WISCONSIN LEGISLATIVE COUNCIL
AMENDMENT MEMO

2005 Senate Bill 288	Senate Substitute Amendment 1
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2005 Senate Bill 288

2005 Senate Bill 288 prohibits a health care plan from denying coverage for a health care service, item, or drug administered in a cancer clinical trial if the service, item, or drug would have been covered had it not been administered in a clinical trial and if the clinical trial satisfies one of the following criteria:

- Tests how to administer a health care service, item, or drug for the treatment of cancer.
- Tests responses to a health care service, item, or drug for the treatment of cancer.
- Compares the effectiveness of health care services, items, or drugs for the treatment of cancer with that of other health care services, items, or drugs for the treatment of cancer.
- Studies new uses of health care services, items, or drugs for the treatment of cancer.

Further, the clinical trial must be approved by one of the following:

- A National Institute of Health.
- The Federal Food and Drug Administration.
- The U.S. Department of Defense.
- The U.S. Department of Veterans Affairs.
- An institutional review board of an institution that is approved by the Office for Human Research Protections of the U.S. Department of Health and Human Services.

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Senate Substitute Amendment 1

The Substitute Amendment prohibits a health care policy, plan, or contract from excluding coverage for the cost of any ***routine patient care*** that is administered to an insured in a cancer clinical trial satisfying certain criteria and that would be covered under the policy, plan, or contract if the insured were not enrolled in a cancer clinical trial.

The Substitute Amendment defines "routine patient care" as follows:

- All health care services, items, and drugs for the treatment of cancer.

- All health care services, items, and drugs that are typically provided in health care; including health care services, items, and drugs provided to a patient during the course of treatment in a cancer clinical trial for a condition or any of its complications; and that are consistent with the usual and customary standard of care, including the type and frequency of any diagnostic modality.

The substitute amendment provides that the following are ***excluded*** from "routine patient care": the health care service, item, or investigational drug that is the subject of the cancer clinical trial; any health care service, item, or drug provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient; and investigational drug or device that has not been approved for market by the Federal Food and Drug Administration; transportation, lodging, food, or other expenses for the patient or a family member or companion of the patient that are associated with travel to or from a facility providing the cancer clinical trial; any services, items, or drugs provided by the cancer clinical trial sponsors free of charge for the patient; or any services, items, or drugs that are eligible for reimbursement by a person other than the insurer, including the sponsor of the cancer clinical trial.

The substitute amendment adds the following criteria, ***all*** of which the cancer clinical trial must satisfy:

- A purpose of the trial is to test whether the intervention potentially improves the trial participant's health outcomes.

- The treatment provided as part of the trial is given with the intention of improving the trial participant's health outcomes.

- The trial has therapeutic intent and is not designed exclusively to test toxicity or disease pathophysiology.

In addition, the substitute amendment retains the bill's requirement that the trial must do one of the following:

- Tests how to administer a health care service, item, or drug for the treatment of cancer.

- Tests responses to a health care service, item, or drug for the treatment of cancer.

- Compares the effectiveness of health care services, items, or drugs for the treatment of cancer with that of other health care services, items, or drugs for the treatment of cancer.

- Studies new uses of health care services, items, or drugs for the treatment of cancer.

The substitute amendment ***removes***, from the list of entities that may approve a cancer clinical trial, an institutional review board of an institution that is approved by the Office for Human Research Protections of the U.S. Department of Health and Human Services.

The substitute amendment adds a provision that the coverage that may not be excluded must apply to ***all phases*** of a cancer clinical trial. Further, the coverage that may not be excluded is subject to all terms, conditions, restrictions, exclusions, and limitations that apply to any other coverage under the policy, plan, or contract, including the treatment under the policy, plan, or contract of services performed by participating and nonparticipating providers.

Finally, the substitute amendment provides that no policy, plan, or contract is required to offer, or is prohibited from offering, cancer clinical trial services by a participating provider. Further, there is no requirement that services that are performed in a cancer clinical trial by a nonparticipating provider of a policy, plan, or contract to be reimbursed at the same rate as a participating provider of the policy, plan, or contract.

Legislative History

On November 8, 2005, Senate Substitute Amendment 1, offered by Senator Roessler, was adopted by the Senate on a voice vote and the bill, as amended, was passed on a voice vote.

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