

Oklahoma Health Care Authority

It is very important that you provide your comments regarding the proposed rule change by the comment due date. Comments are directed to the [Oklahoma Health Care Authority \(OHCA\) Proposed Changes Blog](#).

OHCA COMMENT DUE DATE: January 15, 2017

The proposed policy is a Permanent Rule. The proposed policy was presented at the September 6, 2016 Tribal Consultation and is scheduled to be presented to the Medical Advisory Committee on January 19, 2017 and the OHCA Board of Directors on February 9, 2017.

Reference: APA WF 16-26

SUMMARY:

Molecular Pathology Changes- Proposed Laboratory Services policy clarifies reimbursement requirements for molecular pathology tests that examine multiple genes in a single test panel.

LEGAL AUTHORITY

The Oklahoma Health Care Authority Board; The Oklahoma Health Care Authority Act, Section 5003 through 5016 of Title 63 of Oklahoma Statutes; 42 CFR 440.30

RULE IMPACT STATEMENT:

STATE OF OKLAHOMA OKLAHOMA HEALTH CARE AUTHORITY

TO: Tywanda Cox
Federal and State Policy

From: Likita Gunn
Federal and State Authorities

SUBJECT: Rule Impact Statement
APA WF # 16-26

A. Brief description of the purpose of the rule:

Proposed revisions to Laboratory Services policy clarify reimbursement requirements for molecular pathology tests that examine multiple genes in a single test panel. The proposed changes will require providers to utilize a one code for one

test approach to billing molecular pathology tests. If an appropriate code is not available, providers are permitted to bill one unit of an unlisted molecular pathology procedure code.

- B. A description of the classes of persons who most likely will be affected by the proposed rule, including classes that will bear the cost of the proposed rule, and any information on cost impacts received by the agency from any private or public entities:

Providers performing molecular pathology tests may be impacted by this change in policy as it may require a change to billing practices.

- C. A description of the classes of persons who will benefit from the proposed rule:

No classes of persons will benefit from the proposed rule.

- D. A description of the probable economic impact of the proposed rule upon the affected classes of persons or political subdivisions, including a listing of all fee changes and, whenever possible, a separate justification for each fee change:

The proposed rule should have no economic impact and no fee changes, as the proposed rule change should only require a change in business practice for providers.

- E. The probable costs and benefits to the agency and to any other agency of the implementation and enforcement of the proposed rule, the source of revenue to be used for implementation and enforcement of the proposed rule, and any anticipated affect on state revenues, including a projected net loss or gain in such revenues if it can be projected by the agency:

Agency staff has determined that the proposed rule may result in cost savings for the OHCA. A one year proposed budget savings is estimated at \$50,000 total dollars; State share \$20,715; Federal Share \$29,285. The estimate is based on analyzing all molecular pathology claims paid for more than two codes per claim, then comparing what would have been reimbursed if the claims were paid based on the appropriate single code for each test and projecting those savings for calendar year 2016.

- F. A determination of whether implementation of the proposed rule will have an economic impact on any political subdivisions or require their cooperation in implementing or enforcing the rule:

The proposed rule will not have an economic impact on any political subdivision or require their cooperation in implementing or enforcing the rule.

- G. A determination of whether implementation of the proposed rule will have an adverse effect on small business as provided by the Oklahoma Small Business Regulatory Flexibility Act:

The proposed rule will not have an adverse effect on small businesses as provided by the Oklahoma Small Business Regulatory Flexibility Act.

- H. An explanation of the measures the agency has taken to minimize compliance costs and a determination of whether there are less costly or nonregulatory methods or less intrusive methods for achieving the purpose of the proposed rule:

There are no other legal methods to minimize compliance costs.

- I. A determination of the effect of the proposed rule on the public health, safety and environment and, if the proposed rule is designed to reduce significant risks to the public health, safety and environment, an explanation of the nature of the risk and to what extent the proposed rule will reduce the risk:

The agency has taken measures to determine that there is no less costly or non-regulatory method or less intrusive method for achieving the purpose of the proposed rule. Opportunities for public input are provided throughout the rulemaking process, in addition to formal public comment periods and tribal consultations.

- J. A determination of any detrimental effect on the public health, safety and environment if the proposed rule is not implemented:

OHCA does not believe there is a detrimental effect on the public health and safety if the rule is not passed.

- K. The date the rule impact statement was prepared and if modified, the date modified:

This rule impact statement was prepared on October 17, 2016.

RULE TEXT

TITLE 317. OKLAHOMA HEALTH CARE AUTHORITY CHAPTER 30. MEDICAL PROVIDERS-FEE FOR SERVICE

SUBCHAPTER 5. INDIVIDUAL PROVIDERS AND SPECIALTIES

PART 1. PHYSICIANS

317:30-5-20. Laboratory services

This Section covers the guidelines for payment of laboratory services by a provider in his/her office, a certified laboratory and for a pathologist's interpretation of laboratory procedures.

(1) **Compensable services.** Providers may be reimbursed for compensable clinical diagnostic laboratory services only when they personally perform or supervise the performance of the test. If a provider refers specimen to a certified laboratory or a hospital laboratory serving outpatients, the certified laboratory or the hospital must bill for performing the test.

(A) Reimbursement for lab services is made in accordance with the Clinical Laboratory Improvement Amendment of 1988 (CLIA). These regulations provide that payment may be made only for services furnished by a laboratory that meets CLIA conditions, including those furnished in physicians' offices. Eligible providers must be certified under the CLIA program and have obtained a CLIA ID number from CMS and have a current contract on file with the OHCA.

(B) Only medically necessary laboratory services are compensable.

(2) **Non-compensable laboratory services.**

(A) Separate payment is not made for blood specimens obtained by venipuncture or urine specimens collected by a laboratory. These services are considered part of the laboratory analysis.

(B) Claims for inpatient full service laboratory procedures are not covered since this is considered a part of the hospital rate.

(C) Billing multiple units of nucleic acid detection for individual infectious organisms when testing for more than one infectious organism in a specimen is not permissible. Instead, OHCA considers it appropriate to bill a single unit of a procedure code indicated for multiple organism testing.

~~(D) Laboratory services must be medically indicated to be compensable.~~

(D) Billing multiple Current Procedural Terminology (CPT) codes or units for molecular pathology tests that examine multiple genes or incorporate multiple types of genetic analysis in a single run or report is not permissible. Instead, OHCA considers it appropriate to bill a single CPT code for such test. If an appropriate code does not exist, then one unit for an unlisted molecular pathology procedure may be billed.

(3) Covered services by a pathologist.

(A) A pathologist may be paid for the interpretation of inpatient surgical pathology specimen when the appropriate CPT procedure code and modifier is used.

(B) Full service or interpretation of surgical pathology for outpatient surgery performed in an outpatient hospital or Ambulatory Surgery Center setting.

(4) Non-compensable services by a pathologist. The following are non-compensable pathologist services:

(A) Experimental or investigational procedures.

(B) Interpretation of clinical laboratory procedures.