

# CSI - Ohio

The Common Sense Initiative

## Business Impact Analysis

**Agency Name:** Ohio Department of Developmental Disabilities

**Regulation/Package Title:** ICFIID Pediatric Ventilator Services

**Rule Number(s):** 5123:2-7-29

**Date:** August 12, 2016

**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Rescinded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.*

Rule 5123:2-7-29 sets forth requirements for pediatric ventilator services provided at Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFIID). ICFIID are residential facilities licensed by the Department that must meet federal Medicaid requirements to participate in the program. Approximately 5,600 Ohioans with developmental disabilities live at ICFIID, which provide all aspects of residents' care and support.

Rule 5123:2-7-29 was implemented in 2013 when the Department first designated pediatric ventilator services as an outlier service available at ICFIID. Pediatric ventilator services are for residents under age 22 who are dependent on invasive mechanical ventilators. Five of the

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

[CSIOhio@governor.ohio.gov](mailto:CSIOhio@governor.ohio.gov)

approximately 430 ICFIID provide pediatric ventilator services. Approximately 13 residents receive pediatric ventilator services.

The rule is being revised to add a provision to allow the Department to waive an existing requirement that an individual has had to have been an inpatient for at least 90 days within the past 12 months in an acute care hospital for treatment of a life-threatening or complex medical condition to be eligible for pediatric ventilator services. This revision was recommended by ICFIID that provide pediatric ventilator services and is being incorporated to better serve residents by allowing more flexibility.

Additional revisions to the rule are being made to update citations to the Administrative Code, eliminate references to outdated forms, and standardize use of terms. These "clean-up" revisions affect more than 50% of the rule. For that reason, the Department is proposing to rescind the existing rule and bring forth a new replacement rule. Although the Department is planning to rescind the existing rule and bring forth a "clean" new rule, a version of the rule that tracks revisions is being provided so stakeholders can readily see what is changing.

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

5123.04, 5124.02, 5164.02

**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.**

No.

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

Not applicable. The rule does not exceed a federal requirement.

**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 public purpose for this rule is to provide standards for ICFIID to provide and be paid for providing services to children who are dependent on invasive mechanical ventilators.

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

The Department will measure success by the extent to which pediatric ventilator services are

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[CSIOhio@governor.ohio.gov](mailto:CSIOhio@governor.ohio.gov)

available at a sufficient level and provided in a safe manner that meets the needs of children with developmental disabilities who require the services.

### **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.***

On June 29, 2015, Department staff conducted a conference call to discuss the rule with representatives of four of the five ICFIID that provide pediatric ventilator services:

- Hattie Larlham
- Heinzerling Foundation
- St. Joseph Home
- Sunshine Communities

Stillwater Center, the fifth ICFIID that provides pediatric ventilator services, was unable to have a representative participate in the call and provided input in advance of the call.

An advance copy of the rule with proposed revisions was shared with the five ICFIID on July 8, 2016.

Through the Department's rules clearance process, the rule and the Business Impact Analysis will be 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 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 Department of Medicaid  
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

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## Values and Faith Alliance

The rule and the Business Impact Analysis will be posted at the Department's *Rules Under Development* webpage (<http://dodd.ohio.gov/RulesLaws/Pages/Rules-Under-Development.aspx>) during the clearance period.

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

Stakeholders recommended that the Department revise the rule to permit waiving the requirement that the individual who needs pediatric ventilator services shall have been an inpatient for at least 90 days within the past 12 months in an acute care hospital for treatment of a life-threatening or complex medical condition.

**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?**

Department staff reviewed data regarding utilization of pediatric ventilator services and determined that there may be other valid indicators (such as medical stability and the ability of the ICFIID to provide additional services that may be needed) of an individual's need for pediatric ventilator services which supported the recommendations that a 90-day hospital stay should not be required in every case.

**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 accepted the recommendation to revise the rule in the proposed manner without considering alternatives because the recommendation is reasonable and affords more flexibility in meeting the needs of individuals with developmental disabilities.

**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 Department is required to adopt rules to implement standards, requirements, and procedures to govern the ICFIID program. The federal Centers for Medicare and Medicaid Services requires Ohio to administer Medicaid programs in a manner that ensures statewide-ness. The purpose of this rule is to establish federally-compliant standards of accountability for Ohio's ICFIID that provide pediatric ventilator services.

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

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The rule applies to operation of ICFIID that provide pediatric ventilator services. The Department is charged with regulating the ICFIID program and consults with the Ohio Department of Medicaid with regard to rules governing the program.

**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 communicate information about the changes, to all affected ICFIID in advance of the effective date of the rule (projected to be November 2016) and provide guidance and technical assistance directly to staff of ICFIID to ensure the rule is understood and applied consistently throughout the state.

**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;**

There are approximately 430 ICFIID that could potentially follow the process outlined in the rule to become approved to provide pediatric ventilator services; there are currently only five ICFIID that provide pediatric ventilator services.

**b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and**

The revisions being made to the rule do not have an adverse impact. The nature of the adverse impact of the rule in its entirety as it exists today are the requirements to be prior-approved by the Department to provide pediatric ventilator services generally and approved to provide pediatric ventilator services to a specific individual. Securing and maintaining the Department's approval requires the ICFIID to submit an application and information and consent to be monitored by the Department. Meeting these requirements consumes staff resources and time.

**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.*

This rule provides a means for ICFIID that provide pediatric ventilator services to be

reimbursed at a higher rate that reflects the additional costs associated with serving children with this special need. The rule already exists; the proposed revisions do not expand requirements and therefore, are not expected to increase costs of compliance.

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

The rule is necessary to ensure the health and safety of children living in ICFIID who are dependent on invasive mechanical ventilators.

**Regulatory Flexibility**

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

The revision being proposed to paragraph (C)(5) is incorporating a provision whereby an existing requirement of the rule may be waived (i.e., provides an exemption).

**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?**

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 Division of Medicaid Development and Administration will be available to answer questions and provide technical assistance as necessary.