

### Overview

The Patient Protection and Affordable Care Act (PPACA) establishes new coverage requirements for approved clinical trials. Effective January 1, 2014, group health plans and health insurance issuers offering group or individual health insurance coverage may not 1) deny “qualified individuals” participation in certain “approved clinical trials”; 2) deny the coverage of “routine patient costs” furnished in connection with the clinical trials; or 3) discriminate against the individual on the basis of the individual’s participation in such trials.

#### ***What are the new coverage requirements?***

Most clinical trials involve drugs or devices, and those drugs or devices are generally provided without cost during the trial period. Effective January 1, 2014, PPACA requires that if a “qualified individual” is in an “approved clinical trial,” the plan cannot deny coverage for related services. For example, if the member requires temporary hospitalization or monitoring in connection with the trial and there is a charge for those services. Plans are not required to cover treatments that fall outside the designated class of approved clinical trials, and plans may not deny coverage because a member is participating in an approved clinical trial conducted outside of the state in which the member lives.

#### ***What is a “qualified individual”?***

A “qualified individual” is someone who is eligible to participate in an “approved clinical trial” and either the individual’s doctor has concluded that participation is appropriate or the participant provides medical and scientific information establishing that their participation is appropriate.

#### ***What is an “approved clinical trial”?***

An “approved clinical trial” is defined as a Phase I, II, III or IV clinical trial for the prevention, detection or treatment of cancer or other life-threatening condition or disease (or other condition described in PPACA, such as federally funded trials, trials conducted under an investigational new drug application reviewed by the FDA or drug trials exempt from having an investigational new drug application). A life-threatening condition is any disease from which the likelihood of death is probable unless the course of the disease is interrupted.

#### ***What are “routine patient costs”?***

“Routine patient costs” include all items and services consistent with the coverage provided in the plan that is typically covered for a qualified individual who is not enrolled in a clinical trial. Routine patient costs do not include 1) the investigational item, device or service itself; 2) items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient; and 3) a service that is clearly inconsistent

with the widely accepted and established standards of care for a particular diagnosis. Plans are not required to provide benefits for routine patient care services provided outside of the plan’s network area unless out-of-network benefits are otherwise provided under the plan.

#### ***May a plan require a qualified individual to participate in a trial through a participating provider?***

Yes. If a participating provider is participating in an approved clinical trial, the plan may require the individual to participate in the trial through that participating provider if the provider will accept the individual as a participant in the trial.

Plan sponsors should review their process and procedures related to clinical trials to ensure that their practices comply with PPACA, and consult with their own legal counsel.

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