SUMMARY OF MATERIAL MODIFICATIONS No. 3

This modification is made effective **May 16, 2011,** by the **City of Rapid City** to the **City of Rapid City Medical and Dental Plans.** All other terms and provisions of the Plan remain unaltered and in effect.

Distribution of the attached amendment will be handled in the following manner:

_____ The Plan Administrator will be responsible for distribution.

_____ First Administrators, Inc. will provide a formal copy of the amendment to the Plan Administrator for distribution.

_____ First Administrators, Inc. will provide the Plan Administrator with _____ copies of the amendment for distribution.

_____ Other:_____

The following **"S5.18 Clinical Trials"** is **added** to the current Summary Plan Description.

S5.18 CLINICAL TRIALS

Coverage for medically necessary routine patient care costs incurred for treatment in an approved clinical trial to the same extent coverage is provided if the patient were receiving standard treatment.

Includes:

- Otherwise covered physician fees, laboratory expenses, and expenses associated with hospitalizations;
- Evaluation and treatment of the patient associated with the underlying disease;
- Care that would be covered if such items and services were provided other than in connection with an approved clinical trial;
- Care costs that are consistent with the usual standards of care whenever a patient receives medical care associated with an approved clinical trial.

Excludes:

- Any treatments, procedures, drugs, devices, services, or items that are otherwise the subject of the approved clinical trial or any other investigational treatments, procedures, drugs, devices, services or items;
- Non-health care services that the patient is required to receive as a result of participation in the approved clinical trial;
- Costs associated with managing the research that is associated with the approved clinical trial;
- Costs that would not be covered if non-investigational treatments were provided;
- Costs of any services, procedures, or tests provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient;
- Costs paid for, or not charged for, by the approved clinical trial providers;
- Costs for transportation, lodging, food, or other expenses of the patient, a family member, or a companion of the patient that are associated with travel to or from a facility where an approved clinical trial is conducted;
- Costs associated with approved clinical trials designed exclusively to test toxicity or disease pathophysiology.

The following **replaces** the **"Experimental or Investigational"** exclusion in the **"General Exclusions"** section in the current Summary Plan Description.

19. **Experimental or Investigational.** Any treatment of a disability, injury, or disease which is not widely used, generally accepted treatment for the disability, injury or disease, and which treatment, surgery or drug is considered experimental or investigational as defined in *Article IX*, unless otherwise specified as covered by the plan.

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The **"Clinical Trials"** definition is **added** and **"Experimental and Investigational"** definition is **replaced** in the **"Definitions"** section of the current Summary Plan Description.

CLINICAL TRIALS

An approved clinical trial is a scientific study of a new therapy of the treatment of human beings and consists of a scientific plan of treatment that includes all of the following:

- Specified goals;
- A rationale and background for the plan;
- Criteria or patient selection;
- Specific directions for administering therapy and monitoring patients;
- A definition of quantitative measures for determining treatment response; and
- Methods for documenting and treating adverse reactions.

Must be approved or authorized by one of the following:

- The National Institutes of Health (NIH), or one of its cooperative groups or centers, under the U.S. Department of Health and Human Services (HHS).
- The U.S. Food and Drug Administration (FDA)
- The U.S. Department of Defense (DOD)
- The U.S. Department of Veterans Affairs (VA)
- An institutional review board of an institution that is approved by the office for human research protections of the federal department of health and human services.

EXPERIMENTAL OR INVESTIGATIONAL

Experimental or Investigational means that one or more of the following is true:

(a) The device, drug or medicine cannot be lawfully marketed without approval of the U.S. Food and Drug Administration and approval for marketing has not been given at the time the device, drug or medicine is furnished, with the exception of covered clinical trials;

(b) The drug, device, medical treatment or procedure, or the patient informed consent document utilized with the drug, device, treatment or procedure was reviewed and approved by the treating facility's Institutional Review Board or other body serving a similar function, or if federal law requires such review and approval, and furthermore, that the treating facility's Institutional Review Board is reviewing such drug, device, treatment or procedure as being experimental or investigational; and/or

(c) Reliable evidence shows that the consensus of opinion among experts regarding the treatment, procedure, device, drug or medicine is that further studies or clinical trials are necessary to determine its maximum tolerated dose, its toxicity, its safety, its efficacy, or its efficacy as compared with the standard means of treatment or diagnosis.

Reliable evidence means only published reports and articles in the authoritative medical and scientific literature; the written protocol or protocols used by the treating facility or the protocol(s) of another facility studying substantially the same treatment, procedure, device, drug or medicine; or the written informed consent used by the treating facility or by another facility studying substantially the same treatment, procedure, device, drug or medicine.

In addition, no reimbursement is available for payments of any: (1) treatments, services or supplies that are educational or provided primarily for research; or (2) treatments, procedures, devices, drugs or medicines or other expense relating to transplants of nonhuman organs.

SUMMARY OF MATERIAL MODIFICATIONS No. 3

CITY OF RAPID CITY

_____	_____
(Authorized Signature)	(Date)
_____	_____
(Printed Authorized Signature)	(Title)