ASCO
American Society of Clinical Oncology

Summary the Affordable Care Act Statute Regarding
Insurance Coverage for Individuals Participating in Approved Clinical Trials

Section 2709 of the Patient Protection and Affordable Care Act (the "ACA"), now codified at 42 U.S.C. §300gg-8, provides three guarantees and protections. First, a payer may not prevent a "qualified individual" from participating in an "approved clinical trial." Second, a payer may not discriminate against a clinical trial participant. Third, a payer must cover qualified individuals' "routine patient costs" for services delivered "in-network." This statute applies to all third-party payers of health benefit or insurance claims, including group health plans, self-insured employers' health benefit plans, health insurance issuers and federal employee health benefit plans. In addition, Section 2709 does not preempt state laws relating to clinical trials that have more stringent requirements or provide greater protection to patients.

A phase I, II, III or IV trial meets the definition of an **approved clinical trial** if it is conducted for prevention, detection, or treatment of cancer or another disease or condition likely to lead to death unless the course of the disease or condition is interrupted, *and* (A) "federally funded," *or* (B) is either (1) conducted under an investigational new drug application (IND) reviewed by the Food and Drug Administration or (2) a drug trial that is exempt from the IND application requirements.

A clinical trial is **federally funded** if it is approved and funded by one or more enumerated agencies or entities. Funding from the following agencies and entities, individually, qualifies: the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Agency for Health Care Research and Quality (AHRQ), the Centers for Medicare and Medicaid Services (CMS), or a non-governmental research entity identified in the NIH guidelines for center support grants. If a clinical trial has undergone an unbiased, scientific peer review by experts without a conflict and the Department of Health and Human Services Secretary deems the review to be comparable to the NIH peer review system, that trial will be considered federally funded if the Department of Defense (DOD), the Department of Veterans Affairs (VA) or the Department of Energy provides funding. Alternatively, a clinical trial funded by a cooperative group of two or more of the above agencies, including DOD and VA, will meet the federally funded requirement.

To be entitled for the statutory protections and guarantees, a patient must be a **qualified individual**. The statute requires, first, that the patient meet the trial protocol of an approved clinical trial. Second, and related to the first, the individual's physician must determine the individual's participation is appropriate, or the individual must provide medical and scientific information establishing that the individual meets the trial protocol and his or her participation is appropriate.

Routine patient costs include all items and services that the payer would cover for a patient not enrolled in a clinical trial. Items and services are not routine patient costs if they are investigational, solely for data collection and analysis purposes and not for direct clinical management of the patient, or for a service inconsistent with the established standards of care for the patient's diagnosis.

Payers may require a qualified individual to use an **in-network** provider for the approved clinical trial if that provider is a trial participant and will accept the patient. Payers are not required to provide out-of-network benefits unless such benefits are part of the patient's coverage or the approved clinical trial is only offered outside the patient's state of residence.