

Affordable Care Act and Coverage of Clinical Trials Frequently Asked Questions

This FAQ was developed by ASCO to answer common questions relating to Section 2709 of the Patient Protection and Affordable Care Act (the “ACA”), entitled “Coverage for Individuals Participating in Approved Clinical Trials,” now codified as 42 U.S.C. §300gg-8. The information contained in this FAQ document is based exclusively on Section 2709 of the ACA and may change with the release of proposed and final regulations. The information in this document has been prepared and provided for informational purposes only and should not be construed as legal advice. The contents of this FAQ should not be relied upon or used as a substitute for obtaining legal advice from a knowledgeable, licensed attorney.

General Background:

- 1) When does this provision of the ACA go into effect?

The clinical trials coverage provision becomes effective on January 1, 2014.

- 2) Will more information or guidance about this provision be forthcoming?

Yes, HHS is expected to publish proposed regulations regarding this provision in the Federal Register no later than 2013. The purpose of the regulations will be to provide further guidance and potentially propose a structure for coverage. Interested parties will have the opportunity to comment on the proposed rule.

- 3) Why is Section 2709 of the Affordable Care Act important?

This provision of the Affordable Care Act outlines statutory language requiring insurance coverage of approved clinical trials.

- 4) How does this statutory language change the current coverage environment for clinical trials?

This is the first federal law mandating group health plans (including new self-funded arrangements) and state-licensed health insurance issuers to cover the standard of care costs associated with participation in clinical trials. Thirty-four states and the District of Columbia previously passed laws or coverage agreements related to private insurers covering cancer (and, in some cases, other serious or life-threatening illness) clinical trials; however, not all states passed these types of laws and the laws vary by state.

Of note, Medicare covers the standard of care costs associated with beneficiaries’ participation on most types of clinical trials. This was the result of a National Coverage Determination that became effective on September 19, 2000. Medicare coverage will not be impacted by Section 2709 of the Affordable Care Act.

Definitions from the Affordable Care Act:

- 5) What is the impact for patients participating in clinical trials?

To be entitled to the statutory protections and guarantees, a patient must be a **qualified individual**.

First, the patient must meet the eligibility requirements of the trial protocol of an **approved clinical trial**.

Second, 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 eligibility standards of the trial protocol and his or her participation is appropriate.

- 6) How does the ACA clinical trials provision define an "approved clinical trial"?

A phase I, II, III or IV trial meets the definition of an **approved clinical trial** if it is (1) conducted for the 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* (2) is one of the following:

- (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.

- 7) Some entities currently do not provide for coverage of Phase I clinical trials. Does the statutory language address the different clinical trial phases?

Yes, the ACA language explicitly states that Phase I, II, III and IV trials are covered.

- 8) How does the statute define the term "federally funded"?

A clinical trial is **federally funded** if it is approved and funded by one or more enumerated agencies or entities.

- National Institutes of Health (NIH),
- Centers for Disease Control and Prevention (CDC),
- Agency for Health Care Research and Quality (AHRQ),
- Centers for Medicare and Medicaid Services (CMS),
- A non-governmental research entity identified in the NIH guidelines for center support grants,



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- Department of Defense, Department of Veterans' Affairs or Department of Energy (If it the 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), or
- Cooperative group or center of any of the above agencies, other than Department of Energy

9) What does it mean if a drug trial is exempt from the IND application requirements?

According to the Code of Federal Regulations (CFR 312.2(b)), the definition of Exemptions is:

“(b)Exemptions. (1) The clinical investigation of a drug product that is lawfully marketed in the United States is exempt from the requirements of this part if all the following apply:

- (i) The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug;
- (ii) If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the Investigation is not intended to support a significant change in the advertising for the product;
- (iii) The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product;
- (iv) The investigation is conducted in compliance with the requirements for institutional review set forth in part 56 and with the requirements for informed consent set forth in part 50; and
- (v) The investigation is conducted in compliance with the requirements of 312.7.”

- Link to CFR 312.2 (b) “Exemptions”:
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.2>
- Link to FDA **DRAFT** Guidance for Industry “Investigational New Drug Applications (INDs)- Determining Whether Human Research Studies Can Be Conducted Without an IND”:
<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm229175.pdf>

Coverage Details:

10) What costs are third party payers mandated to cover?

Payers must cover the **routine patient costs** for items and services furnished in connection with participation in an approved clinical trial.

11) There has been much discussion around what routine care costs are. Did the ACA language provide explanation of “routine patient costs”?

According the statute, **routine patient costs** include all items and services that the payer would cover for a patient not enrolled in a clinical trial.

12) What costs are third-party payers not mandated to cover?

Payers do not have an obligation to cover items and services that are not routine patient costs, including:

- the investigational item, device or service itself
- items and services solely for data collection and analysis purposes and not for direct clinical management of the patient, or
- any service inconsistent with the established standard of care for the patient’s diagnosis.

In-Network and Out-of-Network Benefits:

13) Does the statute apply in situations in which a patient is being treated by an out-of-network provider for participation in the clinical trial?

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.

14) Are insurers required to allow use of out-of-network providers?

Payers are only required to allow patients to cover routine patient costs of services and items delivered by out-of-network providers if the approved clinical trial is only offered outside the patient’s state of residence.

15) Are payers required to provide out-of-network benefits?

Payers are only required to provide out-of-network benefits if such benefits are part of the patient’s coverage or plan.

Types of Payers Mandated to Comply:

16) What types of payers must comply with these provisions?

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.

17) Does the ACA language apply to health plans covered by the Employee Retirement Income Security Act (ERISA), the federal law governing employee health benefits plans?

The statute applies equally to plans covered by ERISA and plans that are not covered by ERISA. This is important because ERISA plans are not mandated to comply with state insurance laws or coverage agreements **but are required** to comply with the federal law, including the ACA provision related to coverage of clinical trials.

18) Does this also apply to the Federal Employees Health Benefits Program (FEHBP)?

Yes, the statute applies to the FEHBP plans.

19) I've heard some talk about plans having grandfathered status. What does that mean?

Under the ACA, "grandfathered" plans are subject only to certain provisions of the new law. A "grandfathered" plan is defined as a group health plan (which includes single employer plans and multiemployer plans, whether insured or self-funded) or health insurance coverage in which an individual was enrolled on March 23, 2010 (the date of enactment of the ACA). Plans with grandfathered status are exempt from the clinical trials coverage provision. Once a plan either reduces benefits or increases costs to enrollees, however, it loses grandfathered status and must comply with all ACA provisions, including the clinical trials coverage provision.

20) Does Section 2709 apply to health plans that have grandfathered status?

No, third-party payers with grandfathered status are not mandated to comply with the clinical trial coverage provision as long as they have grandfathered status. However, many plans with grandfathered status voluntarily cover the standard of care costs associated with beneficiaries' participation in clinical trials or are required to maintain this coverage because it was a benefit provided to beneficiaries prior to March 23, 2010.



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21) How does the language of ACA impact those states that have clinical trial laws?

If a state's clinical trials' coverage policy or law has more generous requirements or provides greater protections to patients, health insurance plans subject to state regulation (i.e., not ERISA or FEHB plans) will need to comply with that state policy or law. In effect, Section 2709 establishes the floor or minimum standard for clinical trial coverage. Thus, in states without a law or with coverage requirements that are less stringent (e.g., no requirement for phase I trials or coverage for cancer trials only), payers must comply with Section 2709.