Oklahoma Health Care Authority

The Oklahoma Health Care Authority (OHCA) values your feedback and input. It is very important that you provide your comments regarding the proposed rule change by the comment due date. Comments can be submitted on the OHCA's Proposed Changes Blog.

OHCA COMMENT DUE DATE: September 24, 2018

The proposed policy is an Emergency Rule. The proposed policy was presented at the May 16, 2018 Tribal Consultation. This proposal is scheduled to be presented to the Medical Advisory Committee on September 20, 2018 and the OHCA Board of Directors on October 11, 2018.
Reference: APA WF 18-01

SUMMARY:
Laboratory Services Policy Update – The proposed revisions update laboratory services policy.

LEGAL AUTHORITY
The Oklahoma Health Care Authority Act, Section 5007 (F)(1) and (3) of Title 63 of Oklahoma Statutes; Section 5003 through 5016 of Title 63 of Oklahoma Statutes; The Oklahoma Health Care Authority Board; 42 CFR §440.230

RULE IMPACT STATEMENT:

STATE OF OKLAHOMA
OKLAHOMA HEALTH CARE AUTHORITY

TO: Tywanda Cox
Federal and State Policy

FROM: Harvey Reynolds
Federal and State Authorities

SUBJECT: Rule Impact Statement
APA WF # 18-01

A. Brief description of the purpose of the rule:

The proposed revisions to the lab services policy strengthens the language delineating medical necessity and compensable and non-compensable lab services. Additional revisions add language to define penalties that can be enforced if a provider does not abide by the rules regarding medical necessity of lab services. The revisions also clarify that OHCA does not pay

for all lab services listed in the CMS fee schedule but only those that are medically necessary in addition to the four other conditions required for payment.

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:

Clinical laboratories and providers that perform laboratory services will be affected by the proposed rule changes. These rule changes should not place any cost burden on private or public entities. No information on any cost impacts were received from any entity.

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

The proposed rule will benefit the taxpayers of Oklahoma by ensuring that the standard for medical necessity is met before SoonerCare funds are expended for laboratory services.

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 changes may have an economic impact on providers who perform laboratory services and on providers who order laboratory services.

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 changes will result in a budget savings by decreasing reimbursement of medically unnecessary laboratory tests. Between 2014 and 2017, despite a decrease in member enrollment of 1.8%, there has been a 9.8% increase in members receiving laboratory tests and an increase of approximately $502,384 in reimbursement for laboratory tests.

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

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 agency does not anticipate that the proposed rule changes will have an adverse effect on small businesses.

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

The agency has taken measures to determine that there are no other legal methods to achieve the purpose of the proposed rule changes. Measures included a formal public comment period and tribal consultation.

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 proposed rule changes should reduce risks to the public health, because they help avoid imminent reduction to the agency's budget by directing limited funds away from services that are not medically necessary and were never intended to be covered.

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

The agency anticipates that in the absence of these rule changes, medically unnecessary laboratory testing will continue and may even increase.

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

Prepared date: April 3, 2018

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~~Centers for Medicare and Medicaid Services and have a current contract on file with the ~~OHCA~~Oklahoma Health Care Authority (OHCA). Providers performing laboratory services must have the appropriate CLIA certification specific to the level of testing performed.

(B) Only medically necessary laboratory services are compensable.

(i) Testing must be medically indicated as evidenced by patient-specific indications in the medical record.

(ii) Testing is only compensable if the results will affect patient care and are performed to diagnose conditions and illnesses with specific symptoms.

(iii) Testing is only compensable if the services are performed in furtherance of the diagnosis and/or treatment of conditions that are covered under SoonerCare.

(C) Laboratory testing must be ordered by the physician or non-physician provider, and must be individualized to the patient and the patient's medical history or assessment indicators as evidenced in the medical documentation.

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

(A) Laboratory testing for routine diagnostic or screening tests performed without apparent relationship to treatment or diagnosis of a specific illness, symptom, complaint or injury is not covered.

(B) Non-specific, blanket panel or standing orders for laboratory testing, custom panels particular to the ordering provider, or lab panels which have no impact on the patient's plan of care are not covered.

(C) Split billing, or dividing the billed services for the same patient for the same date of service by the same rendering laboratory into two or more claims is not allowed.

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

~~(C)~~(F) 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)~~(G) 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~~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.

(5) **Penalties.** The OHCA reserves the right to take such action as it may deem appropriate against any provider as a result of medically unnecessary laboratory testing, including, without limitation, recoupment and possible termination of the provider's underlying provider agreement with OHCA. In

addition, appropriate cases may be referred for further investigation and possible action by the Office of the Attorney General's Medicaid Fraud Control Unit.

PART 3. HOSPITALS

317:30-5-40.1. General information

(a) This Chapter applies to coverage in an inpatient and/or outpatient setting. Coverage is the same for adults and children unless otherwise indicated.

(b) **Professional Services**. Payment is made to a participating hospital group or corporation for hospital based physician's services. The hospital must have a Hospital Group Physician's Contract with OHCA for this method of billing.

(c) **Prior Authorization**. OHCA requires prior authorization for certain procedures to validate the medical need for the service.

(d) **Medical necessity.** Medical necessity requirements are listed at OAC 317:30-3-1(f) and 317:30-5-20.

317:30-5-42.10. Laboratory

~~Payment is made for all laboratory tests listed in the Clinical Diagnostic Laboratory fee schedule from CMS.~~ To be eligible for payment as a laboratory/pathology service, the service must be:

(1) Ordered and provided by or under the direction of a physician or other licensed practitioner within the scope of practice as defined by state law;

(2) Provided in a hospital or independent laboratory;

(3) Directly related to the diagnosis and treatment of a medical condition; ~~and~~

(4) Authorized under the laboratory's CLIA certification~~.~~; and

(5) Considered medically necessary as defined in OAC 317:30-3-1(f) and 317:30-5-20.