WISCONSIN LEGISLATIVE COUNCIL
ACT MEMO

2005 Wisconsin Act 194 **[2005 Assembly Bill 617]**	**Coverage for Health Care Costs in Cancer Clinical Trials**

2005 Wisconsin Act 194 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 (as discussed below) and that would be covered under the policy, plan, or contract if the insured were not enrolled in a cancer clinical trial.

The Act 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 Act 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; an investigational drug or device that has not been approved for market by the federal Food and Drug Administration (FDA); 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 sponsors of the cancer clinical trial free of charge for the patient; and 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 Act's provisions apply only if the cancer clinical trial satisfies all of the following criteria:

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- 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.
- The trial does 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 trial is approved by one of the following:
    - A National Institute of Health or one of its cooperative groups or centers under the U.S. Department of Health and Human Services.
    - The FDA.
    - The U.S. Department of Defense.
    - The U.S. Department of Veterans Affairs.

The Act specifies 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.

The Act also 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 be reimbursed at the same rate as a participating provider of the policy, plan, or contract.

Effective Date: November 1, 2006.

Initial Applicability: In general, the Act applies to insurance policies issued or renewed on or after November 1, 2006 and self-insured health plans established, extended, modified, or renewed on or after November 1, 2006. However, if an insurance policy covers employees under a collective bargaining

agreement containing provisions inconsistent with the Act, the Act first applies to a policy issued or renewed on the earlier of: (a) the date the collective bargaining agreement expires; or (b) the date the collective bargaining agreement is extended, modified, or renewed. If a self-insured plan covers employees under a collective bargaining agreement containing provisions inconsistent with the Act, the Act first applies to a plan established, extended, modified, or renewed on the earlier of: (a) the date the collective bargaining agreement expires; or (b) the date the collective bargaining agreement is extended, modified, or renewed.

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