

# FAQ: Clinical Trial Coverage

Section 2709:

Affordable Care Act

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# What is section 2709(a) of the ACA?

If the group health plan/insurer in the group and individual health insurance market provides coverage to a qualified individual, then such plan or issuer may not deny:

- Participation in an approved clinical trial with respect to the treatment of cancer or another life-threatening disease or condition
- Coverage of routine patient costs for items/services furnished in connection with participation in the trial

Also, they may not discriminate against the individual on the basis of the individual's participation in the trial

# What if I am on Medicare?

- 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
- Generally, cancer treatment and diagnostic trials are covered if they are funded by the National Cancer Institute (NCI), NCI-Designated Cancer Centers, cancer cooperative groups, or other federal agencies that fund cancer research
- Thus Medicare coverage will not be affected by Section 2709 of the Affordable Care Act

# Am I eligible?

- Qualified participant of insurance company
- Eligible by clinical trial protocol
- Deemed appropriate by personal physician or provide medical and scientific information establishing that the individual's participation in such trial would be appropriate

# Is the trial eligible?

- 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
- Federally funded, or either conducted under an investigational new drug application (IND) / exempt from the IND application requirements.

(NIH, CDC, ARHQ, CMS, DoD, DVA, etc)

# What does the clinical trial site provide?

- Study drug, device, or intervention
- All lab tests and physical exams required by the clinical trial protocol
- Anything required by protocol that is outside of standard of care
- Sometimes, reimbursement for travel to and from study site
- Sometimes meals and other small reimbursements

# What does my insurance company pay for?

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

# Can I go out-of-network for my clinical trial?

- If there is a trial participant who will accept you as a patient in your network, the payers may require you to use that doctor/center.
- The insurance company is only required to provide out-of-network benefits if you would already had these benefits as part of your plan.
- 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





# My state already had clinical trial coverage; what now?

- Before ACA, 34 states and one district already had coverage laws
- In this case, the more generous of the two laws (ACA vs. state) will win for coverage mandate

# The End

- Consider clinical trials as an option if you can find one that is right for you
- Please care for yourself in a holistic and complete manner
- Please remember, you deserve to be Well Treated and Treated Well!
- Any questions?
  - Email me @ [personalhealth4U@gmail.com](mailto:personalhealth4U@gmail.com)





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