

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Department of Developmental Disabilities

Regulation/Package Title: Behavioral Support

Rule Number(s): 5123:2-2-06 (New), 5123:2-3-25 (Rescind), Paragraph (J) of 5123:2-1-02 (Rescind)

Date: May 12, 2014

Rule Type:

☒ New

☐ Amended

☐ 5-Year Review

☒ Rescinded

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. Please briefly describe the draft regulation in plain language.

Please include the key provisions of the regulation as well as any proposed amendments.

Proposed new rule 5123:2-2-06 limits the use of and sets forth requirements for development and implementation of behavioral support strategies that include restrictive measures. The purpose of the rule is to ensure that:

- restrictive measures are used only when necessary to keep people safe;
- individuals with developmental disabilities are supported in a caring and responsive manner that promotes dignity, respect, and trust and with recognition that they are equal citizens with the same rights and personal freedoms granted to Ohioans without developmental disabilities;

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- services and supports are based on an understanding of the individual and the reasons for his or her actions; and
- effort is directed at creating opportunities for individuals to exercise choice in matters affecting their everyday lives and teaching and supporting individuals to make choices that yield positive outcomes.

Restrictive measures are measures of last resort which may be used only after obtaining approval from a human rights committee. Restrictive measures include manual restraint, mechanical restraint, time-out, chemical restraint, and restriction of an individual's rights; these terms are defined in paragraph (C)(11) of the rule. The proposed new rule applies broadly across the developmental disabilities service delivery system and will replace paragraph (J) of existing rule 5123:2-1-02 (*County Board Administration*) and existing rule 5123:2-3-25 (*Discipline, Restraint, Behavior Modification, and Abuse of Residents* [in licensed residential settings]).

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

5123.04, 5123.19, 5123.62, 5124.02, 5124.03, and 5126.08

3. Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program? If yes, please briefly explain the source and substance of the federal requirement.

Yes; the rule also implements federal requirements to ensure the health and welfare of individuals who are enrolled in Medicaid Home and Community-Based Services waivers and individuals who reside at Intermediate Care Facilities for Individuals with Intellectual Disabilities ("Intermediate Care Facilities"). The Centers for Medicare and Medicaid Services (CMS), the federal Medicaid agency, requires states to implement rules to administer Medicaid programs. CMS also requires that an individual's services be based upon person-centered planning, a process directed by the individual that assists the individual to identify and access a personalized mix of paid and non-paid supports that will enable him or her to achieve personally-defined outcomes in the most inclusive community setting. The personally-defined outcomes and the supports, therapies, treatments, and or other services the individual is to receive to achieve those outcomes becomes part of the plan of care.

4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

The rule sets forth, for the first time, uniform standards for behavioral support that apply across Ohio's entire developmental disabilities service delivery system. Ohio is one of several states in front of a national trend to shift the culture of supporting individuals with developmental disabilities from one of coercion and control to one of positive and caring

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support. The standards for how individuals with developmental disabilities are treated should not vary based on where individuals live or how their services are funded; such distinctions do not justify unequal treatment or a lesser recognition of an individual's rights.

While federal law is not specific, person-centered planning as described in 42 C.F.R. 441.301(c)(2) supports these provisions:

- Paragraph (C)(8) of the rule prohibits all forms of prone restraint. Prone restraint has been found to be potentially fatal due to the impact this maneuver has on reducing a person's ability to breathe. Prone restraint has been banned in Ohio's developmental disabilities system since 2008 and statewide since 2009.
- Paragraph (C)(11) of the rule sets forth that restrictive measures such as manual restraint, mechanical restraint, time-out, chemical restraint, and restriction of an individual's rights may be used only when necessary to keep people safe and with prior approval by a human rights committee. Paragraph (D)(2) specifies that manual restraint, mechanical restraint, time-out, or chemical restraint may be used only when an individual's actions pose a direct and serious risk of physical harm to the individual or another person. Paragraph (D)(3) of the rule specifies that restriction of an individual's rights may be used only when an individual's actions pose a direct and serious risk of physical harm to the individual or another person or are very likely to result in the individual being the subject of legal sanction such as eviction, arrest, or incarceration.
- Paragraph (D)(6) of the rule establishes that persons who develop behavioral support strategies that include restrictive measures shall hold professional license or certification, a certificate to practice as a certified Ohio Behavior Analyst, or a Bachelor's or graduate-level degree with three years of experience in developing and/or implementing behavioral support or risk reduction strategies. Although the federal regulations governing Intermediate Care Facilities are not as specific—42 C.F.R. 483.440(c)(1) requires that each resident have an individual program plan developed by an interdisciplinary team of professionals, paraprofessionals, and non-professionals who possess the knowledge, skills, and expertise necessary to accurately identify the comprehensive array of the resident's needs—Intermediate Care Facilities are well-positioned to have staff who meet the standards established in the new rule.

5. What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?

The rule is necessary to ensure individuals with developmental disabilities are supported in a caring and responsive manner with respectful solutions that recognize their rights, advance their personal growth and emotional wellbeing, and ensure their health and welfare.

6. How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?

The Department will measure the success of the regulation in terms of the health and welfare

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of individuals receiving services, individuals' satisfaction with the services they receive, Ohio's compliance with Medicaid regulations governing Home and Community-Based Services waivers and Intermediate Care Facilities, and the effectiveness of restrictive measures in terms of increasing or decreasing behavior as intended. Data points will include the nature of antecedent factors that trigger utilization of restrictive measures, the number and duration of behavior support strategies that include restrictive measures, the types and number of restrictive measures employed, and the number of unapproved behavior supports employed.

Development of the Regulation

7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

If applicable, please include the date and medium by which the stakeholders were initially contacted.

The Department convened a group of stakeholders representing the broad-ranging perspectives of Ohio's developmental disabilities services delivery system. The group met three times in 2013 (October 11, November 4, and December 13) and twice in 2014 (February 21 and March 19). The following people participated:

- Bill Adams, People First
- Anita Allen, Ohio Provider Resource Association
- Susan Blum, Alvis House
- Dana Charlton, Ohio Self Determination Association
- Richard Cirillo, Cuyahoga County Board of Developmental Disabilities
- Betty Davis, Community Concepts
- Jeff Davis, Ohio Provider Resource Association
- Wayne Davis, Community Concepts
- Sasha Ferryman, Creative Foundations
- Cindy Ison, Advocacy and Protective Services, Inc.
- Willie Jones, Ohio Association of County Boards Serving People with Developmental Disabilities
- David Lewis, The Arc of Ohio
- Steve Maenle, Champaign Residential Services, Inc.
- Jeff Marinko-Shrivers, Franklin County Board of Developmental Disabilities
- Sarah Mossburg, Ohio Self Determination Association/Project STIR
- Steve Mould, Ohio Health Care Association
- Angela Ray, Franklin County Board of Developmental Disabilities
- Karla Rinto, Advocacy and Protective Services, Inc.
- Brenda Scroggs, People First/Creative Foundations
- Tara Shambaugh, Richland County Board of Developmental Disabilities

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- Kerstin Sjoberg-Witt, Disability Rights Ohio
- Jeanne Stuntz, Ohio Self Determination Association/Dynamic Pathways/On the Mark Services
- Rae Sutherland, People First Ohio
- Gary Tonks, The Arc of Ohio
- Pat Uhlenhake, Advocacy and Protective Services, Inc.
- Dustin Watkins, Values and Faith Alliance/Bittersweet Farms
- Marilyn Weber, Ohio Centers for Intellectual Disabilities
- Adonna Wilson-Baney, Disability Rights Ohio

On January 10, 2014, the Department disseminated the draft rule to representatives of the following organizations to obtain pre-clearance feedback:

Advocacy and Protective Services, Inc.
 The Arc of Ohio
 Autism Society of Ohio
 Councils of Governments
 Disability Housing Network
 Disability Rights Ohio
 Down Syndrome Association of Central Ohio
 Family Advisory Council
 The League
 Ohio Association of County Boards Serving People with Developmental Disabilities
 Ohio Developmental Disabilities Council
 Ohio Health Care Association
 Ohio Provider Resource Association
 Ohio Self Determination Association
 Ohio SIBS (Special Initiatives by Brothers and Sisters)
 Ohio Superintendents of County Boards of Developmental Disabilities
 Ohio Waiver Network
 People First of Ohio
 Values and Faith Alliance

Through the Department's official rules clearance process, the draft rule and the Business Impact Analysis are being disseminated to representatives of the organizations listed above and will be simultaneously posted at the Department's *Rules Under Development* webpage (<https://doddportal.dodd.ohio.gov/rules/underdevelopment/Pages/default.aspx>) for feedback from the general public.

8. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

Many of the concepts addressed in the rule elicit passionate discourse reflecting a full

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spectrum of opinions. The stakeholder meetings provided a venue for frank discussion on these important and challenging issues and led to development of a balanced rule. Throughout the process, there were significant differences from one draft of the rule to the next until the very last, which had comparatively fewer changes.

Individuals with developmental disabilities and representatives of advocacy organizations indicated the rule must acknowledge that individuals with developmental disabilities are equal citizens with the same rights and personal freedoms granted to Ohioans without disabilities. This principle is featured prominently in paragraph (A)(2) of the rule.

Some workgroup participants suggested that time-out should be prohibited; others maintained that time-out was an effective tool that is sometimes less restrictive and less traumatic than alternative measures for keeping an individual safe. Advocates suggested that the maximum period for time-out be reduced from one hour—as permitted in paragraph (J)(2)(q)(ix) of existing rule 5123:2-1-02—to thirty minutes; paragraph (C)(11)(c)(i) was adjusted accordingly.

Representatives of Intermediate Care Facilities wanted the rule to reference the federal regulation governing development of a resident's individual plan. A reference was added to the definition of "team" in paragraph (C)(15) of the rule.

Provider representatives suggested that there are situations in which it might be appropriate to restrict an individual's rights even though the individual's actions do not pose a risk of physical harm to self or others. After lengthy discussion, paragraph (D) of the rule was revised to permit restriction of an individual's rights in cases when the individual's actions pose risk of physical harm or are very likely to result in the individual being the subject of legal sanction such as eviction, arrest, or incarceration.

Workgroup participants and other system stakeholders expressed various opinions regarding the qualifications, set forth in paragraph (D)(6) of the rule, for persons developing behavioral support strategies that include restrictive measures. Some were concerned that the qualifications were too stringent and would create a hardship in smaller, rural counties. Some thought the qualifications were not sufficiently stringent, given the complexity of serving individuals with very challenging behavior and/or the seriousness of imposing restrictive measures. The Department tried to strike a balance that recognizes the value of both professional licensure and practical experience.

Another topic of considerable debate was the composition of the Human Rights Committee described in paragraph (F)(1) of the rule. Some stakeholders said recruiting an individual who receives services or the family member of an individual would be too difficult; advocates said including an individual who receives services was essential. Again, the Department's goal was to achieve balance, in the rule as well as in the Committee membership. Ultimately, a requirement that each Committee include at least one individual

who receives services was incorporated as paragraph (F)(1)(b).

9. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

Data regarding the nature and frequency of interventions currently utilized throughout Ohio's developmental disabilities service delivery system were considered. The data, which indicate that some inappropriate interventions are still employed, served as the impetus to set forth clearly, in paragraph (C)(8), types of interventions that are prohibited and to twice make the point, in paragraph (D)(3), that arbitrary rights restrictions are not allowed.

10. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?

The Department considered requests by some stakeholders to entirely refrain from using any form of the word "behavior" in the rule to refocus the system on positive support, but determined instead that minimal use of the word "behavioral" to modify "support strategies" was necessary to ensure that all system stakeholders would recognize this critical rule.

The Department considered suggestions that Intermediate Care Facilities, because they are governed by federal regulations, should not be subject to this rule. The Department was persuaded instead by individuals and families who receive services and have advocated relentlessly for a service delivery system in which the standards for care are uniform and focused on best outcomes for individuals served, irrespective of funding streams and service delivery settings. While the rule focuses on the rights and interests of individuals being served, its provisions are compatible with the federal requirements.

11. Did the Agency specifically consider a performance-based regulation? Please explain. *Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.*

No; the federal Centers for Medicare and Medicaid Services requires Ohio to promulgate and enforce rules that regulate requirements and processes to be followed by administrators, providers of services, and recipients of services under Medicaid waivers. Further, the paramount importance of the subject of this rule dictates the need to be sufficiently prescriptive to ensure individuals are not harmed.

12. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

The Department is responsible for promulgating rules regarding Ohio's developmental disabilities service delivery system. The new rule establishes uniform standards for

supporting individuals across the system, regardless of where they live or how their services are funded. Representatives of Intermediate Care Facilities who participated in development of the rule served as watchdogs to ensure that the rule does not conflict with federal regulations governing those facilities. In addition, paragraph (B)(2) was added to make clear that Ohio Department of Education rules and policies prevail while individuals are in school settings.

13. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

The Department will work with stakeholder organizations including The Arc, the Ohio Self Determination Association, People First of Ohio, the Ohio Association of County Boards Serving People with Developmental Disabilities, and the Ohio Provider Resource Association, to coordinate implementation and provide training to all affected persons. In collaboration with stakeholders, the Department will develop a training plan and curriculum and ensure training is available as webinars for those who cannot attend in-person sessions. The Department will include related articles in its *Pipeline* newsletter, share information with the Family Advisory Council, and make presentations at meetings and conferences of other organizations. The Department will send targeted informational memos to groups such as Superintendents and Directors of Service and Support Administration at county boards of developmental disabilities.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

- a. Identify the scope of the impacted business community;**
- b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and**
- c. Quantify the expected adverse impact from the regulation.**

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a "representative business." Please include the source for your information/estimated impact.

The new rule impacts all providers of specialized services including independent providers, agency providers, licensed residential facilities, and Intermediate Care Facilities. The rule specifies record-keeping and reporting requirements that are new for some segments of the service delivery system. The requirements are necessary because absent collection and analysis of data, there is no way to know if specific interventions are effective or to measure system efforts to reduce use of restrictive measures. The new rule allows the use of

restrictive measures only when necessary to prevent harm or to prevent a legal sanction. Under the new parameters, it is estimated that behavioral support strategies that include restrictive measures may be appropriate for a small percentage of the individuals receiving specialized services. The adverse impact of new record-keeping and reporting requirements, therefore, is expected to be small. Providers are accustomed to documenting services provided and analyzing trends and patterns of data regarding the individuals they serve.

- Paragraph (H) requires Intermediate Care Facilities to notify the Department prior to implementing a behavioral support strategy that includes restrictive measures. Pursuant to paragraph (J)(3)(f) of existing rule 5123:2-1-02, county boards of developmental disabilities and other providers are already required to report strategies that include restraint or time-out.
- Paragraph (I) requires each provider to maintain a record of the date, time, duration, and antecedent factors regarding use of a restrictive measure. This requirement aligns with 42 C.F.R. 483.450, which requires Intermediate Care Facilities to document use of restrictive techniques such as restraint and time-out.
- Paragraph (J)(1) requires Intermediate Care Facilities to compile and analyze data regarding behavioral support strategies that include restrictive measures.

Paragraph (K)(1) which sets forth that the Department shall take immediate action as necessary to protect the health and welfare of individuals served which may include referral of a provider to other state agencies or licensing bodies, is merely a restatement of the Department's existing authority and responsibility.

15. Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?

Ensuring the health and welfare of Ohioans with developmental disabilities is mission critical for the Department, county boards of developmental disabilities, and every provider of services.

Regulatory Flexibility

16. Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.

Yes; paragraph (L) of the rule permits the Director of the Department to waive a condition or specific requirement of the rule except the Director shall not allow use of a prohibited measure as defined in paragraph (C)(8) of the rule.

17. How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?

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It is the policy of the Department to waive penalties for first-time or isolated paperwork or procedural regulatory noncompliance whenever appropriate. The Department believes the waiver of these penalties is appropriate under the following circumstances:

1. When failure to comply does not result in the misuse of state or federal funds;
2. When the regulation being violated, or the penalty being implemented, is not a regulation or penalty required by state or federal law; and
3. When the violation does not pose any actual or potential harm to public health or safety.

18. What resources are available to assist small businesses with compliance of the regulation?

Staff of the Department's Office of Provider Standards and Review, Major Unusual Incident Investigation Unit, and Developmental Centers are available to provide training and technical assistance.