

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

Agency Name

Tommi Potter

Contact

Division

50 Town St 4th floor Columbus OH 43218-2709**614-752-3877****614-995-1301**

Agency Mailing Address (Plus Zip)

Phone

Fax

tommi.potter@medicaid.ohio.gov

Email

5160-4-12

Rule Number

AMENDMENT

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)? **Yes**
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:

The filing of this rule fulfills the requirement for five-year review.

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 5160-4-12, "Immunizations, injections and infusions (including trigger-point injections), and provider-administered pharmaceuticals," sets forth coverage and payment provisions for injections and other pharmaceuticals administered by a professional practitioner. This rule is being proposed for amendment.

The proposed changes move the coverage and payment policy for covered skin substitutes from rule 5160-4-35 to rule 5160-4-12, which will be re-titled

"Immunizations, injections and infusions (including trigger-point injections), skin substitutes, and provider-administered pharmaceuticals." The amendment to rule 5160-4-12 references a payment table/fee schedule on the department's web site, <http://medicaid.ohio.gov>, which houses codes for all covered skin substitutes. Adding the skin substitute coverage and payment provisions to rule 5160-4-12 directs a reader to one rule that combines all of the coverage and payment provisions. Coverage and payment for the professional application of skin substitute graft(s) will be unchanged by these rule amendments.

Additionally, references to a discontinued limited family planning benefit have been removed. Am. Sub. H.B. 64 of the 131st General Assembly terminated this optional limited eligibility benefit effective December 31, 2015. Individuals that were eligible for this limited benefit were instructed to apply for either the full Medicaid benefit through Ohio Benefits or for medical insurance through the Federally Facilitated Marketplace.

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:

In paragraph (B)(3), the unnecessary phrase 'based on age or gender' has been removed.

Paragraphs (B)(3)(b) and (B)(3)(c), which concern coverage of certain varieties of HPV vaccine, have been removed and replaced by a single new paragraph (B)(3)(b), which states the general principle that HPV vaccines are covered in accordance with the Advisory Committee on Immunization Practices (ACIP) schedule.

In paragraph (C)(3)(b), a rule reference has been updated.

Paragraph (E), which addresses skin substitutes, has been restructured and streamlined.

The wording of paragraph (F)(1) has been made consistent and grammatically correct.

In paragraph (F)(1)(b)(ii), nomenclature has been updated, and reference is made to a specific rule rather than to a chapter of the OAC.

12. Five Year Review (FYR) Date: 5/24/2017

(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

The proposed changes will have no impact on the budget.

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 is the dictation and maintenance of required documentation in the individual's medical record. Rule 5160-4-12 requires providers of trigger-point

injections to document the following information in the individual's medical record: (1) a proper evaluation including a patient history and physical examination leading to diagnosis of the trigger point, (2) the reason or reasons for selecting this therapeutic option, (3) the affected muscle or muscles, (4) the muscle or muscles injected and the number of injections, (5) the frequency of injections required, (6) the name of the medication used in the injection, (7) the results of any prior treatment, and (8) corroborating evidence that the injection is medically necessary. Also, it must be documented in the individual's medical record that the application of skin substitutes must result in 50% or greater improvement to a wound in order for continued use (re-applications). If the skin substitutes are not resulting in a 50% or greater improvement in the wound healing process, then the practitioner shall not continue applying the skin substitutes and must seek another form of wound treatment to promote healing.

The costs of updating an individual's medical record can and do vary from practitioner to practitioner depending on a variety of factors. For example, the technology used by a practitioner to dictate in the medical record could significantly decrease the amount of time spent in documentation, as could the use of an employee to enter documentation that could simply be reviewed and signed by the practitioner. This cost also depends on who performed the task. The median statewide hourly wage for a billing clerk, according to Labor Market information (LMI) data published by the Ohio Department of Job and Family Services, is \$16.10; for a physician, it is \$58.03. Adding 30% for fringe benefits brings these figures to \$20.96 and \$75.43 generating a necessary documentation cost between \$1.76 (five minutes at \$20.96 per hour) and \$37.71 (thirty minutes at \$75.43 per hour).

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 maintenance of information.