

Rule Summary and Fiscal Analysis (Part A)**Department of Health**

Agency Name

Division

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3701-84-34.2

Rule Number

NEW

TYPE of rule filing

Rule Title/Tag Line

Order to cease operations of an adult cardiac catheterization service.**RULE SUMMARY**1. Is the rule being filed for five year review (FYR)? **No**2. Are you proposing this rule as a result of recent legislation? **No**3. Statute prescribing the procedure in accordance with the agency is required to adopt the rule: **119.03**4. Statute(s) authorizing agency to adopt the rule: **3702.11, 3702.13**5. Statute(s) the rule, as filed, amplifies or implements: **3702.14, 3702.141, 3702.15, 3702.16, 3702.18, 3702.19, 3702.20**

6. State the reason(s) for proposing (i.e., why are you filing,) this rule:

Rules 3701-84-30 through 3701-84-34.2 of the Ohio Administrative Code have been revised in response to changes in the industry and the need for greater structural flexibility in cardiac catheterization service operation. ODH is proposing new rule 3701-84-34.2.

7. If the rule is an AMENDMENT, then summarize the changes and the content of the proposed rule; If the rule type is RESCISSION, NEW or NO CHANGE, then summarize the content of the rule:

The rule establishes the conditions for termination of a cardiac catheterization service. A service's operations may be terminated for failure to comply with the Administrative code, failure of the service to meet designated quality outcomes, or if a determination of serious or life threatening harm is made regarding the facility's clinical outcomes and operations.

8. If the rule incorporates a text or other material by reference and the agency claims the incorporation by reference is exempt from compliance with sections 121.71 to 121.74 of the Revised Code because the text or other material is **generally available** to persons who reasonably can be expected to be affected by the rule, provide an explanation of how the text or other material is generally available to those persons:

This rule references the Ohio Revised Code; the R.C. is generally available in libraries and on the internet to persons who reasonably can be expected to be affected by the rule.

9. If the rule incorporates a text or other material by reference, and it was **infeasible** for the agency to file the text or other material electronically, provide an explanation of why filing the text or other material electronically was infeasible:

Pursuant to R.C. 121.76, the cited text is exempt from inclusion in this filing.

10. If the rule is being **rescinded** and incorporates a text or other material by reference, and it was **infeasible** for the agency to file the text or other material, provide an explanation of why filing the text or other material was infeasible:

Not Applicable.

11. If **revising** or **refiling** this rule, identify changes made from the previously filed version of this rule; if none, please state so. If applicable, indicate each specific paragraph of the rule that has been modified:

1/21/2016 - Subsequent to the original filing of this rule, ODH received input from JCARR that resulted in additional changes to this rule. Instead of using the word "termination," the rule has been revised to say "order to cease operations," which directly reflects ODH's statutory authority under Section 3702.20 of the Revised Code. This change clarifies that ODH is acting within its statutory authority when

issuing an order to cease operations to a cardiac catheterization service as a result of the conditions set forth in the rule.

12. Five Year Review (FYR) Date:

(If the rule is not exempt and you answered NO to question No. 1, provide the scheduled review date. If you answered YES to No. 1, the review date for this rule is the filing date.)

NOTE: If the rule is not exempt at the time of final filing, two dates are required: the current review date plus a date not to exceed 5 years from the effective date for Amended rules or a date not to exceed 5 years from the review date for No Change rules.

FISCAL ANALYSIS

13. Estimate the total amount by which *this proposed rule* would **increase / decrease** either **revenues / expenditures** for the agency during the current biennium (in dollars): Explain the net impact of the proposed changes to the budget of your agency/department.

This will have no impact on revenues or expenditures.

\$0.00

Not applicable

14. Identify the appropriation (by line item etc.) that authorizes each expenditure necessitated by the proposed rule:

Not applicable

15. Provide a summary of the estimated cost of compliance with the rule to all directly affected persons. When appropriate, please include the source for your information/estimated costs, e.g. industry, CFR, internal/agency:

The new 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.

16. Does this rule have a fiscal effect on school districts, counties, townships, or municipal corporations? **No**

17. Does this rule deal with environmental protection or contain a component dealing with environmental protection as defined in R. C. 121.39? **No**

S.B. 2 (129th General Assembly) Questions

18. Has this rule been filed with the Common Sense Initiative Office pursuant to R.C. 121.82? **Yes**

19. Specific to this rule, answer the following:

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**

Rule 3701-84-05 establishes the compliance actions that the Ohio Department of Health may take to enforce standards. The rule authorizes the termination of a service by the Director for failure to meet established criteria.

C.) Does this rule require specific expenditures or the report of information as a condition of compliance? **No**