

## Healthcare Reform & Clinical Trials: Good News/Bad News

by Al B. Benson III, MD, FACP

The Affordable Care Act brings good news for clinical trials. Under the health reform law, insurers are required to provide coverage for routine costs associated with participation in approved clinical trials. Approved clinical trials are defined as Phase I, II, III, or IV clinical trials that are conducted in relation to the prevention, detection, or treatment of cancer or other life threatening diseases or conditions. These include:

- Federally funded or approved trials
- Clinical trials conducted under an FDA investigational new drug application (INDA)
- Clinical trials of drugs that are exempt from the requirement for an FDA investigational new drug application.

Insurance plans impacted by the health reform law include plans covering individual and small group markets, large group plans, self-insured plans, and plans under the Federal Employees Health Benefits Program. For those of us in the cancer community, this news is very good indeed. With expanded coverage, the hope is that more people will enroll in clinical trials, furthering research that is essential to the goals of both evidence-based medicine and personalized cancer care. Currently only a small percentage of patients with cancer are accrued to clinical trials each year. And among elderly patients and minority populations, enrollment in oncology clinical trials is even lower.

Unfortunately, closer reading of the healthcare reform legislation and recent proposed rules reveal some cause for concern. Included are loopholes and clauses that allow certain plans *not* to cover routine costs of clinical trials. Under these scenarios, the status quo of clinical trials cover-



age is not likely to change. Furthermore, consider the following two examples.

First, with employer-sponsored insurance plans, the insurance carrier is required to ask the employer (plan sponsor) what it wants to cover. The employer can choose not to include clinical trials in its plan. Recently I

have conducted several clinical trial audits at institutions where patients had signed consent to participate in a clinical trial and for which the insurer would normally offer reimbursement for routine care expenses on a trial; however, the employer-negotiated plan specifically denied participation in a clinical trial and the patients were therefore withdrawn from the trial and treated "off study."

Second, under interim regulations issued in June, certain plans can be "grandfathered" in under the new law. The goal of grandfathering plans is to allow people to keep the plans they have while ensuring that these plans do not significantly change. This approach essentially assures consumers that they will still have access to insurance plans and coverage that meets their needs. However, grandfathered plans are exempt from some Affordable Care Act mandates, including mandated coverage of clinical trials. Since initially the vast majority of group health plans and group insurance coverage are likely to be grandfathered, the impact of the Affordable Care Act and coverage of routine patient costs associated with approved clinical trials may be significantly compromised.

Thirty-three states have enacted laws requiring health plans to cover the routine costs of care for clinical trial participants. However, as healthcare reform rolls out, the oncology community must remain vigilant in advocating for coverage of routine costs for clinical trial participants. 🗣️

## Coming in Your 2010 Oncology Issues

- ◆ RAC Readiness
- ◆ Mentoring a New Cancer Program Administrator
- ◆ The Role of Genetics in Cancer Care
- ◆ Treatment of Adolescents and Young Adults with Cancer: Implications for Community Cancer Centers
- ◆ Ensuring Long-term Sustainability of Patient Navigation Services
- ◆ Diagnostic Imaging: Usage and Reimbursement
- ◆ Using Your Cancer Registry to Aid in ACoS and NAPBC Accreditation
- ◆ HITECT and HIPAA: Is Your Cancer Center Still HIPAA Compliant?
- ◆ Providing Spiritually Sensitive Care in the Acute Palliative Care Unit
- ◆ Screening for Malnutrition: A Part of Comprehensive Cancer Care
- ◆ Surgery for Metastatic Disease