
42 U.S. Code § 300gg-8

Coverage for individuals participating in approved clinical trials

(a) Coverage

(1) In general

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—

- (A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);
- (B) subject to subsection (c), 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
- (C) may not discriminate against the individual on the basis of the individual's participation in such trial.

(2) Routine patient costs

(A) Inclusion

For purposes of paragraph (1)(B), subject to subparagraph (B), routine patient costs include all items and services consistent with the coverage provided in the plan (or coverage) that is typically covered for a qualified individual who is not enrolled in a clinical trial.

(B) Exclusion

For purposes of paragraph (1)(B), routine patient costs does not include—

- (i) the investigational item, device, or service, itself;
- (ii) 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; or
- (iii) a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis.

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