CLINICAL TRIALS COVERAGE

For many cancer patients, the best treatment option is care in a clinical trial, but no more than 2-3 percent of people with cancer enroll in clinical trials. A survey of researchers, conducted by the American Society of Clinical Oncology (ASCO), found that denials of reimbursement for routine patient care costs are among the obstacles to enrollment in clinical trials. Routine patient care costs include those charges that insurance should be expected to cover, such as physician charges, hospital charges, and routine tests, but do not include research costs or the cost of investigational new drugs.

A number of states have enacted legislation requiring insurers to cover routine patient care costs for clinical trials, and none of those initiatives has resulted in an explosion of costs due to clinical trials enrollment. However, a state-by-state approach is not an adequate solution because it leaves many individuals at risk.

To address this situation, advocates for people with cancer recommend the following:

• **Include a clinical trials coverage provision in the Patients’ Bill of Rights**: The Conference Committee on the Patients’ Bill of Rights should approve strong patient protection measures that will ensure individuals the right to enroll in clinical trials.

• **Broaden clinical trial coverage to include private FDA-approved clinical trials**: Coverage provisions (whether state or federal) should be broad-based and inclusive, covering private, FDA-approved clinical trials as well as NIH-sponsored clinical trials. Much of the cutting-edge cancer research is conducted in the private sector, and cancer patients should have access to these important clinical trial opportunities.

• **Enact the Medicare Cancer Clinical Trials Coverage Act**: The Medicare Cancer Clinical Trials Coverage Act (S. 784/H.R. 1388) has strong bipartisan support, but until it is enacted, Medicare beneficiaries will face uncertainty regarding their ability to enroll in clinical trials. The Institute of Medicine (IOM), noting that senior citizens are underrepresented in cancer trials, recently recommended to Congress that Medicare provide coverage for cancer trials.

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