**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:** March 3, 2022

The proposed policy changes are Permanent Rules. The proposed policy changes were presented at the January 4, 2022 Tribal Consultation. The proposed rule changes will be presented at a Public Hearing on March 8, 2022. Additionally, this proposal is scheduled to be presented to the Medical Advisory Committee on March 10, 2022 and the OHCA Board of Directors on March 16, 2022.

**REFERENCE: APA WF 21-39**

**SUMMARY: Laboratory Services Policy Cleanup —** The proposed rule changes will remove outdated language referencing "custom panels particular to the ordering provider.

**LEGAL AUTHORITY:**
The Oklahoma Health Care Authority Act, Section 5007 of Title 63 of Oklahoma Statutes; the Oklahoma Health Care Authority Board

**RULE IMPACT STATEMENT:**

**STATE OF OKLAHOMA**
**OKLAHOMA HEALTH CARE AUTHORITY**

SUBJECT: Rule Impact Statement
APA WF # 21-39

A. Brief description of the purpose of the rule:

The proposed revisions will remove outdated language referencing "custom panels particular to the ordering provider" from the list of non-compensable laboratory services to reflect current business practices. Further revisions will update policy for better ease and understanding.

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:

No classes of persons will be affected by this proposed rule since the language revisions clean up and align it with current business 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 since the language revisions are to clean up and align policy with current business practices.

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:

There is no economic impact and there are no fee changes associated with the rule change for the above classes of persons or any political subdivision.

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 effect on state revenues, including a projected net loss or gain in such revenues if it can be projected by the agency:

The proposed rule changes are budget neutral.

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 subdivisions 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 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 not have any effect on the public health, safety, or environment. The proposed rule changes are not designed to reduce significant risks to the public health, safety, or environment.

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

The agency does not anticipate any detrimental effect on the public health, safety, or environment if the proposed rule changes are not implemented.

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

Prepared: January 24, 2022

## 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 Centers for Medicare and Medicaid Services and have a current contract on file with the 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.

(D) Laboratory testing for routine diagnostic or screening tests following clinical guidelines such as those found in the American Academy of Pediatrics (AAP) Bright Futures' periodicity schedule, the United States Preventive Services Task Force (USPSTF) A and B recommendations, the American Academy of Family Practitioners

(AAFP), or other nationally recognized medical professional academy or society standards of care, is compensable. Additionally, such sources as named in this subdivision should meet medical necessity criteria as outlined in Oklahoma Administrative Code (OAC) 317:30-3-1(f).

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

(A) Laboratory testing for routine diagnostic or screening tests not supported by the clinical guidelines of a nationally recognized medical professional academy or society standard of care, and/or testing that is 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 (2) or more claims is not allowed.

(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.~~Separate payment is not made for blood specimens obtained by venipuncture or urine specimens collected by a provider who is also performing the laboratory testing as these services are considered part of the laboratory analysis.

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

(F) Billing multiple units of nucleic acid detection for individual infectious organisms when testing for more than one (1) 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.

(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 (1) 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. For more information regarding experimental or investigational including clinical trials, see OAC 317:30-3-57.1.

(B) Interpretation of clinical laboratory procedures.

**317:30-5-20.1. Drug screening and testing**

(a) **Purpose.** Drug Testing is performed for undisclosed drug use and/or abuse, and to verify compliance with treatment. Testing for drugs of abuse to monitor treatment compliance should be included in the treatment plan for pain management when chronic opioid therapy is involved.

(1) Qualitative (presumptive) drug testing may be used to determine the presence or absence of a drug or drug metabolite in the sample and is expressed as a positive or negative result. Qualitative testing can be performed by a CLIA waived or moderate complexity test, or by a high complexity testing method.

(2) Quantitative (definitive) drug testing is specific to the drug or metabolite being tested and is expressed as a numeric result or numeric level which verifies concentration.

(3) Specimen validity testing is used to determine if a specimen has been diluted, adulterated or substituted. Specimen validity tests include, but are not limited to, creatinine, oxidants, specific gravity, urine pH, nitrates and alkaloids.

(b) **Eligible providers**. Providers performing drug testing should have CLIA certification specific to the level of testing performed as described in 317:30-5-20(1)(A).

(c) **Compensable services**. Drug 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.

(1) Compensable testing must be medically indicated as evidenced by patient specific indications in the medical record.

(A) Testing is only compensable if the results will affect patient care.

(B) Drugs or drug classes being tested should reflect only those likely to be present.

(2) The frequency of drug screening and/or testing is determined by the patient's history, patient's physical assessment, behavioral assessment, risk assessment, treatment plan and medication history.

(3) Quantitative (definitive) drug testing may be indicated for the following:

(A) To identify a specific substance or metabolite that is inadequately detected or undetectable by a qualitative (presumptive) test; or

(B) To definitively identify specific drugs in a large family of drugs; or

(C) To identify drugs when a definitive concentration of a drug is needed to guide management; or

(D) To identify a negative, or confirm a positive, qualitative (presumptive) result that is inconsistent with a patient's self-report, presentation, medical history or current prescribed medication plan; or

(E) To identify a non-prescribed medication or illicit use for ongoing safe prescribing of controlled substances.

(d) **Non-compensable services**. The following tests are not medically necessary and therefore not covered by the OHCA:

(1) Specimen validity testing is considered a quality control measure and is not separately compensable;

(2) Drug testing for patient sample sources of saliva, oral fluids, or hair;

(3) Testing of two different specimen types (urine and blood) from the same patient on the same date of service;

(4) Drug testing for medico-legal purposes (court ordered drug screening) or for employment purposes;

(5) Non-specific, blanket panel or standing orders for drug testing, ~~custom panels specific for the ordering provider,~~ routine testing of therapeutic drug levels, or drug panels which have no impact to the member's plan of care;

(6) Scheduled and routine drug testing (i.e. testing should be random);

(7) Reflex testing for any drug is not medically indicated without specific documented indications;

(8) Confirmatory testing exceeding three specific drug classes at an interval of greater than every thirty (30) days will require specific documentation in the medical record to justify the medical necessity of testing; and

(9) Quantitative (definitive) testing of multiple drug levels that are not specific to the patient's medical history and presentation are not allowed. Justification for testing for each individual drug or drug class level must be medically indicated as reflected in the medical record documentation.

(e) **Documentation requirements.** The medical record must contain documents to support the medical necessity of drug screening and/or testing. Medical records must be furnished on request and may include, but are not limited to, the following:

(1) A current treatment plan;

(2) Patient history and physical;

(3) Review of previous medical records if treated by a different physician for pain management;

(4) Review of all radiographs and/or laboratory studies pertinent to the patient's condition;

(5) Opioid agreement and informed consent of drug testing, as applicable;

(6) List of prescribed medications;

(7) Risk assessment, as identified by use of a validated risk assessment tool/questionnaire, with appropriate risk stratification noted and utilized;

(8) Office/provider monitoring protocols, such as random pill counts; and

(9) Review of prescription drug monitoring data or pharmacy profile as warranted.