



Affordable Care Act Provision Requiring Insurance Coverage of Clinical Trials

The Patient Protection and Affordable Care Act (ACA) added Section 2709 to the Public Health Service Act, which is the first federal law requiring that private insurers cover routine patient costs for individuals participating in clinical trials for the prevention, detection, and treatment of cancer or other life-threatening diseases or conditions.

Historically, some health plans have denied coverage for drugs or services associated with clinical trials. In addition, plans have also denied coverage of routine patient costs that are offered as part of the clinical trial. This new provision requiring insurance coverage of these routine costs may enable patients previously denied coverage for participation in a clinical trial, the opportunity to afford clinical trial participation. It is important to understand the law and how it can be used to enable clinical trial participation, whether that involves assisting patients in finding an “approved” clinical trial, advocating for their participation in the trial, or helping them through the appeals process if their plan denies coverage.

The provision prohibits health plans or insurance issuers from:

- Denying participation in clinical trials;
- Denying or limiting coverage of routine patient costs, subject to the plan's out-of-network coverage policy; and/or
- Discriminating against the individual on the basis of participation in a trial.

What is the purpose of this document?

ASCO has created this information to educate physicians, cancer researchers, health professionals, financial counselors, patients, and other stakeholders on Section 2709. ASCO has been a long-time proponent of insurance coverage of clinical trials and has been working to facilitate implementation of the new law, including education and outreach efforts.

Although the coverage requirement is now in statute, the federal government has not yet issued regulations to guide implementation. Instead, the Departments (includes Departments of Labor, Health and Human Services, and the Treasury) **posted a message on their websites** stating the law is “self-implementing” and “group health plans and health insurance issuers are expected to implement the requirements of PHS Act section 2709 using a good faith, reasonable interpretation of the law.” While much of the statutory language is clear, there is no assurance that all parties will agree on the legal interpretation of each element of the provision.

ASCO encourages all individuals and parties involved in clinical trials to consult the plan and insurer for further and more detailed guidance on the available coverage associated with a particular trial. While the statute does set minimum standards for coverage, some factors may vary depending on the trial, as well as existing state regulations. Clinical sites are also encouraged to consult with the clinical trial sponsor concerning some of the requirements.

The information in this guide is not intended as medical or legal advice, or as a substitute for consultation with insurers, plans, or trial sponsors. The mention of any product, service, or treatment should not be constructed as an ASCO endorsement.



Basic Questions Regarding the ACA Clinical Trials Coverage Provision

- What does the law require?
- What types of clinical trials are included in this provision?
 - Federally funded or approved trials
 - Investigational New Drug (IND) application
- Which types of health plans/insurers are required to comply?
 - Self-insured employers' health benefit plans
- What plans are not covered by this provision?
 - Grandfathered plans
- What does a potential trial participant have to do to qualify for coverage?
- What services/items must the insurer/health plan pay for?
 - Routine costs vs. research or investigational costs
- Can potential trial participants go out-of-network to access a clinical trial?
- Can patients seek coverage for a clinical trial at a site that is outside their state?
- When does the requirement become effective?
- How does the new federal law apply in states with laws that already require health plans to cover clinical trials?
- What does it mean for patients?
- Is there an appeals process patients can use?
- Where can I find additional information?

[previous](#) ✧ [top of basic questions](#) ✧ [statutory language](#) ✧ [next](#)

What does the law require?

The ACA provision prohibits insurers from denying or limiting coverage for routine clinical care for individuals enrolled on a clinical trial that would otherwise be provided if the individual was not a study participant. (For more information about routine costs, see also [What services/items must the health plan pay for?](#)). Insurers may not prevent a qualified individual from participating in an approved clinical trial, and may not drop or limit coverage if an individual chooses to participate in a trial.

The [law](#) provides the following information:

If a group health plan or a health insurance issuer offering group or individual health insurance coverage provides coverage to a qualified individual, then such plan or issuer:

1. May not deny the individual participation in the clinical trial;
2. May not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and
3. May not discriminate against the individual on the basis of the individual's participation in such trial.

[previous](#) ✧ [back to basic questions](#) ✧ [statutory language](#) ✧ [next](#)

What types of clinical trials are included in this provision?

Section 2709 applies to all approved clinical trials. An approved clinical trial, as **defined in the statute**, is a **phase I, II, III, or IV** clinical trial that relates to the prevention, detection or treatment of cancer or other life-threatening diseases that also satisfies one of three requirements:

1. The trial is **federally funded**;
2. The trial is conducted under an **investigational new drug application**; *or*
3. The trial is **exempt from such an investigational new drug application**.

Which federally funded trials qualify as “approved trials”?

Many trials will qualify as approved clinical trials because they have an IND or are IND exempt. Alternatively, some clinical trials will qualify because they are funded or approved by the federal government. The statute states that clinical trials “funded or approved” by one of the following entities are covered:

1. The National Institutes of Health (NIH) – which includes the National Cancer Institute (NCI)
2. The Centers for Disease Control and Prevention (CDC);
3. The Agency for Healthcare Research and Quality (AHRQ);
4. The Centers for Medicare & Medicaid Services (CMS);
5. A **cooperative group** or a center of any of the following: NIH, CDC, AHRQ, CMS, Department of Defense (DOD) or Department of Veterans Affairs (VA);
6. A qualified non-governmental research entity identified in the guidelines issued by NIH for center support grants;
7. Clinical trials performed by the VA, DOD or Department of Energy (DOE) are covered if certain additional criteria are met.

In-kind contributions

The law indicates that funding can include monetary contributions or “in kind contributions.” Although the term “in kind contributions” is not further defined in the statute, this phrase typically refers to non-monetary support in the form of items or services. The law does not specify a minimum dollar amount or value that must come from federal sources to qualify.

Approved vs. funded

In addition, the legislation suggests that a study “approved” by one of the listed federal entities is considered to be “federally funded” even if no money or in kind contributions are provided by the federal entity. Although a definition is not provided for what it means for a trial to be “approved” by most of the listed federal agencies, it could mean that a federal agency has reviewed the trial in some manner.

[previous](#) ✧ [back to basic questions](#) ✧ [statutory language](#) ✧ [next](#)

Cooperative groups or centers

The statute also specifies that trials are covered if they are conducted by cooperative groups or centers of the NIH (including NCI, CDC, AHRQ, and CMS). The NCI designates cancer centers and Cooperative Group research networks (including the Children’s Oncology Group, the Alliance for Clinical Trials in Oncology, NRG Oncology, ECOG-ACRIN Cancer Research Group, and SWOG), and is in the process of establishing the National Clinical Trials Network. The NCI also funds the Specialized Programs of Research Excellence (SPORES).

In the case of clinical trials performed directly by VA, DOD or DOE, approval and review of the study by the Department is mandatory and the law provides greater specificity regarding what process must exist for approval and review of the study.

What about cancer control trials?

The statute covers trials being done for “the prevention, detection, or treatment of cancer.”

Investigational New Drug (IND) Application

The Food and Drug Administration (FDA) requires drugs under investigation in a clinical trial that are not already approved by the FDA obtain an investigational new drug (IND) application. The IND number typically is noted on the trial protocol, and the trial sponsor can provide detailed information about the IND status of the drug involved in the trial.

Exempt from having an Investigational New Drug Application

Detailed information about the IND status of the drug or device involved in the trial can be obtained from the sponsor of the clinical trial. The Code of Federal Regulations (21 C.F.R. § 312.2(b)) defines the clinical investigation of a lawfully marketed drug as exempt from the requirements of an IND application if all the following apply:

1. 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;
2. 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;
3. 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;
4. 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
5. The investigation is conducted in compliance with the requirements of §312.7 (relating to the promotion of investigational drugs).

[previous](#) ✧ [back to basic questions](#) ✧ [statutory language](#) ✧ [next](#)



Which types of health plans/insurers are required to comply?

This statute applies to most third-party payers of health benefit or insurance claims, including group health plans, **self-insured employers' health benefit plans** (where the employer, not insurance company, bears the risk of offering health coverage), health insurance issuers, and the Federal Employees Health Benefits Program. Plans sold on the health insurance exchanges (individual and small business plans) and employer sponsored plans are also required to comply with this provision.

Self-insured employers' health benefit plan

Large employers are allowed to offer health plans that are exclusively regulated under the federal Employee Retirement Income Security Act (ERISA), rather than state law. If an employer remains at risk for the health insurance provided to its employees, this self-insured form of ERISA plan is not subject to state insurance laws whether the employer administers the plan directly or the employer hires a separate insurance company to administer the plan. Prior to enactment of the ACA, self-insured ERISA plans were not required to cover the routine costs from clinical trials, even in instances where state laws regarding clinical trials coverage existed. However, the ACA coverage requirement for the routine costs of clinical trials now applies to all ERISA plans, unless they have **grandfathered status**.

[previous](#) ✧ [back to basic questions](#) ✧ [statutory language](#) ✧ [next](#)

What plans are not covered by this provision?

Grandfathered plans | 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 that was in existence on March 23, 2010 (the date of enactment of the ACA). Grandfathered plans are only subject to certain provisions of the ACA, and are exempt from the clinical trials coverage provision. See section: [How do I know if a plan is grandfathered?](#) Plans lose their grandfathered status by **making changes to their benefits and coverage that are defined in regulations**. Once a plan loses its grandfathered status it must comply with all ACA provisions, including section 2709.

Medicaid plans | Unfortunately, the ACA clinical trials coverage provision does not apply to Medicaid plans. Federal law does not require that states provide coverage of clinical trials through Medicaid plans (fee-for-service or Medicaid managed care). ASCO would support legislation would require coverage of clinical trials under Medicaid.

Medicare plans | As a result of [previous coverage policy](#) (effective September 19, 2000), Medicare already covers the routine care costs associated with clinical trial participation on most types of clinical trials and will not be impacted by this provision.

How do I know if a plan is grandfathered?

A grandfathered plan must provide notice to enrollees of its grandfathered status in all informational materials that describe plan benefits. For more information about these plans, contact the U.S. Department of Labor’s Employee Benefits Security Administration:

www.askebsa.dol.gov
 866-444-3272

How do grandfathered plans lose their grandfathered status?

If a grandfathered plan either cuts benefits or increases costs for plan members, it will lose its grandfathered status and all of the ACA provisions will apply –including the clinical trials coverage requirement. Some examples of changes that may result in a plan’s loss of grandfathered status include elimination of benefits to diagnose or treat a particular condition, increased co-insurance percentages, fixed-amount cost-sharing other than a copayment, or fixed-amount copayments, changes in annual limits and/or changes in the plan’s contribution rates.

[previous](#) ✧ [back to basic questions](#) ✧ [statutory language](#) ✧ [next](#)

What does a potential trial participant have to do to qualify for coverage?

The statute requires that the individual receiving clinical trials services be a qualified individual. A qualified individual is an individual who meets the participation eligibility requirements of the trial’s protocol. Eligibility can be determined by (1) a **referring health care professional**, or (2) medical and scientific information provided by the participant. The statute states:

The term ‘qualified individual’ means an individual who is a participant or beneficiary in a health plan or with coverage who meets the following conditions:

1. The individual is eligible to participate in an **approved clinical trial** according to the trial protocol with respect to treatment of cancer or other life-threatening disease or condition.
2. Either –
 - (A) the **referring health care professional is a participating health care provider** concludes that the individual’s participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or
 - (B) the participant or beneficiary provides medical and scientific information establishing that the individual’s participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).

Referring Health Care Professional and “Participating Health Care Provider”

One pathway for a trial participant to demonstrate that they are eligible for a trial is to have a referring health care professional conclude that their participation in the trial “would be appropriate” according to the trial protocol. The reference to a “participating health care provider” in this part of the law appears to refer to a health care professional who both refers the patient to the trial and is able to enroll the patient on the trial.

[previous](#) ✧ [back to basic questions](#) ✧ [statutory language](#) ✧ [next](#)

What services/items must the insurer/health plan pay for?

The insurer or health plan must provide coverage of ***routine patient costs***. The definition of these costs included in the statute is written broadly. To simplify, routine 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 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. These investigational costs, sometimes referred to as “research costs,” may be covered by the trial sponsor, so it is advised to contact all involved parties including the payer or plan issuer and for clinical sites, the trial sponsor to discuss coverage.

Service that is “Clearly Inconsistent with Standard of Care”

The provision states that routine patient costs do not include a service that is “clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.” An insurer may attempt to deny coverage on the grounds that the service or item is “clearly inconsistent with the established standard of care.” Providers may consider requesting that the insurers prove that the item or service is inconsistent with the standard of care. Providers, patients, and representatives from the clinical trial should work together and with financial counselors and billing specialists to ensure understanding of the trial and coverage.

[previous](#) ✧ [back to basic questions](#) ✧ [statutory language](#) ✧ [next](#)



Can potential trial participants go out-of-network to access a clinical trial?

The ACA does not guarantee individuals access to health care providers who are not participating in a health plan or insurer's network. Payers are only required to cover routine patient costs of items and services delivered by out-of-network providers *if* out-of-network benefits are part of the patient's coverage or plan.

Can patients seek coverage for a clinical trial at a site that is outside their state?

The ACA coverage requirement also applies if a patient has to leave their state of residence to participate in a clinical trial. This provision was included because some states' laws do not provide coverage for clinical trials operated outside the state. If the out-of-state investigator is not within the health plan's network, the plan may deny coverage for services provided by that investigator, unless the patient has coverage for out-of-network providers.

When does the requirement become effective?

The requirement is effective for all plans newly issued or renewed on or after January 1, 2014.

How does the new federal law apply in states with laws that already require health plans to cover clinical trials?

The federal law is now the minimum national standard for insurance coverage of clinical trials. If a state has a law that is more comprehensive, its coverage requirements apply in addition to the federal law –but only for **state-regulated insurance plans**, which does not include ERISA plans. For example, a state law may require coverage of clinical trials for any disease or may require Medicaid to cover clinical trials. ASCO's main page on clinical trials coverage (www.ASCO.org/ClinicalTrialsCoverage) contains helpful information and links to other resources on this topic.

[previous](#) ✧ [back to basic questions](#) ✧ [statutory language](#) ✧ [next](#)

What does it mean for patients?

Historically, some health plans have denied coverage for drugs or services associated with clinical trials. In addition, plans have also denied coverage of routine patient costs that are offered as part of the clinical trial. This new provision requiring insurance coverage of these routine costs may enable patients previously denied coverage for participation in a clinical trial, the opportunity to afford clinical trial participation. It is important to understand the law and how it can be used to enable clinical trial participation, whether that involves assisting patients in finding an “approved” clinical trial, advocating for their participation in the trial, or helping them through the appeals process if their plan denies coverage.

While ASCO believes that the ACA provision is very straightforward, it is likely that securing compliance with the law may require considerable negotiations with some insurers or health plans. ASCO has developed an [attestation form](#) that can be used as a tool to demonstrate that the patient’s circumstances and the trial under consideration meet the requirements of the law.

Is there an appeals process patients can use?

The ACA standardizes the internal and external appeals process for all non-grandfathered group health plans and health insurance issuers offering individual or group health insurance coverage. Information about the appeals process is available at www.healthcare.gov/how-do-i-appeal-a-health-insurance-companys-decision.

[previous](#) ✧ [back to basic questions](#) ✧ [statutory language](#) ✧ [next](#)

Where can I find additional information?

The following organizations can provide further information about clinical trials coverage. This list is by no means exhaustive, especially considering the continually changing nature of programs and services.

State insurance department | Most states have their own departments or agencies that facilitate insurance coverage. The [Medicare website](#) provides links to state health insurance departments.

Information on plans bought through Health Insurance Exchanges/Marketplaces | The ACA establishes state-specific Health Insurance Marketplaces, also referred to as “Exchanges.” Any plan purchased through the Marketplace is considered an “exchange” plan and must comply with the clinical trials coverage provision. You can access information about your specific state at <https://www.healthcare.gov/what-is-the-health-insurance-marketplace/>.

- **State-Based Marketplaces/Exchanges** – Some states have set up their own exchanges. If you live in a state that operates its own Marketplace, you can contact that agency for more information.
- **Federal-Based Marketplaces/Exchanges** – If your state does not currently operate its own Marketplace, [Healthcare.gov](#) is your resource for further information.

For Employer-Sponsored Plans | The Employee Benefits Security Administration, U.S. Department of Labor can answer inquiries at www.askebsa.dol.gov or 866-444-3272.

Patient Organizations | There are various patient organizations that specialize in supporting and advocating for patients and their access to quality care, including participation in clinical trials.

- Patient Advocate Foundation (www.patientadvocate.org)
- CancerCare (www.cancercare.org)
- Cancer Support Community (www.cancersupportcommunity.org)

ASCO | ASCO does not have the resources to intervene in specific patient cases, but has general information including an article on www.cancer.net/clinicaltrials that providers can offer patients on this law. ASCO has also developed a patient information fact sheet at www.cancer.net/factsheets which contains helpful information on this clinical trials coverage provision and has been reviewed by a central IRB. The Cancer.Net site also offers [general information about clinical trials](#) including participation, phases of trials, informed consent, and how to find a trial.

ASCO is monitoring implementation of the ACA provision and solicits information on any challenges you encounter with the law. Please contact ResearchPolicy@asco.org with any comments or questions.

[previous](#) ✧ [back to basic questions](#) ✧ [statutory language](#)