

**Resolution in Support of Health Plan Coverage for Routine Patient
Care Costs Associated with Clinical Trials**

The Greater Houston Partnership supports legislation that results in health benefit plan coverage for routine patient care costs incurred by those individuals who participate in clinical trials. Clinical trials are conducted on human patients to test the safety and effectiveness of new treatments that result in the saving of many lives.

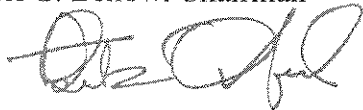
The Greater Houston Partnership acknowledges that:

- The lack of coverage for the costs associated with basic patient care is a significant barrier to many patients who wish to participate in clinical trials, which in many cases, produce lifesaving health benefits.
- Coverage of these routine patient care costs is essential to advance medical research that improves prevention and treatment options for residents of our state and beyond.

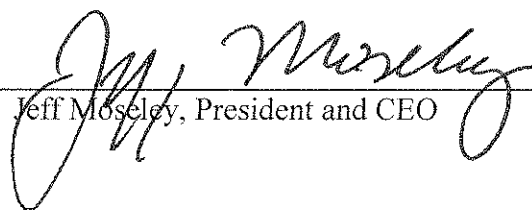
The Greater Houston Partnership urges lawmakers to support legislation that will result in increased participation in clinical trials by those individuals whose only barrier is prohibitive routine patient care costs.



Daniel G. Bellow, Chairman



Patrick Oxford, Secretary



Jeff Moseley, President and CEO

MEMORANDUM

DATE: April 15, 2009

TO: Greater Houston Partnership Executive Committee

FROM: Daniel J. Wolterman, Chairman
Health Care Policy Advisory Committee

SUBJECT: Resolution of the Executive Committee In Support of
Health Plan Coverage for Routine Patient Care Costs
Associated with Clinical Trials

RECOMMENDATION

The Greater Houston Partnership supports legislation resulting in health plan coverage for routine patient care costs associated with clinical trials.

The Greater Houston Partnership acknowledges that:

- The lack of coverage for the costs associated with basic patient care is a significant barrier to many patients who wish to participate in clinical trials, which in many cases, produce lifesaving health benefits.
- Coverage of these routine patient care costs is essential to advance medical research that improves prevention and treatment options for residents of our state and beyond.

The Greater Houston Partnership urges lawmakers to support legislation that will result in increased participation in clinical trials by those individuals whose only barrier is prohibitive routine patient care costs.

BACKGROUND

Clinical trials are research studies to test the effectiveness of new treatments and medications on human patients. These studies answer scientific questions and attempt to develop better ways to prevent, screen for, diagnose or treat a disease. People who participate in these trials have an opportunity to contribute to the knowledge of and progress against potentially life-threatening illnesses. The dramatic progress made in treating many diseases in recent years is attributable, in large part, to individuals who participate in clinical trials.

As outlined by the National Institute of Health, clinical trials are conducted in four phases:

- Phase I tests a new intervention in 20 to 80 people for an initial evaluation of safety, e.g., to determine a safe dosage range and identify side effects.
- Phase II studies an intervention in a larger group of people, usually several hundred, to determine efficacy and further evaluate safety.
- Phase III studies the efficacy of an intervention in large groups of several hundred to several thousand subjects by comparing it to other standard or experimental interventions, while monitoring adverse events and collecting information that will allow safe use.
- An NIH-defined phase III clinical trial is a broad-based, prospective study, including community and other population-based trials, usually involving several hundred or more people, to compare an experimental intervention with a standard or control, or to compare existing treatments. It often aims to provide evidence for changing policy or standard of care. It includes pharmacologic, non-pharmacologic and behavioral interventions for disease prevention, prophylaxis, diagnosis or therapy.
- Phase IV is a study done after an intervention has been marketed to monitor its effectiveness in the general population and collect information about adverse effects associated with widespread use.

It is important to researchers, and the overall health of the people of the State of Texas, to have access to the largest population possible to conduct trials having the possibility of discovering cures for many life-threatening diseases. Due to restrictions on the payment of the routine patient care costs incurred in a phase I, II, III or IV clinical trial by insurers, many individuals who would participate in these trials are excluded as a result of financial considerations.

“Routine patient care costs” are the usual costs of medical care. These costs include visits to the doctor’s office, hospital stays, clinical laboratory tests and x-rays that patients receive separate and distinct from the clinical trial. Any costs associated with the actual clinical trial are covered by the organization conducting the research – not the patient or the health plan carrier.

Texas is home to one of the largest and most progressive research centers in the world – the Texas Medical Center. However, the state is far behind twenty-five states requiring health plans to cover patient care costs in clinical trials. Rhode Island was the first state to adopt similar legislation in 1995. Our neighboring state of Louisiana has provided this coverage since 1999, as have Maine, New Jersey and Virginia. Maryland adopted legislation in 1998. New Mexico, Arizona, California, Delaware and New Hampshire

provided this coverage starting in 2001. Connecticut, Georgia, Michigan, Missouri and North Carolina followed in 2002, with Massachusetts and West Virginia adopting legislation in 2003. Tennessee required this coverage beginning in 2005. Vermont, Nevada and Wisconsin enacted legislation in 2006. Ohio, Washington D.C, and Wyoming just passed legislation adopting this coverage in 2008.

Lack of coverage for standard care costs is a significant barrier for many patients who might enroll in a trial and possibly benefit from such participation. Texans with life threatening diseases often make the choice to bypass participation in a clinical trial which might save their lives because their health plan does not provide for basic patient care costs. For example, it is estimated that less than three percent of potentially eligible oncology patients enroll in trials in large part because routine health care costs are not covered by many insurance plans when clinical trials are involved. The number could be much greater – which means the potential life-saving research lost could be greater as well.

While routine patient care costs would be covered, the health plan provider is not required to reimburse the research institution conducting the clinical trial, unless the research institution agrees to accept reimbursement under the health plan at the rates established by the plan. In addition, a health plan provider is not required to provide benefits that are part of the subject matter of the clinical trial and are customarily paid for by the research institution.

LEGISLATION NEEDED

The Greater Houston Partnership requests legislative initiatives that require health plan providers to cover costs for routine patient care that is associated with participation in clinical trials. These provider costs would not include reimbursement to the research institutes conducting the trial; nor would the costs provide benefits that are a component of the clinical trial which, as a rule, are paid by the research institution.

FISCAL IMPACT

The bill currently before the legislature regarding this matter makes no appropriation but could provide the legal basis for an appropriation of funds to implement the provisions of the bill.

KNOWN OPPOSITION:

There is no known opposition.

RESOURCES REQUIRED:

None.