# SENATE
## STATE OF MINNESOTA
## EIGHTY-SEVENTH LEGISLATURE

# S.F. No. 1314

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| DATE | D-PG | OFFICIAL STATUS |
|---|---|---|
| 04/27/2011 | 1432 | Introduction and first reading<br>Referred to Commerce and Consumer Protection |

A bill for an act

relating to insurance; requiring health insurance to cover routine health care received while participating in a qualified clinical trial under certain circumstances; proposing coding for new law in Minnesota Statutes, chapter 62Q.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. **[62Q.526] COVERAGE OF QUALIFIED CLINICAL TRIALS.**

Subdivision 1. **Definitions.** (a) For purposes of this section, the terms described in this subdivision have the meanings given.

(b) "Clinical trial" means a type of research study that tests how well new medical treatments or other approaches work in human beings, including new methods of screening, prevention, diagnosis, or treatment of a disease or other condition.

(c) "Cooperative group" means a formal network of facilities that collaborate on research projects and that have an established peer review program approved by the National Institutes of Health operating within the group.

(d) "Health plan" means a health plan, as defined in section 62Q.01, subdivision 3.

(e) "Multiple project assurance contract" means a contract between an institution and the federal Department of Health and Human Services that defines the responsibilities of the institution and the procedures that will be used by the institution to protect human subjects.

(f) "Nonroutine patient cost" means:

(1) the cost of an investigational drug or device that is not approved by the federal Food and Drug Administration to market for any indication;

(2) the cost of a nonhealth care service that an enrollee is required to receive as a result of the treatment being provided for purposes of the clinical trial;

(3) costs associated with managing the research associated with the clinical trial;

(4) costs that would not be covered for noninvestigational treatments;

(5) any item, service, or cost that is reimbursed, otherwise paid for, or eligible for payment or reimbursement by, the sponsor of the study;

(6) transportation, lodging, food, or other expenses for the enrollee or a family member or companion of the enrollee that are associated with travel to or from a facility at which a clinical trial is conducted;

(7) the costs of services that are provided primarily to meet the needs of the clinical trial, including but not limited to tests, measurements, and other services that are typically covered under the health plan but which are provided under the clinical trial at a greater frequency, intensity, or duration; and

(8) costs of services or items that are not covered under the health plan.

(g) "Qualified clinical trial" means a clinical trial approved by one of the following:

(1) one of the National Institutes of Health;

(2) a National Institutes of Health cooperative group or a National Institutes of Health center;

(3) the federal Food and Drug Administration in the form of an investigational new drug application;

(4) the federal Department of Veterans Affairs;

(5) the federal Department of Defense; or

(6) an institutional review board of an institution that has a multiple project assurance contract approved by the Office of Protection from Research Risks of the National Institutes of Health.

(h) "Routine patient care cost" means the cost of any medically necessary health care service that is incurred as a result of treatment being provided to an enrollee of a health plan. Routine patient care costs are those for which the health plan regularly covers its enrollees under the terms of the enrollee's health plan and that would be covered if the enrollee were not participating in a clinical trial. Routine patient costs do not include nonroutine patient costs.

Subd. 2. **Coverage requirement.** A health plan must cover the routine patient care costs incurred by an enrollee in a qualified clinical trial if:

(1) the qualified clinical trial is:

(i) a phase I, phase II, phase III, or phase IV investigation of prevention, including prevention of reoccurrence, early detection, treatment, or palliation of cancer; or

(ii) treatment of a life-threatening condition;

(2) there is no clearly superior noninvestigational treatment alternative;

(3) the available clinical or preclinical data provides a reasonable expectation that the treatment will be at least as effective as the best noninvestigational alternative; and

(4) the enrollee's treating physician, who is providing covered health care services to the enrollee under the health plan, has stated in a written opinion that it is reasonable to expect that the treatment will provide a medical benefit that is commensurate with the risks of participation in the clinical trial.

Subd. 3. **Conforming and other related provisions.** (a) Coverage of services required under this section does not create a legal presumption that the health plan company recommended, directed, or required the enrollee to participate in the clinical trial.

(b) A health plan's definitions of "experimental," "investigational," and similar terms for purposes of coverage exclusion must not include coverage required under this section.

(c) If the providers providing health care services under the clinical trial are parties to a provider agreement that applies to the enrollee's health plan, the payment rates required for services provided under this section are the rates provided in the provider agreement, and the provider may not balance-bill the enrollee for the services except as permitted under the health plan and provider agreement for deductibles, co-payments, and other normal enrollee cost sharing. If the providers do not have a provider agreement described in this paragraph, the health plan company may pay the amount, if any, that it would normally pay for out-of-network care, and the enrollee is responsible for the balance, unless otherwise agreed.

**EFFECTIVE DATE.** This section is effective August 1, 2011, and applies to coverage offered, sold, issued, renewed, or continued as defined in Minnesota Statutes, section 60A.02, subdivision 2a, on or after that date.