CABINET FOR HEALTH AND FAMILY SERVICES

Department for Medicaid Services

Division of Fiscal Management

(New Administrative Regulation)

907 KAR 3:190. Reimbursement for treatment related to clinical trials.

RELATES TO: KRS 205.520, 205.5605, 205.5606, 205.5607, 42 U.S.C. 1396d

STATUTORY AUTHORITY: KRS 194A.030(2), 194A.050(1), 205.520(3),

NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Health and Family Services, Department for Medicaid Services, has responsibility to administer the Medicaid Program. KRS 205.520(3) authorizes the cabinet, by administrative regulation, to comply with any requirement that may be imposed, or opportunity presented, by federal law to qualify for federal Medicaid funds. 42 U.S.C. 1396d(gg) establishes federal requirements for reimbursement relating to a qualifying clinical trial. In keeping with that federal requirement, this administrative regulation establishes the department's coverage and reimbursement for routine patient costs relating to a qualifying clinical trial.

Section 1. Definitions. (1) "Department" means the Department for Medicaid Services or its designee.

(2) "Qualifying clinical trial" has the same meaning as in 42 U.S.C. 1396d(gg)(2).

(3) "Routine patient costs" has the same meaning as in 42 U.S.C. 1396d(gg)(1).

Section 2. Policy. Consistent with 42 U.S.C. 1396d(gg), services related to qualifying clinical trials shall be reimbursable if:

(1) The services are covered services pursuant to Title 907 KAR;

(2) The services would otherwise be provided to a participant who is not participating in a clinical trial; and

(3) The services are not covered by the clinical trial sponsor.

Section 3. Qualifying Clinical Trial Treatment Related Expenses. (1) The department shall comply with 42 U.S.C. 1396d and provide coverage for routine patient costs associated with a qualifying clinical treatment.

(2) Any required coverage determination shall be expedited and completed within seventy-two (72) hours.

(3) In complying with this section, the provider shall not be:

(a) Required to provide the geographic location or network affiliation of a provider associated with a qualifying clinical trial and treating an enrolled Medicaid recipient.

(b) Required to submit:

1. Protocols of the qualifying clinical trial;

2. Proprietary documentation; or

3. Any information determined by the federal Health and Human Services cabinet to be burdensome to provide.

(4)(a) A provider and principal investigator shall attest to the appropriateness of the qualifying clinical trial by completion of the form located on the Medicaid.gov Web site at this link: https://www.medicaid.gov/resources-for-states/downloads/medicaid-attest-form.docx.

(b) The form established in paragraph (a) shall be submitted upon request and available for auditing purposes.

Section 4. Federal Approval and Federal Financial Participation. The department's coverage and reimbursement of services pursuant to this administrative regulation shall be contingent upon:

(1) Receipt of federal financial participation for the coverage and reimbursement; and

(2) Centers for Medicare and Medicaid Services' approval of the coverage and reimbursement.

Section 5. Use of Electronic Signatures. The creation, transmission, storage, or other use of electronic signatures and documents shall comply with the requirements established in KRS 369.101 to 369.120.

Section 6. Appeal Rights. (1) An appeal of a department decision regarding a Medicaid recipient based upon an application of this administrative regulation shall be in accordance with 907 KAR 1:563.

(2) An appeal of a department decision regarding Medicaid eligibility of an individual shall be in accordance with 907 KAR 1:560.

(3) An appeal of a department decision regarding a Medicaid provider based upon an application of this administrative regulation shall be in accordance with 907 KAR 1:671.

907 KAR 3:190
REVIEWED:

2/1/2023
Date

DocuSigned by:
Lisa Lee
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Lisa D. Lee, Commissioner
Department for Medicaid Services

APPROVED:

2/2/2023
Date

DocuSigned by:
Eric Friedlander
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Eric C. Friedlander, Secretary
Cabinet for Health and Family Services

PUBLIC HEARING AND PUBLIC COMMENT PERIOD:

A public hearing on this administrative regulation shall, if requested, be held on April 24, 2023, at 9:00 a.m. using the CHFS Office of Legislative and Regulatory Affairs Zoom meeting room. The Zoom invitation will be emailed to each requestor the week prior to the scheduled hearing. Individuals interested in attending this virtual hearing shall notify this agency in writing by April 17, 2023, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends virtually will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until April 30, 2023. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Krista Quarles, Policy Analyst, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, KY 40621; Phone: 502-564-6746; Fax: 502-564-7091; CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation #: 907 KAR 3:190
Agency Contact Persons: Jonathan Scott, (502) 564-4321, ext. 2015, jonathant.scott@ky.gov; and Krista Quarles, (502) 564-6746, CHFSregs@ky.gov

(1) Provide a brief summary of:
(a) What this administrative regulation does: This administrative regulation establishes the coverage and reimbursement requirements for routine patient costs as required by the federal Clinical Treatment Act. In addition, this administrative regulation will allow Medicaid beneficiaries to more fully participate in clinical trials.
(b) The necessity of this administrative regulation: This administrative regulation is necessary to implement the federal requirement to cover routine patient costs under the Clinical Treatment Act.
(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of the authorizing statutes by establishing reimbursement for allowable expenses related to clinical trials pursuant to the federal Clinical Treatment Act.
(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of the statutes by establishing a reimbursement mechanism for clinical trial expenses as required by federal law.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:
(a) How the amendment will change this existing administrative regulation: This is a new administrative regulation.
(b) The necessity of the amendment to this administrative regulation: This is a new administrative regulation.
(c) How the amendment conforms to the content of the authorizing statutes: This is a new administrative regulation.
(d) How the amendment will assist in the effective administration of the statutes: This is a new administrative regulation.

(3) List the type and number of individuals, businesses, organizations, or state and local government affected by this administrative regulation: This will impact all recipients in Medicaid who are enrolled in a clinical trial, as well as primary care providers.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:
(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment.
(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3). Enrollees and recipients should not

experience any additional costs in complying with this administrative regulation.
(c) As a result of compliance, what benefits will accrue to the entities identified in question (3). Enrollees and recipients will be able to access a new Medicaid benefit.

(5) Provide an estimate of how much it will cost to implement this administrative regulation:
(a) Initially: The Department for Medicaid Services (DMS) anticipates no additional costs to implement this administrative regulation.
(b) On a continuing basis: The Department for Medicaid Services (DMS) anticipates no additional costs to implement this administrative regulation.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The sources of revenue to be used for implementation and enforcement of this administrative regulation are federal funds authorized under Title XIX of the Social Security Act and matching funds from general fund appropriations.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: Neither an increase in fees nor funding will be necessary to implement this administrative regulation.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation neither establishes nor increases any fees.

(9)Tiering: Is tiering applied? (Explain why tiering was or was not used) Tiering is not applied as the policies apply equally to the regulated entities.

FEDERAL MANDATE ANALYSIS COMPARISON

Regulation Number: 907 KAR 3:190
Agency Contact Persons: Jonathan Scott, (502) 564-4321, ext. 2015, jonathant.scott@ky.gov; and Krista Quarles, (502) 564-6746, CHFSregs@ky.gov

1. Federal statute or regulation constituting the federal mandate. 42 C.F.R. Part 11

2. State compliance standards. KRS 205.520(3) and KRS 194A.050(1).

3. Minimum or uniform standards contained in the federal mandate. 42 C.F.R. Part 11 establishes requirements relating to clinical trials. DMS has also been instructed to submit a state plan amendment by the federal government.

4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate? No.

5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. Stricter or different requirements are not imposed.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Regulation Number: 907 KAR 3:190

1 Agency Contact Persons: Jonathan Scott, (502) 564-4321, ext. 2015, jonathant.scott@ky.gov; and
2 Krista Quarles, (502) 564-6746, CHFSregs@ky.gov

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Department for Medicaid Services (DMS) will be affected by this administrative regulation.

2. Identify each state or federal regulation that requires or authorizes the action taken by the administrative regulation. 42 C.F.R. Part 11

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

   (a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? DMS does not expect this administrative regulation to generate revenue for state or local government.
   (b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? DMS does not expect this administrative regulation to generate revenue for state or local government.
   (c) How much will it cost to administer this program for the first year? The Department for Medicaid Services (DMS) anticipates no additional costs as a result of this administrative regulation.
   (d) How much will it cost to administer this program for subsequent years? The Department for Medicaid Services (DMS) anticipates no additional costs as a result of this administrative regulation.

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year? DMS does not anticipate that cost savings will be generated for regulated entities as a result of the amendments to this administrative regulation in the first year. This administrative regulation may result in higher reimbursement for regulated entities.

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years? DMS does not anticipate that cost savings will be generated for regulated entities as a result of the amendments to this administrative regulation in subsequent years. This administrative regulation may result in higher reimbursement for regulated entities.

(c) How much will it cost the regulated entities for the first year? DMS does not anticipate that regulated entities will incur costs as a result of this amendment in the first year.

(d) How much will it cost the regulated entities for subsequent years? DMS does not anticipate that regulated entities will incur costs as a result of this amendment in subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Cost Savings(+/-):

Expenditures (+/-):

Other Explanation:

(5) Explain whether this administrative regulation will have a major economic impact, as defined below. *"Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars ($500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)]*

The administrative regulation will not have a major economic impact – as defined by KRS 13A.010 – on regulated entities. DMS anticipates that this amendment may result in additional reimbursement for some providers.