Rule 5123-2-06 (Development and Implementation of Behavioral Support Strategies)
Clearance Period: September 2-17, 2021

Paragraph (C)(1) Comments:

Kelly Barnett, LISW-S, Clinical Program Manager, Nisonger Behavior Support Services, The Ohio State University	Several questions for consideration: 1. The proposed definition includes that the drug produce an overall sedating effect that interferes with the person's ability to complete daily living activities. Was this added to exclude PRNs that do not have this result, such as PRNs for anxiety that may take the edge off but not sedate a person? 2. The proposed definition of chemical restraint would apparently include any medication that would result in a "blunt suppression of behavior," regardless of whether or not it was indicated by a DSM diagnosis. Would all use of an antipsychotic, for example, be considered chemical restraint? Perhaps further clarification could be made that there must be a discernable difference in the ability to complete activities of daily living? 3. What about extrapyramidal side effects, rather than blunting of behavior? The risk-benefit analysis (tremoring versus psychotic symptoms) is one that would normally involve the prescriber and the guardian and/or client.
Wylie Jones, Ph.D., Director of Service and Compliance, Total Homecare Solutions	The criteria of "results in a noticeable or discernable difference in the individual's ability to complete activities of daily living" is overly broad and will include medications that are probably not meant to be included. Many common medications such as cold medications and pain medications will carry warnings about their effect on activities of daily living (from drowsiness to not operating machinery). Further, most seizure medications and many psychotropics may have similar effects when being used to treat diagnosed conditions (not as restraints). The criteria by which a particular medication would be considered a restraint is too subjective. The old rule specified that a medication prescribed to treat a diagnosed condition in the *Diagnostic and Statistical Manual of Mental Disorders* would not be considered a restraint (so it was clear what documentation one would need to have to demonstrate one was not imposing a chemical restraint). Further, the medication needed to be prescribed to affect behavior. This makes sense as many medications which are perfectly legitimate and desirable to prescribe for a variety of conditions will have side-effects that affect activities of daily living, but which really aren't being prescribed as a restraint, they just have unfortunate side effects (even the COVID vaccines often impact one's activities of daily living for a day or two).

Julie P. Gentile, M.D., M.B.A.; Professor and Chair, Wright State University Department of Psychiatry; Distinguished Fellow, American Psychiatric Association; Program Director, Ohio's Telepsychiatry Project for Intellectual Disability; Program Director, Ohio's Coordinating Center of Excellence, ID/MI	I served on this committee and am fully aware of the impact of the previous rule and how it was interpreted differently in various counties. I am the Project Director of a statewide, grant-funded Telepsychiatry Program that provides psychiatric care to over 1,800 patients with Intellectual Disability and Mental Illness ID/MI) from 85 counties in Ohio. My inquiry is regarding the phrase "and not for the purpose of treating a diagnosed psychiatric or medical condition" which was stricken from part (d) (please see below). I view that phrase as critical to allow prescribers to make decisions to appropriately treat depression, anxiety, and psychosis, and not be blocked by Human Rights Committees if we are treating a diagnosed psychiatric condition. If it was stricken to make the sentence more grammatically correct, please consider adding it to part (ii) (please see below). Without this verbiage added, physicians and other prescribers' medication orders can be denied by the Human Rights Committees. While I fully realize there are prescribers who practice polypharmacy, the vast majority are committed to this medically fragile patient population and are prescribing state-of-the-art psychopharmacologic medication regimens. The majority are competent to accurately assess and diagnose patients with ID/MI. We are also committed to treating mental illness so that persons with ID do not have to struggle with depression, anxiety, or psychosis. There is a longstanding shortage of physicians and psychiatrists who are confident in treating the ID patient population. When prescribers receive feedback that their medication orders are denied, this worsens the situation. I respectfully request this fragment of a sentence be added into the final version. While the Human Rights Committees should absolutely review prescriptions that negatively affect patients, in my humble opinion, this should only pertain to medications that are not linked directly to a diagnosed medical or psychiatric condition. (d) Chemical restraint. "Chemical restraint" means the use of medication in accordance with scheduled dosing or pro re nata ("PRN" or as needed) that results in a general or non-specific blunt suppression of behavior (i.e., the effect of the medication results in a noticeable or discernible difference in the individual's ability to complete activities of daily living) ~~and not for the purpose of treating a diagnosed psychiatric or medical condition~~. (i) "Chemical restraint" includes a medication such as medroxyprogesterone acetate ("Depo-Provera") prescribed for the treatment of sexual offending behavior. (ii) "Chemical restraint" does not include a medication that is routinely prescribed in conjunction with a medical procedure for patients without developmental disabilities, nor does it include medication prescribed for a diagnosed medical or psychiatric condition.

Kimi Remenyi, Behavior Support Manager, Hamilton County Developmental Disabilities Services	Revise as indicated: "Chemical restraint" means the use of medication in accordance with scheduled dosing or pro re nata ("PRN" or as needed) that results in a general or non-specific blunt suppression of behavior (i.e., the effect of the medication results in a noticeable or discernible difference in the individual's ability to complete activities of daily living. <u>"Chemical restraint" does not include a medication that is routinely prescribed in conjunction with a medical procedure for patients without developmental disabilities.</u> (i) "Chemical restraint" includes a medication such as medroxyprogesterone acetate ("Depo-Provera") prescribed for the treatment of sexual offending behavior. ~~(ii) "Chemical restraint" does not include a medication that is routinely prescribed in conjunction with a medical procedure for patients without developmental disabilities.~~ We feel it is important to include (d)(ii) in the overall definition of "chemical restraint" so as to avoid this specification from being mutually exclusive of the definition itself. In the past, guidance as well as reviews have seen medication as being isolated from the general technicalities within the rule definition. Including (d)(ii) in the overall definition shows an association between the two sets of verbiage allowing the practitioner to consider those medications, that when used attenuate feelings of unease associated with medical appointments, free from restriction unless they cause blunt suppression of behavior as indicated in the overall rule definition of "chemical restraint."

Department's Response:

Based on your feedback, paragraph (C)(1) was revised as indicated:

"Chemical restraint" means the use of medication in accordance with scheduled dosing or pro re nata ("PRN" or as needed) ~~that results in~~ <u>for the purpose of causing</u> a general or non-specific blunt suppression of behavior (i.e., the effect of the medication results in a noticeable or discernible difference in the individual's ability to complete activities of daily living).

(a) "Chemical restraint" includes a medication such as medroxyprogesterone acetate ("Depo-Provera") prescribed for the treatment of sexual offending behavior.

(b) "Chemical restraint" does not include a medication that is routinely prescribed in conjunction with a medical procedure for patients without developmental disabilities.

<u>(c) A behavioral support strategy may include chemical restraint only when an individual's actions pose risk of harm or an individual engages in a precisely-defined pattern of behavior that is very likely to result in risk of harm.</u>

We concluded that with this revised definition, it is not necessary to differentiate medication for a psychiatric or medical condition. If the purpose of the medication is to achieve a blunt suppression of behavior, the medication is in fact a chemical restraint.

Please note that we relocated the definition for each specific type of restrictive measure (i.e., chemical restraint, manual restraint, mechanical restraint, rights restriction, and time-out) from under the definition of "restrictive measure" so the definitions could be more easily found. We also added the justification necessary to use a specific restrictive measure to the definition of each restrictive measure.

Paragraph (C)(13) Comment:

Lori Stanfa, Chief Policy Officer, Ohio Association of County Boards Serving People with Developmental Disabilities	Add new paragraph: "Precisely-defined pattern of behavior" means a predictable pattern or sequence of actions that if left uninterrupted will lead to or result in a risk of harm to self or others.

Department's Response:

In response to your suggestion, a new paragraph (C)(13) was added:

"Precisely-defined pattern of behavior" means a documented and predictable sequence of actions that if left uninterrupted, will very likely result in physical harm to self or others.

Paragraph (C)(14)(e) Comments:

Willie Jones, Director of Health, Safety, and Wellness, Ohio Association of County Boards Serving People with Developmental Disabilities	Revise as indicated: Denial of breakfast, lunch, dinner, snacks, or beverages (excluding ~~denial~~ planned-limiting of snacks or beverages for an individual with a compulsive eating disorder attributed to a diagnosed medical condition, such as "Prader-Willi" syndrome. ~~, and denial is based on a specific medical order for~~ Any such planned-limiting shall be based on a specific plan for the treatment of ~~the~~ a diagnosed medical condition and approved by the human rights committee).
Kimi Remenyi, Behavior Support Manager, Hamilton County Developmental Disabilities Services	Revise as indicated: Denial of breakfast, lunch, dinner, snacks, or beverages (excluding denial of snacks or beverages for an individual with a compulsive eating disorder or primary polydipsia attributed to a diagnosed ~~medical~~ condition, such as "Prader-Willi" syndrome, and denial is based on a specific medical order for treatment of the diagnosed ~~medical~~ condition and approved by the human rights committee).
Lori Stanfa, Chief Policy Officer, Ohio Association of County Boards Serving People with Developmental Disabilities	Revise as indicated: Denial of breakfast, lunch, dinner, snacks, or beverages (excluding denial of snacks or beverages for an individual with a compulsive eating disorder or primary polydipsia attributed to a diagnosed medical condition, such as "Prader-Willi" syndrome, and denial is based on a specific medical ~~order for~~ treatment of the diagnosed medical condition and approved by the human rights committee).

Department's Response:

Based on your feedback, paragraph (C)(14)(e) was revised as indicated:

Denial of breakfast, lunch, dinner, snacks, or beverages (excluding denial of snacks or beverages for an individual with primary polydipsia or a compulsive eating disorder attributed to a diagnosed ~~medical~~ condition~~,~~ such as "Prader-Willi" syndrome, and denial is based on ~~a~~ specific medical ~~order for~~ treatment of the diagnosed ~~medical~~ condition and approved by the human rights committee).

Paragraph (C)(14)(e) Comment:

Beth Packo, Parent and Professional	Denial of snacks - individuals with severe needs do not understand the ramifications of eating as much as they want. Why do they have guardians if they can make educated decisions? Should we let these individuals eat to their heart's content and suffer all the medical issues that also arise with diabetes, obesity, high blood pressure, just to name a few? Plus, think of all the behavioral issues that will pop up if you give someone everything they want and what happens when you don't have it? Also, those with severe needs have a greater chance of choking.

Department's Response:

Members of the rule workgroup thought it important to avoid expanding use of restrictive measures. Supporting an individual to make healthy lifestyle choices must be addressed through the person-centered planning process which will be enhanced through implementation of Ohio Individual Service Plan (Ohio ISP), the web-based information technology platform being implemented statewide to carry out the person-centered process for assessing and planning with Ohioans with developmental disabilities. A person's supports are based on what is important to the person and important for the person. The team must consider all aspects of a person's life. When there are dietary concerns for any reason--whether choking risk, food allergies, or weight loss/gain--the team should explore and identify supports to help the person reach identified goals and live the best life possible. Examples of supports to be considered might include meeting with a dietician or physical trainer, exercise classes, nutritional programs, joining a support group, or shopping assistance.

Paragraph (C)(14)(h) Comment:

Lori Stanfa, Chief Policy Officer, Ohio Association of County Boards Serving People with Developmental Disabilities	Revise as indicated: Application of electric shock to an individual's body (excluding electroconvulsive therapy prescribed and administered by a physician <u>as a clinical intervention to treat a diagnosed medical condition</u>).

Department's Response:

Paragraph (C)(14)(h) was revised in accordance with your suggestion.

Paragraph (C)(19) Comments:

Kimi Remenyi, Behavior Support Manager, Hamilton County Developmental Disabilities Services	Revise as indicated. "Risk of harm" means there exists a direct and serious risk of physical harm to the individual or another person. For risk of harm, the individual must be capable of causing physical harm to self or others and the individual must be causing physical harm or very likely to begin causing physical harm <u>(as indicated by precisely-defined patterns of behavior that are very likely to result in risk of harm)</u>. We would like to see the "precisely-defined patterns of behavior" clause in all definitions of "risk of harm."

Lori Stanfa, Chief Policy Officer, Ohio Association of County Boards Serving People with Developmental Disabilities	Revise as indicated: "Risk of harm" means there exists a direct and serious risk of physical harm to the individual or another person. For risk of harm, the individual must be capable of causing physical harm to self or others and the individual must be causing physical harm or very likely to begin ~~causing physical harm~~ doing so (qualified by precisely-defined patterns of behavior that are very likely to result in risk of harm).

Department's Response:

We believe adding the phrasing you suggest to the definition of "risk of harm" would have the effect of limiting this concept in a manner we do not support. In some situations, it may be apparent that an individual is very likely to begin causing physical harm even though there is no pre-established precisely-defined pattern of behavior.

Paragraph (D)(2)(b) Comment:

Karen Hughes, Mother	The behavioral assessment that is utilized by county boards must be the same assessment for all county boards within Ohio for the behavioral add-on rate. Contained within the behavioral assessment (AND MUST BE DEFINED BY THIS RULE) should be provisions for individuals with behavioral needs that are not a danger to self or others but instead impede their ability to be integrated into their communities since this is at the forefront of DODD goals for individuals with disabilities. Individuals with these behaviors many times have more frequent behaviors that require more frequent and intensive support strategies (that may not even be restrictive) but require training by day hab staff, natural supports, Homemaker/Personal Care staff, etc. This must also be addressed and is a paramount need for those individuals that have behaviors severely affecting and interfering with their lives.

Department's Response:

Rule 5123-2-06 does not address the behavioral support rate modification that applies to some Home and Community-Based Services. The behavioral support rate modification is addressed in each rule for the specific service that is subject to the rate modification (e.g., rule 5123-9-30 for the Homemaker/Personal Care service). Many individuals who qualify for the behavioral support rate modification do not have a behavioral support strategy that includes restrictive measures.

Paragraph (D)(2)(b) Comment:

Lori Stanfa, Chief Policy Officer, Ohio Association of County Boards Serving People with Developmental Disabilities	Add new paragraph: An assessment of the degree of risk of harm to the individual when the restrictive measure is implemented.

Department's Response:

Based on your suggestion, a new paragraph (D)(2)(b)(v) was added:

The nature and degree of risk to the individual if the restrictive measure is implemented.

Paragraph (D)(2)(c) Comments:

Kimi Remenyi, Behavior Support Manager, Hamilton County Developmental Disabilities Services	We are asking to show linkage in (D)(2)(c) to the results found in (D)(2)(b) by adding a new paragraph (D)(2)(c)(iv): Ensure the information assessed in (D)(2)(b)(iv) is incorporated into the individual's plan and made available to all members of the individual's team.
Lori Stanfa, Chief Policy Officer, Ohio Association of County Boards Serving People with Developmental Disabilities	Add new paragraph: Ensure the information assessed in (D)(2)(b)(iv) and (D)(2)(b)(v) is incorporated into the individual's plan and made available to all members of the individual's team.

Department's Response:

The result you seek will be achieved through implementation of Ohio ISP, the web-based information technology platform being implemented statewide to carry out the person-centered process for assessing and planning with Ohioans with developmental disabilities.

Paragraph (D)(5)(c) Comment:

Lori Stanfa, Chief Policy Officer, Ohio Association of County Boards Serving People with Developmental Disabilities	Revise as indicated: Describe tangible outcomes and how progress toward achievement of outcomes will be identified in terms of <u>any combination of (D)(5)(c)(i) through (D)(5)(c)(iv)</u>: The rationale for "any combination" is that there are concerns that DODD will require reporting for each item (i) through (iv) when positive gains in any of the outcome categories is an indicator or improvement. Also, regarding item (D)(5)(c)(i), the frequency may not change but the severity or intensity may change or lessen which would be an indicator of achievement. The reporting on (i) through (iv) would be an excess burden on county boards of developmental disabilities, intermediate care facilities, and service providers.

Department's Response:

In response to your feedback, paragraph (D)(5)(c) was revised as indicated:

Describe tangible outcomes and how progress toward achievement of outcomes will be identified ~~in terms of:~~;

~~(i) Numeric data on changes in the frequency of behaviors that had been targeted for reduction due to a threat to safety or wellbeing;~~

~~(ii) New skills that have been developed which have eliminated or mitigated threats to safety or wellbeing;~~

~~(iii) The individual's self-report of his or her overall satisfaction in achieving desired outcomes and pursuing interests; and~~

~~(iv) Observations by paid staff and/or natural supports as they relate to safety or wellbeing and the individual's achievement of desired outcomes and pursuit of interests.~~

The concepts formerly in paragraphs (D)(5)(c)(i) through (D)(5)(c)(iv) were relocated to paragraph (D)(7)(f)(i) for consideration as part of the 90-day review. Also based on your feedback, what is now paragraph (D)(7)(f)(i)(a) was revised as indicated:

Numeric data on changes in the <u>severity or</u> frequency of behaviors that had been targeted for reduction due to a threat to safety or wellbeing;

Paragraph (D)(7)(d) Comment:

Lori Stanfa, Chief Policy Officer, Ohio Association of County Boards Serving People with Developmental Disabilities	Add two new paragraphs to clarify "risk of harm": (iv) Risk of harm that justifies the proposed restrictive measure. (v) Risk of harm to the individual when the restrictive measure is utilized or implemented. The rational for (iv) is that the team and persons who conduct assessments and develop behavioral support strategies are able to clearly identify the risk of harm that is being assessed or determined by the team to be significant enough to justify a restrictive measure. The rational for (v) is that the team and persons who conduct assessments and develop behavioral support strategies consider and assess trauma and abuse histories to evaluate the personal risk of harm that the individual may experience when the restrictive measure is utilized.

Department's Response:

Risk of harm that justifies the proposed restrictive measure was already addressed in paragraph (D)(7)(d). Based on your feedback, however, paragraph (D)(7)(d) was restructured and two new provisions, (D)(7)(d)(i) and (D)(7)(d)(ii), were added:

> Submit to the human rights committee the strategy and documentation, including the record of restrictive measures described in paragraph (E)(4) of this rule, based upon an assessment that clearly indicates:
> (i) The justification for the proposed restrictive measure, that is:
> *(a)* When manual restraint, mechanical restraint, or time-out is proposed—risk of harm;
> *(b)* When chemical restraint is proposed—risk of harm or how the individual's engagement in a precisely-defined pattern of behavior is very likely to result in risk of harm; or
> *(c)* When rights restriction is proposed—risk of harm or how the individual's actions are very likely to result in the individual being the subject of a legal sanction.
> (ii) The nature and degree of risk to the individual if the restrictive measure is implemented.

General Comment:

Beth Packo, Professional and Mother	I felt so passionate about the behavioral rule, that I took off work, and sat on the committee the last year, to express my thoughts. I am a professional who has worked directly with students ages 3-21 with behavioral challenges. I am also a mother, Michael, my son, is 22 and has severe autism, OCD, anxiety, and behavioral challenges (aggressive and self-injurious). They have been managed throughout the years in a behavioral based school by a Board Certified Behavioral Analyst (BCBA). This BCBA is imperative for my son and others like him to function/participate in the communities. Plus, they give families support in managing their son's/daughter's behavior. Why when individuals turn 22 are they no longer guaranteed the lifetime support they need? I have expressed that preventative measures must be taken into account in this rule. Why are we being reactive and not proactive? How can you have restrictive measures without preventive measures? There is no room for error when dealing with adults with severe behavioral issues. Why aren't we looking for the individuals that have been in behavioral schools or have a history of behavioral challenges and have a plan in place once they age out of school? Why do families need to fight for the services they need? Who is going to oversee our loved ones once we are gone? Why aren't we following what is working in programs such as ABA schools, schedules, structure, reinforcement, etc.? Especially for those individuals that have used the techniques throughout their lives.

Department's Response:

Supporting more proactive approaches was a theme expressed by several participants on the rule workgroup. As a result of extensive discussion, wording was added to multiple paragraphs to permit proactive interventions in response to precisely-defined patterns of behavior.

Paragraph (D)(1) was revised to require proactive creation of supportive environments with an emphasis on implementation of positive measures. Although members of the rule workgroup were not inclined to impose restrictions used for school-age individuals upon adults, the rule does not prohibit use of schedules and structure, which should be addressed in the individual service plan. Indeed, adjusting schedules is included as an example of a positive measure in paragraph (D)(1)(d).

A BCBA would meet the requirements set forth in paragraph (D)(4) to conduct assessments and develop behavioral support strategies that include restrictive measures. Requiring all persons who conduct assessments and develop strategies to be BCBAs, however, is not viable because there are not enough BCBAs in Ohio. The rule allows more than one type of assessor and encourages getting expertise when needed; the person who receives services and his or her team can decide what works best.