Common Sense Initiative

Mike DeWine, *Governor*
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Business Impact Analysis

Agency, Board, or Commission Name: Ohio Department of Developmental Disabilities

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Regulation/Package Title (a general description of the rules' substantive content):

Medication Administration

Rule Number(s):
Rescind: 5123:2-6-01, 5123:2-6-02, 5123:2-6-03, 5123:2-6-04, 5123:2-6-05
New: 5123-6-01, 5123-6-02, 5123-6-03, 5123-6-04, 5123-6-05
Amend: 5123-6-06, 5123-6-07

Date of Submission for CSI Review: September 18, 2023

Public Comment Period End Date: October 2, 2023

Rule Type/Number of Rules:
New/_5_ rules **No Change/____ rules (FYR? ___)**
Amended/__2__ rules (FYR? _yes__) **Rescinded/__5__ rules (FYR? _yes_)**

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

Which adverse impact(s) to businesses has the agency determined the rule(s) create?

The rule(s):

a. ☒ Requires a license, permit, or any other prior authorization to engage in or operate a line of business.

b. ☒ Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.

c. ☒ Requires specific expenditures or the report of information as a condition of compliance.

d. ☐ Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.

Regulatory Intent

2. Please briefly describe the draft regulation in plain language.
Please include the key provisions of the regulation as well as any proposed amendments.

The rules in Chapters 5123:2-6 and 5123-6 of the Administrative Code implement Sections 5123.41 to 5123.47 of the Revised Code. The rules set forth requirements for administration of medication and performance of health-related activities via certification and nursing delegation to unlicensed persons who provide services to individuals with developmental disabilities (i.e., "developmental disabilities personnel"). Additional information about the program is available at the Department's website: https://dodd.ohio.gov/home/med-admin

The five rules in Chapter 5123:2-6 of the Administrative Code are due for five-year review. In accordance with its established course, the Department is rescinding the rules and adopting replacement rules so the rules may be renumbered to Chapter 5123-6. Although the Department is planning to rescind rules 5123:2-6-01, 5123:2-6-02, 5123:2-6-03, 5123:2-6-04, and 5123:2-6-05 and adopt replacement rules, versions tracking proposed revisions are provided so stakeholders can readily see what is changing.

Rule 5123:2-6-01 (Definitions of terms used in Chapter 5123:2-6 of the Administrative Code) is being rescinded and replaced by rule 5123-6-01 (Definitions of terms used in Chapter 5123-6 of the Administrative Code). New rule 5123-6-01 reflects revisions to:

- Update citations to the Administrative Code.
- Align wording with newer rules.

Rule 5123:2-6-02 (Self-administration or assistance with self-administration of prescribed medication) sets forth the right of an individual with developmental disabilities who can safely administer prescribed medication or receive assistance with self-administration of prescribed medication to do so, establishes procedures for determining whether an individual can safely self-administer or receive assistance with self-administration of prescribed medication, and defines parameters for providing assistance with self-administration of prescribed medication. Rule 5123:2-6-02 is being rescinded and replaced by rule 5123-6-02

of the same title. New rule 5123-6-02 reflects revisions to:

- Add a purpose statement as paragraph (A).
- Add section headings.
- Update citations to the Administrative Code.
- Align wording with newer rules.

Rule 5123:2-6-03 (Authorization of developmental disabilities personnel to perform health-related activities and administer prescribed medication) sets forth conditions under which developmental disabilities personnel may perform health-related activities and administer prescribed medication. Rule 5123:2-6-03 is being rescinded and replaced by rule 5123-6-03 of the same title. New rule 5123-6-03 reflects revisions to:

- Add a purpose statement as paragraph (A).
- Update citations to the Administrative Code.
- Align wording with newer rules.

Rule 5123:2-6-04 (Qualifications, training, and certification of registered nurse instructors and registered nurse trainers) establishes requirements for registered nurse instructors and registered nurse trainers as well as the curriculum for the registered nurse train-the-trainer program. Rule 5123:2-6-04 is being rescinded and replaced by rule 5123-6-04 of the same title. New rule 5123-6-04 reflects revisions to:

- Add a purpose statement as paragraph (A).
- Adjust wording regarding Registered Nurses to reflect changes made to Section 4723. of the Revised Code regarding the multistate license.
- State, in paragraph (C)(5), that the Department may audit a Registered Nurse Trainer's continuing education.
- Update citations to the Administrative Code.
- Align wording with newer rules.

Rule 5123:2-6-05 (Qualifications and training of developmental disabilities personnel to activate a vagus nerve stimulator; use an epinephrine auto-injector; and administer topical over-the-counter medication for the purpose of cleaning, protecting, or comforting the skin, hair, nails, teeth, or oral surfaces) establishes requirements for developmental disabilities personnel to activate a vagus nerve stimulator, use an epinephrine auto-injector, and administer topical over-the-counter medication. Rule 5123:2-6-05 is being rescinded and replaced by rule 5123-6-05 of the same title. New rule 5123-6-05 reflects revisions to:

- Add a purpose statement as paragraph (A).
- Update citations to the Administrative Code.
- Align wording with newer rules.

Two additional rules included in the package are not due for five-year review, but received a comprehensive review, so that all seven rules in Chapter 5123-6 will have the same five-year review date moving forward:

Rule 5123-6-06 (Qualifications, training, and certification of developmental disabilities personnel who perform health-related activities and administer prescribed medication) sets forth qualifications and requirements for three training programs and resulting certification held by developmental disabilities personnel. The rule is being amended to:

- Add a purpose statement as paragraph (A).
- Clarify that the background check of developmental disabilities personnel must be completed prior to enrollment in training.
- Add detail to paragraph (C)(1)(c) regarding the content of the *Health-Related Activities and Prescribed Medication Administration* training program.
- Revise paragraph (C)(1)(c)(xix) to add the word "intermittent" in advance of "delivery of continuous positive airway pressure to treat obstructive sleep apnea or sleep-related hypoventilation," to emphasize the sleep-specific indications for application of continuous and biphasic positive airway pressure machines.
- Rename the *Prescribed Medication Through Feeding Tube by Nursing Delegation* training program described in paragraph (C)(2) *Prescribed Medication Administration Through Gastrostomy and Jejunostomy Tube by Nursing Delegation* training program.
- Rename the *Subcutaneous Injection by Nursing Delegation* training program *Administration of Insulin and Medication for the Treatment of Metabolic Glycemic Disorders by Nursing Delegation* training program.
- Clarify requirements for transcription of prescribed medication to be administered through stable labeled gastrostomy or jejunostomy tube, prescription for insulin and prescription for medication for the treatment of metabolic glycemic disorders to be transcribed on a medication administration record by only the delegating nurse or a licensed nurse in coordination/communication with the delegating nurse.
- Update citations to the Administrative Code.
- Align wording with newer rules.

Rule 5123-6-07 (General provisions and compliance for performance of health-related activities and administration of prescribed medication) sets forth requirements for the medication administration information system database, documentation of performance of health-related activities and administration of medication, compliance and quality assessment, and actions that may be taken by the department regarding certification issued pursuant to Chapter 5123-6 of the Administrative Code. The rule is being amended to:

- Add a purpose statement as paragraph (A).
- Add paragraph (H)(4) to clarify that the Department may audit a Registered Nurse's training of developmental disabilities personnel to determine compliance with rule 5123-6-06.
- Update citations to the Administrative Code.
- Align wording with newer rules.

3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.

	Authorize	Amplify
5123-6-01	5123.04, 5123.42, 5123.46	5123.04, 5123.41 to 5123.47
5123-6-02	5123.04, 5123.42, 5123.46, 5123.65	5123.04, 5123.41 to 5123.47, 5123.65, 5123.651, 5126.36
5123-6-03	5123.04, 5123.42, 5123.46	5123.04, 5123.41 to 5123.47, 5126.36
5123-6-04	5123.04, 5123.44, 5123.45, 5123.46	5123.04, 5123.41 to 5123.47
5123-6-05	5123.04, 5123.43, 5123.46	5123.04, 5123.41 to 5123.47
5123-6-06	5123.04, 5123.42, 5123.43, 5123.45, 5123.46	5123.04, 5123.41 to 5123.47
5123-6-07	5123.04, 5123.45, 5123.46	5123.04, 5123.41 to 5123.47, 5126.36

4. **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.

   No.

5. **If the regulation implements a federal requirement, but includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

   Not applicable.

6. **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 Department is required to adopt rules to implement the standards, requirements, and procedures to govern administration of medication and performance of health-related activities by developmental disabilities personnel via certification and nursing delegation. Ultimately, the rules are necessary to ensure individuals with developmental disabilities are healthy and safe.

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

   The Department measures the success of the rules in terms of the number of individuals benefiting from appropriate, safe, and supervised administration of medication and performance of health-related activities by developmental disabilities personnel via certification and nursing delegation.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**
If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

No.

Development of the Regulation

9. **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.

In July 2023, the rules with proposed amendments were shared by email with:

Ohio Board of Nursing
- Anita DiPasquale, Advisory Attorney, Education, Practice, and Licensure
- Lisa Emrich, RN Program Manager
- Lisa Eschbacher, Chief Legal Counsel

Ohio Nurses Association
- Erica Bell, Director of Nursing Practice
- Benitha Garrett, Board Member

Ohio Society for Respiratory Care
- Nancy Colletti, President
- David Corey, Executive Director
- Courtney Kallergis, Legislative Committee Chair

State Medical Board of Ohio
- Kimberly Anderson, Chief Legal Counsel

Through the Department's rules clearance process, the rules and the Business Impact Analysis form are disseminated to representatives of the following organizations for review and comment:

Advocacy and Protective Services, Inc.
The Arc of Ohio
Autism Society of Central Ohio
Councils of Governments
Disability Rights Ohio
Down Syndrome Association of Central Ohio
Family Advisory Council
The League
Ohio Association of County Boards of Developmental Disabilities

Ohio Council for Home Care and Hospice
Ohio Department of Medicaid
Ohio Developmental Disabilities Council
Ohio Health Care Association/Ohio Centers for Intellectual Disabilities
Ohio Provider Resource Association
Ohio Self Determination Association
Ohio SIBS (Special Initiatives by Brothers and Sisters)
Ohio Statewide Independent Living Council
Ohio Superintendents of County Boards of Developmental Disabilities
Ohio Waiver Network
People First of Ohio
Values and Faith Alliance

The rules and the Business Impact Analysis form are posted at the Department's website during the clearance period for feedback from the general public: https://dodd.ohio.gov/forms-and-rules/rules-under-development/proposed+rules+for+review

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

Based on questions received from stakeholders, wording was added to rule 5123-6-06 to clarify that results of background checks for developmental disabilities personnel must be in hand before the personnel begin a training program.

In accordance with Section 5123.46 of the Revised Code, the Department shared the draft rules with representatives of the Ohio Board of Nursing, the Ohio Nurses Association, the State Medical Board of Ohio, and the Ohio Society for Respiratory Care. The Ohio Nurses Association and the State Medical Board of Ohio responded to say they did not have comments. The Ohio Society for Respiratory Care suggested a revision to rule 5123-6-06 which the Department incorporated. Paragraph (C)(1)(c)(xix) was revised to add the word "intermittent" in advance of "delivery of continuous positive airway pressure to treat obstructive sleep apnea or sleep-related hypoventilation," to emphasize the sleep-specific indications for application of continuous and biphasic positive airway pressure machines.

Any feedback provided by stakeholders during the clearance process will be considered for incorporation before the rule is filed.

11. 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?

Department staff routinely review data regarding medication and treatment errors to identify patterns and trends of adverse outcomes. The analyses are used to inform policy and adjust when indicated.

12. **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?** ***Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.***

    The rules were comprehensively reviewed. As part of the review, feedback from stakeholders was considered (e.g., based on questions received, wording was added to rule 5123-6-06 to clarify that results of background checks for developmental disabilities personnel must be in hand before they begin a training program). More recently, a provider of services suggested a revision to the definition of "medication/treatment error" in rule 5123-6-01 might be needed to address an individual's refusal to take medication. Department staff reviewed the rule and the *Health-Related Activities and Prescribed Medication Administration* training program curriculum (described in rule 5123-6-06) and determined a rule revision is not indicated; the definition of "medication/treatment error" is consistent with the training program curriculum.

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

    The rules apply specifically to certification of developmental disabilities personnel and nursing delegation for administration of medication and performance of health-related activities in the developmental disabilities service delivery system. The Department is charged with regulating the program and consults with the Ohio Board of Nursing, the Ohio Nurses Association, the Ohio Society for Respiratory Care, and the State Medical Board of Ohio with regard to rules governing the program.

14. **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 disseminate the rules to county boards of developmental disabilities and the approximately 4,200 persons who subscribe to the Department's Rules Notification listserv two times:

    - Along with the notice of public hearing when the rules are original-filed and
    - When the rules are final-filed and the effective date is set.

    The Department will communicate information about the changes to all affected stakeholders in advance of the effective date of the rules and provide guidance and training directly to Registered Nurse Instructors, Registered Nurse Trainers, and Quality Assessment Registered Nurses to ensure the rules are understood and applied consistently across all settings in which administration of medication and performance of health-related activities are delegated.

Program staff will update training program curricula to reflect new rule numbers and are available to provide technical assistance as needed.

Adverse Impact to Business

15. Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:

a. Identify the scope of the impacted business community, and

b. Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).
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 rules apply to providers of specialized services to individuals with developmental disabilities. The Department's medication administration information system database tracks the Registered Nurse Trainers (approximately 500) and certified developmental disabilities personnel (approximately 37,400) participating in the program.

The rules require nurses and employers of developmental disabilities personnel to report information and make notifications. The rules set forth consequences for non-compliance. The impact varies widely based on the number of developmental disabilities personnel trained or employed.

The primary adverse impact is the cost associated with completion of training necessary for Registered Nurses to complete train-the-trainer programs and for unlicensed developmental disabilities personnel to complete training necessary to be certified to administer medication and perform health-related activities:

The initial Registered Nurse Train-the-Trainer program is a minimum of eight hours; most programs are actually 16 to 18 hours. Upon successful completion of initial training, the Registered Nurse is certified for two years. To be eligible to renew certification, the Registered Nurse must complete four hours of continuing education during the effective period of certification.

The initial training program for developmental disabilities personnel has three components:

- *Health-Related Activities and Prescribed Medication Administration* (14 hours)
- *Prescribed Medication Administration Through Gastrostomy and Jejunostomy Tube by Nursing Delegation* (4 hours)
- *Administration of Insulin and Medication for the Treatment of Metabolic Glycemic Disorders by Nursing Delegation* (4 hours)

Completion of the *Health-Related Activities and Prescribed Medication Administration* component is a prerequisite for enrolling in the other two components. Developmental disabilities personnel may or may not, depending on the individuals they serve, complete the *Administration of Insulin and Medication for the Treatment of Metabolic Glycemic Disorders by Nursing Delegation* component. Upon successful completion of initial training, developmental disabilities personnel are certified for one year. During the effective period of certification, developmental disabilities personnel must complete two hours of continuing education and skill performance as verified by the Registered Nurse Trainer.

In addition, without certification, developmental disabilities personnel who have successfully completed training in accordance with a Department-provided curriculum may administer emergency epinephrine auto-injector, manually activate a vagal nerve stimulator for seizures, and apply topical over-the-counter medications for cleaning, protecting, or comforting the skin, hair, nails, teeth, or oral surfaces. The training takes approximately:

- One-half hour for administration of an epinephrine auto-injector,
- One-half hour for activation of a vagal nerve stimulator, and
- One hour for application of topical over-the-counter medications.

This program reduces the cost of providing services to Ohioans with developmental disabilities. Providers are not required to participate in the program; as an alternative to having unlicensed staff trained in accordance with these rules, providers may engage the services of additional licensed nurses. The rules already exist; the revisions being made are not expected to increase costs of compliance.

16. Are there any proposed changes to the rules that will <u>reduce</u> a regulatory burden imposed on the business community? Please identify. *(Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors).*

Rule 5123-6-04 reflects changes made to Chapter 4723. of the Revised Code that enable nurses from other states to practice nursing in Ohio.

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

The rules are necessary to ensure that administration of medication and performance of health-related activities via certification of unlicensed developmental disabilities personnel and nursing delegation are implemented in a manner that ensures the health and safety of individuals with developmental disabilities.

Regulatory Flexibility

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

No; the purpose of the regulations is to ensure that medication is administered and health-related activities are performed in an appropriate and uniform manner throughout Ohio's developmental disabilities service delivery system to ensure that individuals who receive services are healthy and safe.

19. 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?

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 waiving these penalties is appropriate when:

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

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

Program staff are available to answer questions and provide technical assistance:

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