

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

Agency Name

Division

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5160-4-12

Rule Number

NEW

TYPE of rule filing

Rule Title/Tag Line

Immunizations, injections and infusions (including trigger-point injections), and provider-administered pharmaceuticals.**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: **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 rule is being proposed to update and clarify policy related to the administration of the Medicaid program.

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:

This rule sets forth general provisions for coverage of and payment for injections and pharmaceuticals administered by eligible providers. It is being proposed to replace current rule 5160-4-12. Words based on 'reimburse' (such as 'reimbursement') are replaced by forms of 'pay' and 'payment'; other unsatisfactory phrases, incorrect or missing references, and unnecessary statements are also cleaned up. Medicaid rule numbers are modified to comport with the new agency designation in the Ohio Administrative Code. Coverage is established for the nine-valent human papilloma virus (HPV) vaccine. A provision concerning the coverage of immune globulin is condensed and streamlined. The current static maximum payment amount for medroxyprogesterone acetate (MPA) is removed; payment for MPA will instead be determined by the method set forth in paragraph (E) of the rule, to which maximum allowable cost (MAC) is added as a reference source. A restriction on how payment is made for vaccine administration is removed.

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 another rule or rules of the Ohio Administrative Code. This question is not applicable to any incorporation by reference to another OAC rule because such reference is exempt from compliance with RC 121.71 to 121.74 pursuant to RC 121.76(A)(3).

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:

Not 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 increase expenditures.

\$1.3 million

The change in how the maximum payment amount for medroxyprogesterone acetate is calculated may result in an annual increase in expenditures of just under \$1 million. This figure is based on two assumptions: a 70% increase in the maximum payment amount and a doubling of the number of injections administered.

Payment for the process of administering vaccines to children will have no impact on the budget, because the maximum payment amount for the relevant vaccine administration will be the same as the current "supplemental fee" for the vaccine itself.

Coverage of the new 9-valent HPV vaccine may result in an annual increase in expenditures of \$18,360. This figure is based on two assumptions: discontinued use of both the 2-valent and 4-valent versions of the vaccine and a number of injections equal to the average number administered in SFYs 2012, 2013, and 2014.

This \$1 million total increase in annual expenditures amounts to an increase of \$1.3 million over 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:

There is no new cost of compliance associated with this rule.

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 has specific reporting and record-keeping requirements: (1) For certain provider-administered pharmaceuticals, instructions are given on the reporting of procedure codes and dosage units on claims. (2) As a condition of payment for certain injections, providers must document specific information in the individual's medical record.

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
Yes	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.

To the extent that it is also a school district, county, township, or municipal corporation, a Medicaid provider could be affected by this rule.

A provider that administers medroxyprogesterone acetate will see an initial increase in claim payment of \$30.00, or 71.4%, per injection as a result of the change in how the maximum payment amount is calculated. A provider that administers vaccinations against human papillomavirus will see an increase in claim payment of \$36.74, or 26.8%, per injection if the newly covered 9-valent HPV vaccine is used instead of the 2-valent vaccine and an increase of \$29.27, or 20.3%, per injection if the 9-valent vaccine is used instead of the 4-valent vaccine.

There is no cost of compliance associated with this rule.

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 comprehensive cost estimates are provided in the following sections.

(a) Personnel Costs

The rule is not expected to cause any increase for Medicaid providers in personnel costs.

(b) New Equipment or Other Capital Costs

The rule is not expected to cause any increase for Medicaid providers in new equipment or other capital costs.

(c) Operating Costs

The rule is not expected to cause any increase for Medicaid providers in operating costs.

(d) Any Indirect Central Service Costs

The rule is not expected to cause any increase for Medicaid providers in indirect central service costs.

(e) Other Costs

The rule is not expected to cause any increase for Medicaid providers in other costs.

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.

Incorporation of the proposed payment fee structure changes into the department's claim-processing system is part of the administration of the Medicaid program; it entails no significant new costs for the department.

None of the changes in the proposed rule requires a provider to modify its business practices; therefore, no implementation cost is anticipated for any local government or political subdivision.

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

The rule is not expected to have any impact on economic development.