

**THE COUNTY OF EL PASO**  
**Health Benefits Fund**  
**Medical Plan Document**

**Amendment No. 12**

Effective September 20, 2006 The County of El Paso hereby amends the Health Benefits Fund Medical Plan Document as follows:

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**Please insert the following paragraph into Section 1, "Definitions":**

**Cancer Clinical Trials.** Treatment provided in a phase I, phase II, phase III or phase IV cancer clinical trial that meets all of the following conditions:

- 1) The treatment must either: A) involve a drug that is exempt under federal regulations from a new drug application; **or** B) be approved by (i) one of the National Institutes of Health, (ii) the federal Food and Drug Administration in the form of an investigational new drug application; (iii) the United States Department of Defense, or (iv) the United States Veteran's Administration.
- 2) The participant must have been diagnosed with cancer.
- 3) Participation in the cancer clinical trial must be recommended by the Covered Person's physician based upon his or her medical determination that participation would have a meaningful potential to benefit the Covered Person.
- 4) The cancer clinical trial must have a therapeutic intent. Clinical trials solely for the purpose of testing toxicity are not covered.

**Routine Patient Care Costs.** The costs associated with the provision of services for Cancer Clinical Trials, including drugs, items and services which would otherwise be covered under the Plan, including health services which are: A) typically provided absent a clinical trial; B) required solely for the provision of the investigational drug, item, device or service; C) clinically appropriate monitoring of the investigational item or service; D) prevention of complications arising from the provision of the investigational drug, item, device, or service; and E) reasonable and necessary care arising from the provision of the investigational drug, item, device, or service, including the diagnosis or treatment of the complications.

Routine Patient Care Costs do not include the following costs regarding Cancer Clinical Trials (in addition to the costs of non-covered services): 1) drugs or devices not approved by the federal Food and Drug Administration that are associated with the clinical trial; 2) services other than health care services, such as travel, housing, companion expenses and other non-clinical expenses that the Covered Person may require as a result of the treatment provided for the purposes of the clinical trial; 3) any item or service provided solely to satisfy data collection and analysis needs for information that is not used in the clinical management; 4) health care services that, except for the fact that they are provided in a clinical trial, are otherwise specifically excluded from the Plan; and 5) health care services customarily provided by research sponsors free of charge to persons enrolled in the clinical trial.

**Please insert the following paragraph into Section 9, "Covered Medical Expenses":**

- 20) Routine Patient Care Costs for Cancer Clinical Trials.