

**AMENDMENT EIGHT TO THE  
RESTATED PLAN OF BENEFITS OF THE  
OHIO CARPENTERS HEALTH PLAN**

**WHEREAS**, the undersigned represent the Board of Trustees (“Trustees”) of the Ohio Carpenters Health and Welfare Plan and Trust (“Plan”); and

**WHEREAS**, the Plan’s Trust Agreement empowers the Trustees to promulgate a Plan of Benefits and to amend the same from time to time;

**WHEREAS**, the Trustees now desire to restate the Plan’s provisions on Clinical Trials;

**NOW, THEREFORE**, the Trustees resolve to amend the Plan effective May 1, 2014, as follows:

**Clinical Trials Program**

Benefits are provided for Routine Patient Costs administered to an Eligible Person participating in any stage of an Approved Clinical Trial, if that care would be covered under the Plan if the Eligible Person was not participating in a clinical trial.

In order to be eligible for benefits, the Eligible Person must meet the following conditions (number 2 below is not required for cancer clinical trials in Ohio):

1. The Eligible Person is eligible to participate in an Approved Clinical Trial, according to the trial protocol with respect to treatment of cancer or other Life-threatening Conditions.
2. Either:
  - The referring Provider is a PPO Network Provider and has concluded that the Eligible Person’s participation in such trial would be appropriate based upon the Eligible Person meeting the conditions described in “1” above; or
  - The Eligible Person provides medical and scientific information establishing that his or her participation in such trial would be appropriate based upon the Eligible Person meeting the conditions described in “1” above.

If the clinical trial is not available from a PPO Network Provider, the Eligible Person may participate in an Approved clinical Trial administered by a Non-Contracting Provider. However, the Routine Patient Costs will be covered at the Non-Contracting Amount, and the Covered Person may be subject to balance billing up to the Provider's Billed Charges for the services.

"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 cancer or other Life-threatening disease or Condition and is described in any of the following:

- A federally funded trial.
- The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration.
- The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

"Life-threatening Condition" means any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

"Routine Patient Costs" means all health care services that are otherwise covered under the Plan for the treatment of cancer or other Life-threatening condition that is typically covered for a patient who is not enrolled in an Approved Clinical Trial.

"Subject of a Clinical Trial" means the health care service, item, or drug that is being evaluated in the Approved Clinical Trial and that is not a Routine Patient Cost.

No benefits are payable for the following:

- A health care service, item, or drug that is the subject of the Approved Clinical Trial;
- A health care service, item, or drug provided solely to satisfy data collection and analysis needs and that is not used in the direct clinical management of the patient;
- An Experimental or Investigational drug or device that has not been approved for market by the United States Food and Drug Administration;
- Transportation, lodging, food, or other expenses for the patient, or a family member or companion of the patient, that are associated with the travel to or from a facility providing the Approved Clinical Trial;

- An item or drug provided by the Approval Clinical Trial sponsors free of charge for any patient;
- A service, item, or drug that is eligible for reimbursement by an entity other than this Plan, including the sponsor of the Approved Clinical Trial;
- A service, item, or drug that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

Dated at Columbus, Ohio on the 10<sup>th</sup> day of December, 2014.

**OHIO CARPENTERS' HEALTH PLAN**

By *Doni Moffatt*

And *K. M. Alb*