

Rule Summary and Fiscal Analysis

Part A - General Questions

Rule Number: 3701-84-34.2

Rule Type: Rescission

Rule Title/Tagline: Order to cease operations of an adult cardiac catheterization service.

Agency Name: Department of Health

Division:

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I. Rule Summary

1. Is this a five year rule review? Yes

A. What is the rule's five year review date? 6/10/2025

2. Is this rule the result of recent legislation? Yes

A. If so, what is the bill number, General Assembly and Sponsor? HB 110 - 134 - Scott Oelslager

3. What statute is this rule being promulgated under? 119.03

4. What statute(s) grant rule writing authority? 3702.11, 3702.13

5. What statute(s) does the rule implement or amplify? 3702.14, 3702.141, 3702.15, 3702.16, 3702.18, 3702.19, 3702.20

6. Does the rule implement a federal law or rule in a manner that is more stringent or burdensome than the federal law or regulation requires? No

A. If so, what is the citation to the federal law or rule? Not Applicable

7. What are the reasons for proposing the rule?

Chapter 3701-22 Hospital Licensure was created, and now Health Care Services (HCS) Chapter 3701-84 will be rescinded and moved into Chapter 3701-22 per ORC 3722.

8. Summarize the rule's content, and if this is an amended rule, also summarize the rule's changes.

The rule sets forth the authority of ODH to issue an order to cease operations to services that fail to ensure the quality and safety of procedures performed. The rule has been revised to remove the requirement for membership in the National Cardiovascular Data Registry as a requirement and allow for membership in any appropriate data registry. Seventeen restrictions have been removed in accordance with SB9.

9. Does the rule incorporate material by reference? Yes

10. If the rule incorporates material by reference and the agency claims the material is exempt pursuant to R.C. 121.75, please explain the basis for the exemption and how an individual can find the referenced material.

Ohio Administrative Code and Ohio Revised Code; information is readily available online.

11. If revising or re-filing the rule, please indicate the changes made in the revised or re-filed version of the rule.

Not Applicable

II. Fiscal Analysis

12. Please estimate the increase / decrease in the agency's revenues or expenditures in the current biennium due to this rule.

This will have no impact on revenues or expenditures.

0.00

Not Applicable.

13. What are the estimated costs of compliance for all persons and/or organizations directly affected by the rule?

There are no expected changes to the costs associated with this rule as a result of the requested revisions. There is the potential for cost savings depending on the cost of membership in alternative data registries to the NCDR. The rule authorizes the

termination of a service for failure to meet established quality and safety standards which could result in the loss of operating revenue for the cardiac catheterization service. Cardiac catheterization services are subject to regulation and standards from multiple organizations (e.g., CMS, ACC) which also have the authority to require a service to cease operations and it is as likely as it is not that these other regulating entities would determine the need for such enforcement actions resulting in the same loss of operating revenues. Opportunities for corrective actions are built in to these rules to enable services to meet the standards of these rules.

- 14. Does the rule increase local government costs? (If yes, you must complete an RSFA Part B). No**
- 15. Does the rule regulate environmental protection? (If yes, you must complete an RSFA Part C). No**
- 16. If the rule imposes a regulation fee, explain how the fee directly relates to your agency's cost in regulating the individual or business.**

Not Applicable.

III. Common Sense Initiative (CSI) Questions

- 17. Was this rule filed with the Common Sense Initiative Office? Yes**
- 18. Does this rule have an adverse impact on business? Yes**
 - A. Does this rule require a license, permit, or any other prior authorization to engage in or operate a line of business? No**
 - B. Does this rule impose a criminal penalty, a civil penalty, or another sanction, or create a cause of action, for failure to comply with its terms? Yes**

An order to cease operations may be issued for failure to comply with stated standards.
 - C. Does this rule require specific expenditures or the report of information as a condition of compliance? No**
 - D. Is it likely that the rule will directly reduce the revenue or increase the expenses of the lines of business of which it will apply or applies? No**

IV. Regulatory Restriction Requirements under S.B. 9. Note: This section only applies to agencies described in R.C. 121.95(A).

19. Are you adding a new or removing an existing regulatory restriction as defined in R.C. 121.95? Yes

A. How many new regulatory restrictions do you propose adding to this rule?
0

B. How many existing regulatory restrictions do you propose removing from this rule? 1

(C) Must

C. If you are not removing existing regulatory restrictions from this rule, please list the rule number(s) from which you are removing restrictions.

D. Please justify the adoption of the new regulatory restriction(s).

Not Applicable