Rule Summary and Fiscal Analysis (Part A)

Ohio Department of Medicaid
Agency Name

Division

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5160-11-02
Rule Number

NEW
TYPE of rule filing

Rule Title/Tag Line **Laboratory-related services: general provisions.**

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 comply with the requirement for five-year rule 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:

The nine existing rules in Chapter 5160-11 are being rescinded and replaced with six new rules. Most of the changes made to these rules involve improvements in the organization of the chapter, in the structure of the individual rules, and in the clarity of phrasing.

This particular rule sets forth general provisions for providers of laboratory-related services. Two specific revisions to this rule are worth noting:

* For purposes of payment coordination and program integrity, a provision is added that explicitly requires a portable X-ray supplier to be enrolled in Medicare as a supplier of portable X-ray services.

* Under the existing rules, a written order for a portable X-ray service or for a procedure performed by an independent diagnostic testing facility (IDTF) must include a rationale for the service or procedure. The new rule instead requires that at least one appropriate diagnosis code be included on all written orders, because a diagnosis code is generally easier to provide than a narrative and imparts just as much information.

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 dated references to the Code of Federal Regulations (CFR). This question is not applicable to any dated incorporation by reference to the CFR because such reference is exempt from compliance with RC 121.71 to 121.74 in accordance with RC 121.75(D).

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 have no impact on revenues or expenditures.

$0.00

No change is being made to this rule which will result in an increase or decrease in either revenues or expenditures. Consequently, there is no impact on the agency 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:

This proposed rule contains a number of specific requirements for providers of laboratory-related services. However, almost all of these requirements are federal in origin as set forth in various portions of the Code of Federal Regulations.

The two exceptions to this are the requirement that suppliers of portable x-ray services and Independent Diagnostic Testing Facility (IDTF) services be enrolled in the federal Medicare program. In the case of portable x-ray suppliers, this is a new requirement. In the case of IDTFs, it is a carry-over from the existing rule.

The Department proposes to maintain this requirement for IDTFs and to include portable x-ray suppliers as a program integrity measure and to cost-avoid in those instances where the recipient is dually enrolled in both the Medicare and Medicaid programs. Absent this requirement, the Department would be liable for the full cost of care provided to dually-eligible recipients instead of the typical cost sharing of twenty percent for co-pays and deductibles.

There is no application fee for non-institutional provers to enroll in the Medicare program. In terms of staff time, the Department estimates the cost to a portable x-ray or IDTF provider of enrolling in the Medicare program at approximateley $250.

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? **Yes**

Federal law requires a provider of independendent laboratory services to possess either a certificate of waiver, a certificate of registration, or a certificate of accreditation. While this requirement is referenced in this rule, its origin is federal as set forth in the CFR.

We require portable x-ray suppliers and suppliers of Independent Diagnostic Testing Facility (IDTF) services to be enrolled with the Medicare program as a condition of being enrolled with Medicaid. Mammography suppliers must meet the certification requirements at 42 CFR 410.34.

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 reports of information.

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**	**No**	**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.

   This proposed rule contains a number of specific requirements for providers of laboratory-related services. However, almost all of these requirements are federal in origin as set forth in various portions of the Code of Federal Regulations.

   The two exceptions are the requirement that suppliers of portable x-ray services and independent diagnostic testing facility services (IDTFs) be enrolled in the federal Medicare program. In the case of portable x-ray suppliers, this requirement is new. In the case of IDTFs, it is a carry-over from the existing rule.

   The Department proposes to maintain this requirement for IDTFs and to include portable x-ray suppliers as a program integrity measure and to cost-avoid in those instances where the recipient is dually enrolled in both the Medicare and Medicaid programs. Absent this requirement, the Department would be liable for the full cost of care provided to dually-eligible recipients instead of the typical cost sharing of twenty percent for co-pays and deductibles.

   There is no application fee associated with non-institutional providers enrolling in the Medicare program. In terms of staff time, the Department estimates the cost of enrolling in the Medicare program to a supplier of portable x-ray or IDTF services at approximately $250.

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

ODM does not expect that the proposed rule will result in any increase in personnel costs to Medicaid providers.

(b) New Equipment or Other Capital Costs

ODM does not expect that the proposed rule will result in any increase in new equipment or other capital costs to Medicaid providers.

(c) Operating Costs

ODM does not expect that the proposed rule will result in any increase in operating costs to Medicaid providers.

(d) Any Indirect Central Service Costs

ODM does not expect that the proposed rule will result in any increase in indirect central service costs to Medicaid providers.

(e) Other Costs

ODM does not expect that the proposed rule will result in any increase in other costs to Medicaid providers.

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.

The cost to enroll in Medicare as a supplier of portable x-ray or IDTF services is estimated by the Department at approximately $250.

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 proposed rule.