



Affordable Care Act: Clinical Trials

Research conducted through clinical trials drives development of new evidence that will deliver the next generation of innovations to improve care and patient quality of life.

To boost adult patient enrollment rates and accelerate the timeline for bringing new treatments from the bench to the bedside, the American Cancer Society Cancer Action Network (ACS CAN) has consistently advocated for health insurance coverage of routine costs for patients participating in clinical trials.

Despite increasing expansion of coverage for routine care costs in clinical trials across the United States, uncertainty exists under both public and private insurance plans regarding items and services that will be covered. As a result, the scope of coverage across the states varies considerably.

Fast Facts

- Nearly 20% of cancer patients are eligible for participation in cancer clinical trials, but enrollment among adults consistently ranges between 3-5%.
- Medicare covers routine patient care costs for beneficiaries enrolled in qualified clinical trials.
- Prior to passage of the Affordable Care Act, the vast majority of American workers were not eligible for coverage of patient care costs when enrolled in clinical trials.

Improving access to quality cancer care is a high priority for ACS CAN in health care reform.

Highlights of Clinical Trials Coverage in the Affordable Care Act

- The law includes provisions pulled directly from the Access to Cancer Clinical Trials Act of 2009 – priority legislation for ACS CAN that is consistent with our model state clinical trials legislation. The effective date is not clear and will be determined through the regulatory process.
 - Requires all commercial health insurance plans offering group or individual coverage, health plans offered through the Federal Employee Health Benefit Program (FEHBP), employer-sponsored plans that self insure and operate under ERISA, and state self-insured plans to pay for the routine patient care costs associated with participation in high-quality clinical trials (phases I to IV) for cancer or another life-threatening disease or condition.
 - Coverage extends to clinical trials conducted outside the state in which the patient resides. It does not require coverage for out of network services unless those benefits are otherwise provided under the plan.
 - Tracks Medicare's definition for routine costs to include all items and services that are typically covered for a patient who is not enrolled in a clinical trial.
 - Requires an annual report on self-insured plans beginning one year after enactment and a study to compare characteristics of fully insured and self-insured group health plan markets within one year.

Implications for the American Cancer Society and ACS CAN

- Includes a preemption provision protecting the validity of state clinical trials policies that go beyond the new federal coverage.