

Coverage for Individuals Participating in Approved Clinical Trials under the Patient Protection and Affordable Care Act of 2010 (PPACA)

Section 10103(c) of PPACA added a new provision to the federal Public Health Service Act which imposes requirements on group health plans and health insurance issuers offering individual or group health insurance products to provide for coverage of routine patient costs associated with approved clinical trials. The provision, a new section 2709 of the Public Health Service Act, provides as follows:

Prohibition on denials of coverage or on discrimination. With respect to plan years beginning on or after January 1, 2014, if a group health plan or health insurance issuer offering group or individual coverage provides coverage to a qualified individual, then the plan or issuer is prohibited, under federal law, from doing any of the following:

1. Denying the individual participation in an approved clinical trial.
2. Denying or limiting, or imposing additional conditions on, the coverage of routine patient costs for items or services furnished in connection with participation in the approved clinical trial.
3. Discriminating against the individual on the basis of the individual's participation in the approved clinical trial.

Qualified individual. A qualified individual is defined under the law as an individual who is enrolled or participating in a health plan or coverage and who is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer or another life-threatening disease or condition. To be a qualified individual, there is an additional requirement that a determination be made that the individual's participation in the approved clinical trial is appropriate to treat the disease or condition. That determination can be made based on the referring health care professional's conclusion or based on the provision of medical and scientific information by the individual.

Routine patient costs. The term "routine patient costs" is also defined for purposes of these new federal requirements. With some important exceptions, routine patient costs generally include all items and services consistent with the coverage provided under the plan (or coverage) for a qualified individual (viz. for treatment of cancer or another life-threatening disease or condition) who is not enrolled in a clinical trial. However, costs associated with the following are excluded from that definition, and the plan or issuer is not required under federal law to pay for the following:

1. The cost of the investigational item, device or service.
2. The cost of items and services provided solely to satisfy data collection and analysis needs and that are not used in direct clinical management.
3. The cost for a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

Approved clinical trial. The term "approved clinical trial" is defined in the statute as a phase I, phase II, phase III, or phase IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition and is one of the following:

1. A federally funded or approved trial.

2. A clinical trial conducted under an FDA investigational new drug application.
3. A drug trial that is exempt from the requirement of an FDA investigational new drug application.

Network providers. With respect to an individual's right to select providers, a plan or issuer may require the individual to participate in the approved clinical trial through a participating provider if the provider will accept the individual as a participant in the trial. However, this authority granted to a plan or issuer does not preclude a qualified individual from participating in an approved clinical trial conducted outside the state in which the individual resides.

The provision includes a number of clarifications of the intent of Congress with respect to these new federal requirements on plans and issuers. One clarification is that these new requirements are not intended to require a plan or issuer to provide benefits for routine patient services out of network unless out of network benefits are otherwise provided under the plan or coverage. Another is that the requirements imposed under this section are not intended to limit a plan's or issuer's coverage with respect to clinical trials--these are instead to be regarded as minimum requirements on plans and issuers.

Effective date. These new federal requirements apply generally to group health plans and health insurance coverage offered for plan years beginning on or after January 1, 2014. Thus, the requirements will apply to plans and coverage sold after 2013 in the individual and small group markets, as well as to large group plans, including self-insured plans, and it will also apply to health plans offered under the Federal Employees Health Benefit Program (FEHBP).

Limited application of requirements. It is important to emphasize that these new federal requirements will not apply to grandfathered health plans. Under section 1251 of PPACA, a grandfathered health plan is a group health plan or health insurance coverage in which an individual was enrolled on the date of enactment (3/23/2010) and, unless otherwise specified, is exempt from the requirements of Title I of the Act. A grandfathered plan retains its status even though (1) family members are permitted to enroll after 3/23/2010; and (2) for group health plans, new employees and their families are permitted to enroll in the plan after that date. Given that initially the vast majority of group health plans and health insurance coverage will be grandfathered, the impact of the application of these new federal requirements is far from sweeping.

Interaction with state laws. Section 2709 of the Public Health Service Act (the section imposing these new federal requirements for coverage of approved clinical trials) makes it very clear that it does not preempt any state laws that require a clinical trials policy for state regulated plans that is in addition to the policy required under this section. Thus the federal requirements are minimums; states may impose additional requirements.

Implications for patients. The answers to many of the specific questions that patients, practitioners, and group health plans and issuers will pose about the implications of this provision should first be addressed in the federal regulations that are promulgated to carry out the statutory intent of Congress. These regulations will afford the public notice and opportunity for comment. However, it is unclear whether a patient or provider will find the answers to all questions even with a careful regulatory process. The patient will have to consult with the plan or issuer for guidance on available coverage, and providers would be well-advised to follow federal and to the extent it is applicable state regulatory

requirements on plans for required coverage of costs associated with treatment under an approved clinical trial.