regional Administrator to appoint a group of professionals with clinical expertise, without strict adherence to a specific course of study, to allow for flexibility.

COMMENT: A commenter suggested that the Behavior Policy Review Committee and the Behavior Support Committee defined in N.J.A.C. 10:42-1.3 include an individual to advocate for the individual from a civil rights perspective. (5)

RESPONSE: The functions of the Behavior Policy Review Committee and the Behavior Support Committee require that their members have the appropriate clinical expertise in behavior management and the evaluation of behavior support plans. The Division recognizes the importance of the civil rights of the individuals it serves. Human Rights Committees, defined in N.J.A.C. 10:42-1.3 and more fully discussed in N.J.A.C. 10:41A, function as advisory bodies on

issues affecting the rights of the individual, and have an oversight role within the overall scheme of the rules. Human Rights Committee membership includes a spectrum of stakeholders, specifically, professionals, individuals served, advocates, and/or interested individuals from the community at large. The Division believes that the membership and role of the Human Rights Committee serves to address the rights of the individual.

COMMENT: A commenter agreed with the Division's amendment to the definition of "informed consent" in N.J.A.C. 10:42-1.3 to require that a third party have legal authority to act on another's behalf where the individual does not have sufficient decision-making capacity to make his or her own decisions. However, the commenter stated that before looking to a third party, the Division should make every effort to engage the individual in shared and supported decision making. (5)

RESPONSE: The definition of informed consent provides, in part, a "… formal expression, oral or written, of agreement with a proposed course of action by an individual who has the capacity, the information, and the ability to render voluntary agreement on his or her own behalf." The Division believes that this provision appropriately involves the individual in the decision-making process. In those circumstances where a third party has legal authority to act on another's behalf, the Division must follow the law with respect to that party's authority to provide informed consent.

COMMENT: A commenter believes that N.J.A.C. 10:42-1.4(f) should give more guidance on the detail required in the service plan to justify the use of a particular device, including, at a

minimum, documentation of prior interventions and supports that were tried and were unsuccessful. (5)

RESPONSE: The Division agrees with the importance of documentation of prior interventions and supports that were tried and were unsuccessful. Therefore, the rules readopted with amendments and new rules significantly revises the definition of mechanical restraint to mean a device used when "a behavior will likely endanger the health or safety of the individual or others and less restrictive techniques have proved ineffective or not feasible." Since, by definition, a mechanical restraint cannot be used unless "less restrictive techniques have proved ineffective or not feasible," N.J.A.C. 10:42-1.4(f) requires this issue to be addressed in the service plan. The service plan must also document the threshold question of whether the behavior endangers the health or safety of the individual or others. Additionally, the proposed rules contain a new section on quality management. This section, N.J.A.C. 10:42-3.5(a)6, requires agencies to "maintain documentation of the implementation of teaching strategies or alternate program activities intended to increase the individual's capacity to utilize and/or respond to more proactive and positive coping strategies that are intended to replace the use of mechanical restraints." The Division believes that in light of this documentation requirement contained within the quality management section and the amendment to the definition of "mechanical restraint," it is not necessary to change N.J.A.C. 10:42-1.4(f) to provide more guidance on detail to be included in the service plan, as this would be duplicative.

COMMENT: A commenter believes that N.J.A.C. 10:42-1.4(j) should require documentation that devices were inspected after each use. (5)

RESPONSE: N.J.A.C. 10:42-1.4(j) is contained within the general requirements section of the rules and requires mechanical restraints to be inspected following each use to ensure safety. Subchapter 3 of the rules sets forth the requirement that a service provider requesting to use mechanical restraints must submit comprehensive written procedures governing the use of restraints to the Behavior Policy Review Committee, including staff training. Among other things, staff training must include training on the requirements of the rules for the use of mechanical restraints, which includes the requirement that devices must be inspected following each use. The Division believes that the rules' robust requirements regarding written procedures and training, in addition to the rules' overall documentation requirements, incident reporting, and quality management provisions, will ensure that devices are properly inspected for safety without a need for specific documentation of the inspection.

COMMENT: One commenter objects to the use of mechanical restraints as part of an approved behavior support plan; another states that it is reluctant to support the use of mechanical restraints as part of an approved behavior support plan. If mechanical restraints are to be used pursuant to a behavior support plan, the second commenter would prefer to see very specific justification, timeframes, and outcomes with a requirement for immediate reevaluation if the outcomes are not realized timely. (5 and 9)

RESPONSE: The Division understands the commenters concerns and intends to continue to work with the stakeholder community in the future with the goal of reducing the use of mechanical restraints, and ultimately eliminating their use within a behavior support plan. The Division believes that the proposed rules contain sufficient process and oversight, including comprehensive written procedures, staff training requirements, the delineation of prohibited

practices, and quality management criteria, to ensure that restraints are used only when a health or safety concern exists and other less restrictive techniques have proven ineffective or not feasible. The Division notes, however, that it views the rules as an interim step in developing policy for the use of restraints, with the ultimate goal of eliminating their use within a behavior support plan.

COMMENT: Two commenters support the enumeration of prohibited practices under N.J.A.C. 10:42-2.3. One encourages the Division to continually update this listing as often as necessary. (5 and 9)

RESPONSE: The Division thanks the commenters for their support, and will update the listing as appropriate and necessary.

COMMENT: A commenter supports the notification of families within 24 hours of the use of a mechanical restraint under N.J.A.C. 10:42-3.1(b)10 and strongly supports the reduction in the effective time of an emergency restraint order from 12 hours to one hour in N.J.A.C. 10:42-3.3(a)4. (5)

RESPONSE: The Division thanks the commenter for its support.

COMMENT: A commenter agrees with the requirement in N.J.A.C. 10:42-3.3(a)14 that an unusual incident report be completed when restraints are unauthorized, improperly implemented, or cause injury to the individual. However, the commenter believes that an unusual incident report should also be completed whenever a mechanical restraint is used as an emergency measure. (5)

RESPONSE: The rules provide that when a mechanical restraint is used as an emergency measure, a special meeting of the Interdisciplinary Team (IDT) must be held to review current programming and alternatives. When mechanical restraints are used as an emergency measure for an individual more than three times in a six-month period, the IDT shall forward the results of its review to a Division Human Rights Committee. The Human Rights Committee is required to review the matter and forward the results of its review to the Assistant Commissioner or designee. The Division believes that these provisions provide proper oversight of the use of restraints in emergency situations. An additional requirement to complete an unusual incident report would be duplicative of these provisions, and moreover, outside the scope of the intended use of unusual incident reports.

COMMENT: A commenter supports the additional oversight added to N.J.A.C. 10:42-3.3(a)15 and 16 when mechanical restraints are used for an individual three times in emergency situations within a six-month period and believes the Division should collect sufficient data to determine whether this is an appropriate timeframe to effect a reduction in the use of mechanical restraints. (5)

RESPONSE: The Division thanks the commenter for its support. The quality management provisions of the rules require entities to collect data on the use of mechanical restraints and provide that data to the Division. The Division will utilize this data to analyze the use of restraints with the goal of reducing and eliminating the use of mechanical restraints.

COMMENT: A commenter supports the Division's rulemaking to require agency reporting of the use of mechanical restraints under N.J.A.C. 10:42-3.5 and urges the Division to make the data collected public. (5)

RESPONSE: The Division thanks the commenter for its support. As appropriate, the Division will share data with the stakeholder community as it continues to work with the community to reduce the use of restraints.

COMMENT: A commenter states that the proposed regulation appears to be comprehensive and designed to protect the rights of the population with developmental disabilities and the proposed changes to staff training and documentation also appear to be reasonable and will help ensure quality. (6)

RESPONSE: The Division thanks the commenter for its support.

COMMENT: A commenter suggested that the rules stipulate that the Behavior Policy Review Committee include representation from provider agency clinicians practicing within their agencies. (7)

RESPONSE: The rules provide that the members of the Behavior Policy Review Committee be professionals with clinical expertise in behavior management appointed by the Assistant Commissioner. The Division believes that the rules should not specify where those professionals are employed, to allow for flexibility. The Division also notes that since the primary purpose of the Behavior Policy Review Committee is to review and approve policy and procedures submitted by providers, conflict of interest concerns may arise if a provider agency clinician reviews his or her agency's policies or those submitted by other provider agencies.

COMMENT: A commenter is concerned that the statutory definition of Qualified Intellectual Disabilities Professional (QIDP) is too broad and therefore a narrowed down list would be preferable as a person who meets the definition of a QIDP may not be knowledgeable on the topic of restraint. (9)

RESPONSE: N.J.A.C. 10:42-1.3 defines a Qualified Intellectual Disabilities Professional (QIDP) as a person who meets or exceeds the qualifications as required by 42 CFR Subpart I, Section 483.430 and has completed the training requirements of the rules. The QIDP standard is the standard adopted by the Federal government as the qualifications for those authorized to approve the use of mechanical restraints in Institutional Care Facilities for Individuals with Intellectual Disabilities. The Division believes it appropriate to be in conformity with this Federal standard. Further, the Division notes that the authorizing personnel must be designated by the Chief Executive Officer, Regional Administrator, or Executive Director; must meet or exceed the requirements of a QIDP; and must complete the training requirements of the rule. The Division believes that these requirements will ensure that appropriate professionals serve in the role of authorizing personnel.

COMMENT: A commenter praises the Division for the addition of N.J.A.C. 10:42-3.5, which outlines quality management guidelines. The commenter believes that the newly proposed section offers another layer of oversight and protection. (9)

RESPONSE: The Division thanks the commenter for its support.

COMMENT: A commenter approved of the Division's heavier emphasis and utilization of positive behavioral supports. (9)

RESPONSE: The Division thanks the commenter for its support.

COMMENT: A commenter suggested that N.J.A.C. 10:42-1.4(a)2 be changed from "Access to needed services, activities, and possessions which are enjoyable and individualized" to "Access to needed services, activities, and possessions, which are based on choice, enjoyable and individualized through the use of stimulus preference assessments to identify functional reinforcers." (2)

RESPONSE: The Division agrees that individual choice and preferences should be emphasized. The terms "enjoyable" and "individualized" were intended to encompass individual choice and preferences. However, the Division believes that the wording of this paragraph could be modified for clarity, and is changing N.J.A.C. 10:42-1.4(a)2 upon adoption to "Access to needed services, activities, and possessions, which are based on choice and individual preference." The Division believes that the additional suggested wording is not plain language that would be readily understood by people outside of the field.

COMMENT: A commenter suggested that the sentence "Such equipment should be used in conjunction with the provision of individualized behavior support services (e.g. shaping procedure, positive reinforcement schedules, desensitization) designed to increase the individual's appropriate compliance with the medical procedure" be added to the end of N.J.A.C. 10:42-1.4(i). (2)

RESPONSE: N.J.A.C. 10:42-1.4(i) is located in the general requirements section of the rule. Subchapter 4 more fully sets forth the requirements for the use of safeguarding equipment on a temporary basis to accomplish a needed evaluation, examination, or treatment. This subchapter

provides that the use of the safeguarding equipment must be at the direction of a physician or dentist, documented in the client record, and that informed consent must be obtained unless an emergency exists. The Division believes that these provisions provide appropriate oversight for the use of safeguarding equipment during medical procedures. The Division will, however, explore this issue with stakeholders as it continues to address issues surrounding the use of mechanical restraints and safeguarding equipment in the future.

COMMENT: A commenter was concerned that N.J.A.C. 10:42-3.1(b)2, which provides that the procedure submitted contain "Identification of the training curriculum to be followed, with diagrams, photographs or graphs, and a narrative description providing instructions for the safe application of each mechanical restraint" could be interpreted to require the use of a commercially developed curriculum due to the phrase "identification of the training curriculum." The commenter recommended a change in language to clarify that a commercially developed curriculum is not required. (4)

RESPONSE: The Division notes that this section does not specify that a commercially produced curriculum is required, but rather, that whatever training curriculum is to be followed is identified. The Division thanks the commenter for its input, but does not believe that the sentence is ambiguous or that a change is required.

COMMENT: One commenter noted that there are independent practitioners in the medical field other than physicians, including Physician Assistants, Nurse Practitioners, Clinical Nurse Specialists, and Advanced Practice Nurses, and suggested that "physician," be replaced with "a

practitioner licensed to practice medicine." Another commenter requested that Advanced Practice Nurses be included in the rules in addition to physicians. (4 and 8).

RESPONSE: The Division acknowledges that there are licensed medical practitioners in addition to physicians, and believes that this comment merits consideration. However, this change would be too substantial to make upon adoption of the rules. The Division will address this issue with stakeholders as it continues to work to revise the rules in the future, and will amend the rules to include other licensed medical practitioners, if appropriate.

COMMENT: A commenter expressed concern about that the requirement in N.J.A.C. 10:42-3.3(a)1 and 3.4(a)1 that the IDT review an individual's record to identify areas of potential increased risk in the application of a mechanical restraint, and if they are identified, that a physician "certify" that a technique to be employed is not medically contraindicated for the individual prior to an initial restraint authorization. The commenter noted that physicians are generally unable to provide such "certification," and suggested that the IDT review the record and, if necessary, request an opinion from a health care provider, as opposed to a certification. The commenter notes that this had been suggested several years ago by a workgroup consisting of stakeholders and Division staff convened to revise the standards for the use of mechanical restraints. (4)

RESPONSE: The Division is aware of the difficulties in obtaining a certification from a physician that a technique to be employed is not medically contraindicated, and acknowledges that this issue was discussed within the workgroup meeting several years ago regarding mechanical restraints. Therefore, the Division is changing N.J.A.C. 10:42-3.3(a)1 and 3.4(a)1 upon adoption to change the term "certify." N.J.A.C. 10:42-3.3(a)1 and 3.4(a)1 will be changed

to read "If potential areas of increased risk are identified, the IDT shall obtain an opinion from a physician that the technique to be employed is not medically contraindicated for the individual prior to an initial restraint authorization." This change reflects that in practice, physicians do not provide "certifications" as stated in the rule. Oversight for the individual's safety is maintained by requiring the IDT to obtain an opinion from a physician if potential areas of increased risk are identified.

COMMENT: A commenter expressed concern that the underlined passage in N.J.A.C. 10:42-2.2(f), which requires the IDT to "… review the functional behavior assessment, functional behavior analysis and clinical assessments performed on an individual and/or obtain such information if these procedures have not been completed," could be interpreted to require that these assessments be completed, even in cases in which they may not be needed. The commenter references instances in which an event occurs requiring the use of mechanical restraint that is atypical for the individual. (4)

RESPONSE: N.J.A.C. 10:42-2.2(f) requires that when "an individual exhibits serious assaultive, self-injurious, or destructive behavior, controllable only by use of mechanical restraint" the IDT shall meet to identify possible causes and develop strategies to address the behavior. The IDT is to review the functional behavior assessment, functional behavior analysis, and clinical assessments performed on an individual and/or obtain such information if these procedures have not been completed. The Division agrees that the type and extent of assessment and analysis should be appropriate to the individual and the situation, such as in the event of an atypical serious event, as discussed by the commenter. The Division believes, however, that some level of clinical assessment should be reviewed or obtained where a serious behavior results in the use

of mechanical restraint, although this assessment may not be a functional behavior assessment or analysis. The Division believes that the language in the rule is flexible enough to allow the IDT the discretion to obtain an assessment or analysis appropriate to the individual and the situation.

Federal Standards Statement

The Department has reviewed the applicable Federal statutes and regulations, the Federal Developmental Disabilities Assistance and Bill of Rights Act (42 U.S.C. §§ 15041 et seq.) and the intermediate care facilities for individuals with intellectual disabilities regulations (42 CFR 483.450) and has determined that the rules readopted with amendments and new rules meet, but do not exceed Federal requirements.

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

SUBCHAPTER 1. GENERAL PROVISIONS

10:42-1.4 General requirements

(a) The Division recognizes that the risk of dangerous behavior may be minimized when the following conditions are made available to the individual:

1. (No change.)

2. Access to needed services, activities, and possessions which are *[enjoyable and individualized]* ***based on choice and individual preference***;

3.-7. (No change.)

SUBCHAPTER 3 APPLICATION AND IMPLEMENTATION

10:42-3.3 Implementation standard: developmental centers and private licensed facilities for persons with developmental disabilities licensed pursuant to N.J.A.C. 10:47.

(a) Following approval by the Behavior Policy Review Committee, for use of mechanical restraint**s**, the following standards shall apply:

1. The IDT shall review the client record to identify potential areas of increased risk in the application of mechanical restraints for the individual due to medical conditions, mental health status, physical functioning or other personal characteristics. If potential areas of increased risk are identified, *[a physician must certify]* ***the IDT shall obtain an opinion from a physician*** that the technique to be employed is not medically contraindicated for the individual prior to an initial restraint authorization.

10:42-3.4 Implementation standards: community programs for persons with developmental disabilities.

(a) Following approval by the Behavior Policy Review Committee for the use of mechanical restraints, the following shall apply:

1. The IDT shall review the client record to identify potential areas of increased risk in the application of mechanical restraints for the individual due to medical conditions, mental health status, physical functioning or other personal characteristics. If potential areas of increased risk are identified, *[a physician must certify]* ***the IDT shall obtain an opinion from a physician*** that the technique to be employed is not medically contraindicated for the individual prior to an initial restraint authorization.