

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

Agency Name

Division

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5160-1-17.11

Rule Number

NEW

TYPE of rule filing

Rule Title/Tag Line

Requirements for 340B covered entities.**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: **5162.03, 5164.02**
5. Statute(s) the rule, as filed, amplifies or implements: **5164.02**
6. State the reason(s) for proposing (i.e., why are you filing,) this rule:

This new rule implements Medicaid policy related to the 340B drug pricing program enacted under the Veteran's Health Care Act of 1992.
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:

Rule 5160-1-17.11, entitled "Requirements for 340B covered entities," sets forth ODM's status reporting requirements and process for Ohio Medicaid providers who

participate in the 340B drug pricing program. This includes clearly identifying provider, sub-entity, and contract facility participation in the 340B drug pricing program. This rule requires participating providers to file claims in accordance with ODM's 340B instructions to clearly identify when drugs acquired through the 340B drug pricing program are provided to a Medicaid recipient. This rule requires participating providers to file claims in accordance with ODM's non-340B instructions when a provider uses a drug that is not acquired through the 340B drug pricing program for a Medicaid recipient. This rule requires 340B covered entities to exclude drugs purchased through the 340B drug pricing program from being billed by 340B contract pharmacies. Drugs purchased through the 340B drug pricing program can only be billed by 340B covered entities. A 340B covered entity is responsible for ensuring that the contract pharmacy does not bill for drugs purchased under the 340B drug pricing program. This rule implements a program integrity measure to ensure duplicate discounts are not provided under the 340B drug pricing program and the Medicaid Drug Rebate Program.

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 incorporates one or more references to the United States Code. This question is not applicable to any dated incorporation by reference to the U.S. Code because such reference is exempt from compliance with Revised Code sections 121.71 to 121.74 in accordance with RC 121.75(A).

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:

No applicable.

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:

Not Applicable.

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

This proposed rule is not expected to have an impact on the agency budget for the remainder of the biennium.

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 cost of compliance with this rule, to report 340B covered entity status, is expected to be minimal and administrative in nature. The process of reporting 340B covered entity status on a yearly or situational basis does not require significant resources to complete and will be done electronically when possible, similar to the existing provider enrollment and revalidation process.

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? **No**

C.) Does this rule require specific expenditures or the report of information as a condition of compliance? **Yes**

This rule requires the reporting of 340B drug pricing program participation at least yearly and following any change to 340B drug pricing program participation or entity type. 340B covered entities are required to follow claim submission requirements for 340B and non-340B acquired drugs.