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, 2023

The proposed policy changes are currently in effect as Emergency Rules and must be promulgated as Permanent Rules. The proposed policy was presented at the January 4, 2022, Tribal Consultation. Additionally, this proposal was presented to the Medical Advisory Committee on May 12, 2022. Furthermore, this proposal will be presented at a Public Hearing scheduled for March 7, 2023. Finally, the proposed changes are scheduled to be presented as permanent rules to the OHCA Board of Directors on March 22, 2023.

SUMMARY:

Clinical Trials Routine Service and Dental Out-of-State Services – The proposed rule revisions will add language to the clinical trials policy in section OAC 317:30-3-57.1 that states that the Oklahoma Health Care Authority will provide a coverage determination within 72 hours on whether the study is appropriate and meets the members' medical necessity needs. Additional revisions to the out-of-state services policy, at OAC 317:30-3-90, will add language to assure that clinical trials will be provided in accordance with all federal regulations and that OHCA's out-of-state policy does not apply to certain cases that involve clinical trials. Furthermore, language will be added to allow for the override of prior authorizations that are related to lodging and meals services when they are provided in accordance with an approved clinical trial. Finally, revisions will add language that allows for a SoonerCare member to travel up to one hundred miles (100) from the Oklahoma border to receive dental services.

LEGAL AUTHORITY:
The Oklahoma Health Care Authority Act, Section 5007 (C)(2) of Title 63 of Oklahoma Statutes; The Oklahoma Health Care Authority Board; The Social Security Act § 1905(a)(30) and 1905(gg)(3); 42 C.F.R. § 431.52; The Oklahoma Medicaid State Plan

RULE IMPACT STATEMENT:

STATE OF OKLAHOMA
OKLAHOMA HEALTH CARE AUTHORITY

SUBJECT: Rule Impact Statement
APA WF # 22-03

A. Brief description of the purpose of the rule:

Proposed rule revisions will remove outdated language and add new language to the formerly

named "Clinical Trials" policy OAC 317:30-3-57.1. To comply with new federal guidelines this policy will be renamed "Coverage of routine services in relation to clinical trials" and restructured to address qualifying clinical trials criteria, clinical trials determination standards, routine patient costs, and excluded items. Importantly, new language will be added that states that the Oklahoma Health Care Authority will provide a coverage determination within 72-hours on whether the study is appropriate and meets the members' medical necessity needs. Additional revisions to the out-of-state services policy, at OAC 317:30-3-90, will add language to assure that clinical trials will be provided in accordance with all federal regulations and that clinical trials do not have to follow all of the out-of-state rules. Final revisions will add a clause regarding the override for prior authorizations that are related to lodging and meals services when they are provided in accordance with an approved clinical trial.

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 rule. This rule 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 changes, regarding clinical trials, will benefit members who may be eligible for participating in a qualifying clinical trial as this rule change requires states to ensure that a coverage determination be completed within 72 hours.

Additionally, the proposed rule changes, regarding dental out-of-state services, will benefit members who reside in a particular locality and utilize dental services in a bordering state and out-of-state dental providers who render dental 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:

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 regarding clinical trial routine services are budget neutral. To date the only clinical trials OHCA is aware of, the members were sent to fully contracted providers, where we are already covering the surround expenses.

The proposed rule changes, regarding dental out-of-state services, are budget neutral. These services are already being provided. This change will help to alleviate an unnecessary burden on our SoonerCare members and providers, as well as the Agency.

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 is no less costly or non-regulatory method or less intrusive method for achieving the purpose of the proposed rule.

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 should have no effect on the public health, safety, and 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: February 3, 2022
Modified: April 21, 2022

RULE TEXT:

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

SUBCHAPTER 3. GENERAL PROVIDER POLICIES

PART 3. GENERAL MEDICAL PROGRAM INFORMATION

317:30-3-57.1. ~~Clinical trials~~Coverage of routine services in relation to clinical trials

~~(a) **Definition.** A clinical trial is a federally funded study that is either being conducted under an Investigational New Drug (IND) application or is exempt from having an IND application and helps to prevent, detect, or treat cancer or a life-threatening illness, injury, or disease.~~

~~(b) **Medical necessity.** Clinical trials must be determined to be medically necessary for the individual affected member. Documentation in the member's plan of care should support the medical necessity of the clinical trial for the affected individual member and that the clinical trial is for the medical purposes only. Requests for clinical trials in and of itself shall not constitute medical necessity. The Oklahoma Health Care Authority (OHCA) shall serve as the final authority pertaining to all determinations of medical necessity. Refer to Oklahoma Administrative Code (OAC) 317:30-3-1(f) for policy on medical necessity.~~

~~(c) **Documentation/requirements.** All documentation submitted to request services must demonstrate, through adequate objective medical records, evidence sufficient to justify the member's need for the service, in accordance with OAC 317:30-3-1(f)(2). An OHCA approved clinical trial must include the following:~~

~~(1) The clinical trial does one (1) of the following for the treatment of cancer or a life-threatening illness, injury, or disease:~~

~~(A) Tests how to administer a health care service;~~

~~(B) Tests responses to a health care service;~~

~~(C) Compares effectiveness of a health care service; or~~

~~(D) Studies new uses of a health care service.~~

~~(2) The clinical trial is approved and funded by one (1) of the following:~~

~~(A) Research facilities that have an established peer review program that has been approved by the National Institutes of Health Center (NIH);~~

~~(B) The Centers for Disease Control and Prevention;~~

~~(C) The Agency for Health Care Research and Quality (AHRQ);~~

~~(D) The Centers for Medicare and Medicaid Services (CMS);~~

~~(E) The United State Department of Veterans Affairs (VA);~~

~~(F) The United States Department of Defense (DOD);~~

~~(G) The Food and Drug Administration;~~

~~(H) The United States Department of Energy; or~~

~~(I) Research entities that meet the eligibility criteria for a support grant from a NIH center.~~

~~(3) Is conducted in a facility where the personnel have training and expertise needed to provide the type of care required and there is written protocol for the approved clinical trial;~~

~~(4) Complies with appropriate federal regulations regarding the protection of human subjects; and~~

~~(5) For full guidelines, please refer to www.okhca.org/mau.~~

~~(d) **Routine care costs.**~~

~~(1) The following are included in routine care costs for approved clinical trials and by a SoonerCare contracted provider:~~

~~(A) Costs that are required for the administration of the investigational item or service and are not a covered benefit of the clinical trial;~~

~~(B) Costs regarding the appropriate monitoring of the effects from the item or service; and~~

~~(C) Costs that are necessary for the prevention, diagnosis or treatment of medical complications for a non-covered item or service that was provided in the clinical trial.~~

~~(2) The following are excluded from routine care costs in approved clinical trials:~~

~~(A) The investigational item or service;~~

~~(B) Items or services that the study gives for free;~~

~~(C) Items or services that are only utilized when determining if the individual is eligible for the clinical trial;~~

~~(D) Items or services that are used only for data collection or analysis;~~

~~(E) Evaluations that are designed to only test toxicity or disease pathology;~~

~~(F) Experimental, investigational, and unproven treatments or procedures and all related services provided outside of an approved clinical trial; and~~

~~(G) Any non-FDA approved drugs that were provided or made available to the member during the approved clinical trial will not be covered after the trial ends.~~

~~(3) Applicable plan limitations for coverage for out-of-network and out-of-state providers will apply to routine care costs in an approved clinical trial.~~

~~(4) Applicable utilization management guidelines will apply to routine care costs in an approval clinical trial.~~

~~(e) **Experimental and investigational.** SoonerCare does not cover for medical, surgical, or other health care procedures, which are considered experimental or investigational in nature.~~

(a) **Coverage.** The Oklahoma Health Care Authority (OHCA) will cover routine patient costs provided under a qualifying clinical trial to an eligible member. The OHCA does not:

(1) Determine eligibility for participation in any research study; or

(2) Reimburse for any costs associated in the research study, other than for routine patient costs for clinical studies, as defined in this Section and in the Oklahoma Medicaid State Plan.

(b) **Qualifying clinical trials criteria.**

(1) Clinical trial, as adopted from the National Institute of Health (NIH) definition, means a research study in which one (1) or more human subjects are prospectively assigned to one (1) or more interventions, which may include placebo or other control, to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

(2) Pursuant to Section 1905(a)(30) and 1905(gg) of the Act, as amended and added by Division CC, Title II, Section 210 of the Consolidated Appropriations Act, 2021 (Public Law 116-260, Section 210), qualifying clinical trial means a clinical trial, in any clinical phase of

development, that is conducted in relation to the prevention, detection, or treatment of any serious or life-threatening disease or condition and is described in any of the following clauses:

(A) The clinical trial is approved, conducted, or supported (which may include funding through in-kind contributions) by one (1) or more of the following:

(i) The National Institutes of Health (NIH);

(ii) The Centers for Disease Control and Prevention (CDC);

(iii) The Agency for Healthcare Research and Quality (AHRC);

(iv) The Centers for Medicare and Medicaid Services (CMS);

(v) A cooperative group or center of any of the entities described above or of the Department of Defense or the Department of Veteran Affairs;

(vi) A qualified non-governmental research entity identified in guidelines issued by the National Institutes of Health for center support grants, including guidelines issued after the date of these rules; or

(vii) Any of the following if the clinical trial has been reviewed and approved through a system of peer review that the Secretary determines to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health and assures unbiased review of the highest scientific standards by qualified individuals with no interest in the outcome of the review:

(I) The Department of Veterans Affairs;

(II) The Department of Defense; or

(III) The Department of Energy.

(B) The clinical trial is conducted pursuant to an investigational new drug exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act or an exemption for a biological product undergoing investigation under section 351(a)(3) of the Public Health Service Act.

(C) The clinical trial is a drug trial that is exempt from being required to have an investigational new drug exemption or an exemption for a biological product undergoing investigation.

(3) Serious disease or condition, as adopted from 21 C.F.R. § 312.300, means a disease or condition associated with morbidity that has substantial impact on day-to-day functioning. Short-lived and self-limiting morbidity will usually not be sufficient, but the morbidity need not be irreversible, provided it is persistent or recurrent. Whether a disease or condition is serious is a matter of clinical judgment, based on its impact on such factors as survival, day-to-day functioning, or the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one.

(4) Life-threatening disease or condition, as adopted from 21 C.F.R. § 312.300, means a stage of disease in which there is reasonable likelihood that death will occur within a matter of months or in which premature death is likely without early treatment.

(c) **Clinical trials determination standards.** Pursuant to Section 1905(a)(30) and 1905(gg) of the Act, as amended and added by Division CC, Title II, Section 210 of the Consolidated Appropriations Act, 2021 (Public Law 116-260, Section 210, the OHCA will expedite and complete a coverage determination for routine services under this Section within seventy-two (72) hours of receiving the required attestation as described below. The OHCA will maintain the following standards in any coverage determination under this section:

(1) **Attestation.** The health care provider and principal investigator for the qualifying clinical trial must submit a standardized form attestation to the OHCA regarding the appropriateness of the qualifying clinical trial for the individual member.

(2) **Expedited determination.** Upon receiving the completed required attestation, the OHCA will expedite and complete a coverage determination under this Section within seventy-two (72) hours. All documentation submitted to request services must demonstrate, through adequate objective medical records, evidence sufficient to meet at least one (1) definition in subsection (b)(3)-(4) above for the terms "serious disease or condition" or "life-threatening disease or condition".

(3) **Geographic and network allowance.** The OHCA will determine coverage under this Section without limitation on the geographic location or network affiliation of the health care provider treating the individual member or the principal investigator of the qualifying clinical trial.

(4) **Protocols and proprietary documentation.** The OHCA will determine coverage under this Section without requiring the submission of the protocols of the qualifying clinical trial or any other documentation that may be proprietary or determined by the Secretary to be burdensome to provide.

(5) **Documentation of serious or life-threatening disease or condition.** In determining coverage under this Section, the OHCA will consider existing or newly offered documentation that the individual member has been diagnosed with or is suffering from one (1) or more serious or life-threatening diseases or conditions that are the subject of the qualifying clinical trial as shown in the attestation.

(d) **Routine patient costs.**

(1) **Included items and services.** Routine patient costs include any item or service provided to Medicaid-eligible members under the qualifying clinical trial, including:

(A) Any item or service provided to prevent, diagnose, monitor, or treat complications resulting from participation in the qualifying clinical trial, to the extent that the provision of such items or services to the member would otherwise be covered outside the course of participation in the qualifying clinical trial under the Oklahoma Medicaid State Plan or waiver, including a demonstration project under section 1115 of the Act; and

(B) Any item or service required solely for the provision of the investigational item or services that is the subject of the qualifying clinical trial, including the administration of the investigational item or service.

(2) **Excluded items and services.** The following items and services are excluded from routine patient costs in qualifying clinical trials:

(A) Any investigational item or service that is:

(i) The subject of the qualifying clinical trial; and

(ii) Not otherwise covered outside of the clinical trial under the Oklahoma Medicaid State Plan or waiver, including a demonstration project under section 1115 of the Act; and

(B) Any item or service that is:

(i) Provided to the member solely to satisfy data collection and analysis for the qualifying clinical trial and is not used in the direct clinical management of the member; and

(ii) Not otherwise covered under the Oklahoma Medicaid State Plan or waiver, including a demonstration project under section 1115 of the Act.

PART 6. OUT-OF-STATE SERVICES

317:30-3-90. Out-of-state services

(a) Consistent with Section 431.52 of Title 42 of the Code of Federal Regulations (C.F.R.), an eligible SoonerCare member who is a resident of Oklahoma but who is temporarily out of state, may receive services from an out-of-state provider to the same extent that he or she would receive such services in Oklahoma, if:

(1) Medical services are needed for a medical emergency, as determined by the attending physician or other provider (M.D., D.O., P.A., or A.P.R.N), or a dentist [Doctor of Dental Surgery (DDS), or Doctor of Medicine in Dentistry (DMD)]. For any provider, who is not contracted at the time the services are provided, documentation as requested from the Oklahoma Health Care Authority (OHCA) of the emergency must be submitted, including, but not limited to, emergency room reports, medical histories, discharge summaries, and all other relevant medical reports.

(2) Medical services are needed and the member's health would be endangered if he or she were required to return to Oklahoma for medical care and treatment, as determined by the attending physician or other provider (M.D., D.O., P.A., or A.P.R.N), or a dentist [Doctor of Dental Surgery (DDS), or Doctor of Medicine in Dentistry (DMD)]. For any provider, who is not contracted at the time the services are provided, documentation of the nature and possible extent of the endangerment must be submitted as requested from the OHCA.

(3) The Oklahoma Health Care Authority's (OHCA) Chief Medical Officer (CMO), or his or her designee, determines, on the basis of medical advice, that the needed medical services, or necessary supplemental resources, are more readily available in the state where the member is located at the time of needing medical treatment. Prior authorization must be obtained from the OHCA's CMO, or his or her designee, before the services are rendered~~; or~~.

~~(4) The customary or general practice for members residing in a particular locality within Oklahoma is to use medical resources in another state, and the member is using a provider that is contracted with the OHCA.~~

(b) Per 42 C.F.R. § 431.52, if it is the customary or general practice for SoonerCare members who are residing in a particular locality within Oklahoma to use medical or dental resources in another state, reimbursement is available for services furnished in another State to the same extent that reimbursement for services is furnished within Oklahoma boundaries. The services being rendered must be provided by a provider who is contracted with the OHCA and must be appropriately licensed and in good standing with the state in which they practice.

~~(A)~~(1) Except for out-of-state inpatient psychiatric services, no prior authorization is necessary for services provided in accordance with paragraph ~~(a)~~(4)(b), above, if the member obtains them from an out-of-state provider that is:

~~(i)~~(A) Located in a border state (Arkansas, Colorado, Kansas, Missouri, New Mexico, or Texas) within fifty (50) miles of the Oklahoma border, with exceptions for dental services. The OHCA will allow the member to travel up to one hundred (100) miles of the Oklahoma border to receive dental services; and

~~(ii) Contracted with the OHCA;~~

~~(iii)~~(B) Provided, however, that nothing in this paragraph shall be interpreted to eliminate or otherwise affect a prior authorization requirement established by any other OHCA rule, including, but not limited to, Oklahoma Administrative Code (OAC) 317:30-3-31, that would have to be met if the health care-related good and/or service were provided in Oklahoma.

~~(B)~~(2) In all other instances, prior authorization must be obtained from the OHCA's CMO, or his or her designee, before the services are rendered.

(c) Clinical trials, either in-state or out-of-state, will need to adhere to any federal regulations which provides for certain exceptions to OHCA's out-of-state policy. For the full clinical trials policy, please refer to OAC 317:30-3-57.1.

~~(b)~~(d) Except as provided in subsections (a)(1),(a)(2) ~~and (a)(4)(A),~~(b)(1) and (c), above, SoonerCare will not pay for any services furnished by an out-of-state provider unless prior authorization has been obtained from the OHCA's CMO, or his or her designee, before the services are rendered. Prior authorization for out of state services must be obtained in all instances in which the member is located in Oklahoma at the time the services are determined to be medically necessary.

(1) As part of this authorization process, the following documents must be submitted to the OHCA's CMO, or his or her designee:

(A) Documents sufficient to establish the "medical necessity" of the services requested, as that term is defined by OAC 317:30-3-1(f). See also OAC 317:30-3-31, Prior authorization for health care-related goods and services. Examples of such documents may include, but are not limited to, Histories of Present Illnesses (HPIs), physical exams, laboratory reports, imaging reports, progress notes, hospital charts, and/or other relevant medical records; and

(B) Documents sufficient to establish that the health care needs of the member cannot be met in Oklahoma. Such documents shall include, but not be limited to, a letter from the referring provider that contains:

(i) A clear presentation of the member's medical condition and diagnosis for which out-of-state treatment is requested, including a summary of treatment to date that is supported by the documents in paragraph ~~(b)~~(c)(1)(A), above;

(ii) Names of physicians and/or facilities in Oklahoma that the member has previously been referred to for diagnosis and/or treatment;

(iii) Physicians consulted by the attending physician relative to diagnosis and/or availability of recommended treatment in Oklahoma;

(iv) Recommended treatment or further diagnostic work; and

(v) Reasons why medical care cannot be provided in Oklahoma or the next closest location outside Oklahoma.

(C) Except for emergency medical, behavioral health cases, and as provided in subsections (a)(1),(a)(2) and (b)(1), above, prior authorization requests for out-of-state services must be made in writing with all the necessary documents that show medical necessity and details of the services provided, including but not limited to, relevant medical history, description of services and procedures to be performed, Histories of Present Illnesses (HPIs), physical exams, laboratory reports, imaging reports, and received by the OHCA at least ten (10) calendar days prior to the date services are to be provided in another state or at the discretion of the CMO or his/her designee.

(i) Emergency medical, ~~or~~ behavioral health, and dental cases must be identified as such by the physician or provider in the prior authorization request.

(ii) Any telephone request for prior authorization of out-of-state services will only be accepted in emergency situations, and must be promptly followed by a written request.

(2) Prior authorization requirements for medically necessary lodging, transportation, and/or meals assistance associated with out-of-state services are established in other OHCA rules, including, but not limited to, OAC 317:30-3-92 and 317:30-5-327.1. In accordance with federal regulations, exceptions to prior authorization requirements will be made for members who are participating in a clinical trial that require out-of-state medically necessary services. For the full clinical trials policy, please refer to OAC 317:30-3-57.1.

~~(c)~~(e) The ~~restrictions~~limitations established in subsections (a) through ~~(b)~~(c), above, shall not apply to children who reside outside of Oklahoma and for whom the Oklahoma ~~Department of~~ Human Services (OKDHS) makes Title IV-E adoption assistance payments or Title IV-E foster care maintenance payments.

~~(d)~~(f) Denials of requests for prior authorization may be appealed in accordance with OAC 317:2-1-2(d)(1)(C).

~~(e)~~(g) Out-of-state providers shall, upon request by authorized OHCA representatives, make available fiscal and medical records as required by applicable federal regulations, OHCA rules, and the Provider Agreement. Such records shall be made available for review by authorized OHCA representatives at the OHCA's address in Oklahoma City, Oklahoma.