

**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:

This rule is being refiled to add the RSFA Part B impact on public providers. No changes have been made to the rule text.

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? **Yes**

You must complete Part B of the Rule Summary and Fiscal Analysis in order to comply with Am. Sub. S.B. 33 of the 120th General Assembly.

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.

**Rule Summary and Fiscal Analysis (Part B)**

1. Does the Proposed rule have a fiscal effect on any of the following?

(a) School Districts	(b) Counties	(c) Townships	(d) Municipal Corporations
No	Yes	Yes	Yes

2. Please provide an estimate in dollars of the cost of compliance with the proposed rule for school districts, counties, townships, or municipal corporations. If you are unable to provide an estimate in dollars, please provide a written explanation of why it is not possible to provide such an estimate.

It is not possible to provide an estimate in dollars of the cost of compliance with the proposed rule for counties, townships, or municipal corporations. The rule requires that 340B covered entities notify the Ohio Department of Medicaid (ODM) annually that they participate in the 340B drug pricing program, bill drugs acquired through the 340B drug pricing program according to the ODM 340B billing instructions, and ensure their contract pharmacies do not bill drugs acquired through the 340B drug pricing program to ODM or a Medicaid managed care plan (MCP). ODM is implementing an electronic process to allow 340B covered entities to report their status annually. The form should take less than 15 minutes to complete and submit. The cost of billing medical claims is not generally considered a cost of compliance with a rule, but ODM estimates a small cost to implement the proposed billing instructions, which require a modifier to be added to the claim. Modifiers are a standard feature in billing software, but there may be a cost to program systems and train billing staff. The oversight of contract pharmacies is already a federal requirement of the 340B drug pricing program through the Health Resources and Services Administration (HRSA), but there may be an additional administrative cost to change contract terms to prohibit contract pharmacies from billing ODM or MCPs using drugs acquired through the 340B drug pricing program and to add this work to the provider's existing oversight process.

3. If the proposed rule is the result of a federal requirement, does the proposed rule exceed the scope and intent of the federal requirement? **No**

4. If the proposed rule exceeds the minimum necessary federal requirement, please provide an estimate of, and justification for, the excess costs that exceed the cost of the federal requirement. In particular, please provide an estimate of the excess costs that exceed the cost of the federal requirement for (a) school districts, (b) counties, (c) townships, and (d) municipal corporations.

*Not Applicable.*

5. Please provide a comprehensive cost estimate for the proposed rule that includes the procedure and method used for calculating the cost of compliance. This comprehensive cost estimate should identify all of the major cost categories

including, but not limited to, (a) personnel costs, (b) new equipment or other capital costs, (c) operating costs, and (d) any indirect central service costs.

The rule implements new billing instructions for providers that bill claims for drugs purchased through the 340B drug pricing program, which may require providers to make changes to their billing systems or train staff on the new procedure. The rule requires that 340B covered entities prohibit their contract pharmacies from billing drugs acquired through the 340B drug pricing program which may result in additional personnel costs to change contract terms or add oversight of this requirement.

**(a) Personnel Costs**

It is not possible to provide a comprehensive estimate for the proposed rule that calculates the personnel costs related to compliance. The rule requires 340B covered entities to notify ODM annually of their participation in the 340B drug pricing program. ODM is implementing an electronic process to facilitate this notification and anticipate that this will take less than 15 minutes to complete. The rule also implements new billing instructions for providers that bill claims for drugs purchased through the 340B drug pricing program, which may require providers to train staff on the new procedure. Finally, the rule requires that 340B covered entities prohibit their contract pharmacies from billing drugs acquired through the 340B drug pricing program so there may be personnel costs to change contract terms or add oversight of this requirement.

**(b) New Equipment or Other Capital Costs**

No new equipment or other capital costs are required.

**(c) Operating Costs**

It is not possible to provide a comprehensive estimate for the proposed rule that calculates the operating costs related to compliance. The rule also implements new billing instructions for providers that bill claims for drugs purchased through the 340B drug pricing program, which may require providers to make changes to billing systems. The billing instructions require a modifier to be added to claims for drugs purchased through the 340B drug pricing program, but modifiers are a standard feature of billing systems so this cost is expected to be small.

**(d) Any Indirect Central Service Costs**

No new indirect central service costs should be required.

**(e) Other Costs**

No additional costs should be required.

6. Please provide a written explanation of the agency's and the local government's ability to pay for the new requirements imposed by the proposed rule.

ODM estimates the cost of compliance with this rule is small and administrative in nature. Public providers that bill Medicaid likely have staff in place to perform these functions.

7. Please provide a statement on the proposed rule's impact on economic development.

There is no discernible impact on economic development as a result of this rule.