CHARLENE MIERS FOUNDATION FOR CANCER RESEARCH
PROPOSED LEGISLATION

Oklahoma Routine Patient Care in Clinical Trials Act
Summary

▪ A health benefit plan shall provide benefits for routine patient care costs in connection with a phase I, phase II, phase III, or phase IV clinical trial.

▪ The clinical trial must be conducted in relation to the prevention, detection, or treatment of a life-threatening disease or condition and is approved by the national health agencies, including:

- ▪ US Centers for Disease Control and Prevention,
- ▪ National Institutes of Health,
- ▪ United States Food and Drug Administration.

▪ "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" does not include the cost of an investigational new drug or device that is not approved for any indication by the United States Food and Drug Administration, including a drug or device that is the subject of the clinical trial, or a cost associated with managing a clinical trial.

▪ The providing of routine patient care costs coverage for participants in clinical trials is to be subject to rules, limitations and procedures otherwise generally applicable to enrollees in a health benefit plan.

▪ The provision of routine patient care costs in clinical trials will be required on and after January 1, 2011.