TITLE 41
INSURANCE

CHAPTER 65
COVERAGE FOR PARTICIPANTS IN CLINICAL TRIALS

41-6501. "ROUTINE PATIENT CARE COSTS" DEFINED. "Routine patient care costs" means the costs of any medically necessary health care service for which benefits are provided under a health benefit plan, without regard to whether the enrollee is participating in a clinical trial. Routine patient care costs do not include the cost:

(1) Of an investigational new drug or device that is not approved for any indication by the United States food and drug administration;

(2) Of a service that is not a health care service, regardless of whether the service is required in connection with participation in a clinical trial;

(3) Of a service that is inconsistent with widely accepted and established standards of care for a particular diagnosis;

(4) Associated with managing a clinical trial; or

(5) Of a health care service that is specifically excluded from coverage under a health benefit plan.

[41-6501, added 2019, ch. 192, sec. 1, p. 604.]

41-6502. REQUIRED COVERAGE. The issuer of a health benefit plan shall provide benefits for routine patient care costs to an enrollee in connection with an approved clinical trial. For purposes of this chapter, "approved clinical trial" means a phase I, phase II, phase III, or phase IV clinical trial that is conducted in relation to the prevention, detection, or treatment of a disease or condition and:

(1) The study or investigation is approved or funded, which may include funding through in-kind contributions, by one (1) or more of the following:

(a) The national institutes of health;

(b) The centers for disease control and prevention;

(c) The agency for healthcare research and quality;

(d) The centers for medicare and medicaid services;

(e) A cooperative group or center of any of the entities through the department of defense or the department of veterans affairs; or

(f) A qualified nongovernmental research entity identified in the guidelines issued by the national institutes of health for center support grants;

(2) The study or investigation is conducted under an investigational new drug application reviewed by the food and drug administration;

(3) The study or investigation is not a new drug trial and therefore exempt from having such an investigational new drug application by the food and drug administration; or

(4) The study or investigation has been reviewed and approved by an institutional review board of an institution that has an agreement with the office for human research protections of the United States department of health and human services.

[41-6502, added 2019, ch. 192, sec. 1, p. 604.]

41-6503. RESEARCH INSTITUTIONS. The issuer of a health benefit plan is not required to:

(1) Reimburse a research institution conducting a clinical trial for the cost of routine patient care provided through the research institution unless the research institution, and each health care professional providing routine patient care through the research institution, agrees to accept reimbursement under the health benefit plan at the rates established under the plan as payment in full for the routine patient care provided in connection with the clinical trial; or

(2) Provide benefits under this section for services that are customarily paid for by the research institution conducting the clinical trial in accordance with centers for medicare and medicaid services billing guidelines.

[41-6503, added 2019, ch. 192, sec. 1, p. 605.]

41-6504. LIMITATIONS ON COVERAGE. The issuer of a health benefit plan is not required to provide benefits for routine patient care services provided outside:

(1) Of the plan's health care provider network, unless out-of-network benefits are otherwise provided under the plan; or

(2) This state, unless the health benefit plan otherwise provides benefits for health care services provided outside this state.

[41-6504, added 2019, ch. 192, sec. 1, p. 605.]

41-6505. INSURER LIABILITY. An insurer that provides coverage required by this chapter is not, based on that coverage, liable for any adverse effects of the approved clinical trial.

[41-6505, added 2019, ch. 192, sec. 1, p. 605.]

41-6506. DEDUCTIBLE, COINSURANCE, AND COPAYMENT REQUIREMENTS. Benefits may be made subject to a deductible, coinsurance, or copayment requirement comparable to other deductible, coinsurance, or copayment requirements applicable under the health benefit plan.

[41-6506, added 2019, ch. 192, sec. 1, p. 605.]

41-6507. CANCELLATION OR NONRENEWAL PROHIBITED. The issuer of a health benefit plan may not cancel or refuse to renew coverage under a plan solely because an enrollee in the plan participates in a clinical trial.

[41-6507, added 2019, ch. 192, sec. 1, p. 605.]