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 Health Policy Unit Proposed Changes Blog.

OHCA COMMENT DUE DATE: February 18, 2020

The proposed policy is a Permanent Rule. The proposed policy was presented at the January 7, 2020 Tribal Consultation. Additionally, this proposed change will be presented at a Public Hearing scheduled for February 19, 2020. This proposal is scheduled to be presented to the Medical Advisory Committee on March 12, 2020 and the OHCA Board of Directors on March 18, 2020. **Reference: APA WF 19-25**

SUMMARY:
Polymerase Chain Reaction (PCR) Testing for Infectious Diseases — The proposed rule changes establish guidelines to assure medical necessity and consistency in the prior authorization process for PCR testing.

LEGAL AUTHORITY
The Oklahoma Health Care Authority Act, Section 5007 (C) of Title 63 of Oklahoma Statutes; the Oklahoma Health Care Authority Board; and 42 CFR § 440.230

RULE IMPACT STATEMENT:

STATE OF OKLAHOMA
OKLAHOMA HEALTH CARE AUTHORITY

TO: Maria Maule
Legal Services

FROM: Harvey Reynolds
Federal and State Authorities

SUBJECT: Rule Impact Statement
APA WF # 19-25

A. Brief description of the purpose of the rule:

The proposed rule changes establish guidelines to assure medical necessity and consistency in the prior authorization

(PA) process for Polymerase Chain Reaction (PCR) testing. The guidelines include criteria to meet medical necessity and required documentation for approval of the PA.

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 PCR testing for infectious diseases 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 PCR testing 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 PCR testing services and on providers who order PCT testing 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 budget savings by decreasing reimbursement of medically unnecessary PCR tests. The total spending for calendar year 2018, on PCR infectious disease testing CPT codes which will now be subject to prior authorization, was $6,282,503. With an estimated denial rate of 50% for lack of medical necessity, total

estimated budget savings will be $3,141,252 annually, of which $1,067,397 is state dollars.

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 PCR testing will continue and may even increase.

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

Prepared date: November 4, 2019
Modified date: January 16, 2020

RULE TEXT:

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

SUBCHAPTER 5. INDIVIDUAL PROVIDERS AND SPECIALTIES

PART 1. PHYSICIANS

317:30-5-20.2. Molecular Diagnostic Testing Utilizing Polymerase Chain Reaction for Infectious Diseases

(a) **Definitions.** The following words and terms, when used in this Section, shall have the following meaning, unless the context clearly indicates otherwise.

(1) **"Polymerase Chain Reaction (PCR)"** means a biochemical laboratory technique used to make thousands or even millions of copies of a segment of DNA. It is commonly used to amplify a small amount of specifically targeted DNA from among a mixture of DNA samples. It is also known as Nucleic Acid Amplification Test (NAAT).

(2) **"Direct Probe Technique"** means detection methods where nucleic acids are detected without initial amplification processing.

(3) **"Amplified Probe Technique"** means technique without quantification, a detection method in which the sensitivity of the assay is improved over direct probe techniques.

(4) **"Probe with Quantification Technique"** means methods used to report absolute or relative amounts of nucleic acid sequences in the original sample.

(b) **Medical necessity.**

(1) PCR testing for infectious diseases, following clinical guidelines such as those set forth by the Infectious Disease Society of America's (IDSA) or other nationally recognized medical professional academy or society standards of care, may be compensable.

(2) For the full PCR guideline which includes medically necessity and prior authorization criteria, and a list of codes that require authorization, please refer to www.okhca.org.

(c) **Documentation.**

(1) The medical record must contain documentation that the testing is expected to influence treatment of the condition towards which the testing is directed.

(2) The laboratory or billing provider must have on file the physician requisition which sets forth the diagnosis or condition that warrants the test(s).
(3) Examples of documentation requirements for the ordering provider include, but are not limited to, history and physical exam findings that support the decision making, problems/diagnoses, relevant data (e.g., lab testing results).
(4) Documentation requirements for the performing laboratory include, but are not limited to, lab accreditation, test requisition, test records, preliminary and final report, and quality control record.
(5) Documentation requirements for lab developed tests/protocols include diagnostic test/assay, lab manufacturer, names of comparable assays/services (if relevant), descriptions of assay, analytical validity evidence, clinical validity evidence, and clinical utility.
(6) Billing providers are required to code specificity; however, if an unlisted or not otherwise specified Current Procedural Terminology (CPT) code is used, the documentation must clearly identify the unique procedure performed. When multiple procedure codes are submitted (unique, unlisted, and/or not otherwise specified), the documentation supporting each code should be easily identifiable. If on review the billed code cannot be linked to the documentation, this service may be denied.
(7) When the documentation does not meet the criteria for the service rendered/requested or the documentation does not establish the medical necessity for the service, the service may be denied as not reasonable and necessary.