

OFFICE OF LEGISLATIVE RESEARCH
PUBLIC ACT SUMMARY



PA 11-172—sSB 21

*Insurance and Real Estate Committee
Appropriations Committee*

**AN ACT CONCERNING HEALTH INSURANCE COVERAGE FOR
ROUTINE PATIENT CARE COSTS FOR CERTAIN CLINICAL TRIAL
PATIENTS**

SUMMARY: By law, individual and group health insurance policies and HMO contracts must cover (1) medically necessary hospitalization services and other routine patient care costs associated with cancer clinical trials and (2) off-label cancer prescription drugs. This act expands the coverage requirements to include all disabling or life-threatening chronic diseases rather than cancer only. (The act does not define these terms.)

The act applies to individual and group health insurance policies delivered, issued, renewed, amended, or continued in Connecticut that cover (1) basic hospital expenses; (2) basic medical-surgical expenses; (3) major medical expenses; and (4) hospital or medical services, including coverage under an HMO plan. Due to the federal Employee Retirement Income Security Act (ERISA), state insurance benefit mandates do not apply to self-insured benefit plans.

The act also makes technical and conforming changes.

EFFECTIVE DATE: January 1, 2012

CLINICAL TRIALS

The act defines a “clinical trial” as an organized, systemic, scientific study of interventions for the treatment of cancer or disabling or life-threatening chronic diseases, or therapeutic intervention for prevention.

The act removes the requirement under prior law that a clinical trial for cancer prevention must be a Phase III trial conducted at multiple institutions. (Phase III clinical trials compare a new drug or surgical procedure to the current standard of treatment.) The act does not require a Phase III trial for other types of preventive clinical trials it covers.

Eligibility for Coverage

By law, to be eligible for coverage, a cancer clinical trial must be conducted under an independent, peer-reviewed protocol approved by one of the National Institutes of Health, a National Cancer Institute-affiliated cooperative group, the federal Food and Drug Administration (FDA) as part of an investigational new drug or device exemption, or the U.S. departments of Defense or Veterans’ Affairs. The act applies this requirement to clinical trials for disabling or life-threatening chronic diseases. It also makes eligible for coverage clinical trials for disabling or life-threatening chronic diseases that qualify for Medicare coverage

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under the Medicare Clinical Trials Policy established under the September 19, 2000 Medicare National Coverage Determination. The act also expands coverage to include FDA-approved protocols that are part of an investigational new drug or device application, instead of only a drug or device exemption.

The insurer, HMO, or plan administrator may require the person or entity seeking coverage for the clinical trial to provide:

1. evidence that the patient meets all selection criteria for the clinical trial, including credible clinical evidence showing the clinical trial is likely to benefit the person compared to the risks of participation;
2. evidence that the patient has given his or her informed consent;
3. copies of medical records, protocols, test results, or other clinical information used to enroll the patient in the clinical trial;
4. a summary of the anticipated routine patient costs in excess of the standard treatment costs;
5. information regarding items eligible for reimbursement from other sources, including the entity sponsoring the clinical trial; and
6. additional information reasonably required to review the coverage request.

This is already law for cancer clinical trials.

Routine Patient Care Costs

By law, and extended to all clinical trials by the act, “routine patient care costs” are (1) medically necessary health care services, including physician services, diagnostic or laboratory tests, and hospitalization, incurred as a result of the treatment being provided that would otherwise be covered if they were not rendered as part of a clinical trial and (2) costs incurred for federal FDA-approved drugs. The services must be consistent with the usual and customary standard of care.

Hospitalization must include treatment at an out-of-network facility if such treatment is not available in-network and is not eligible for reimbursement by the clinical trial.

Routine patient care costs must be subject to the terms, conditions, restrictions, exclusions, and limitations of the insurance contract or certificate, including limitations on out-of-network care. But treatment at an out-of-network hospital must be made available by the out-of-network hospital and the insurer or HMO at no greater cost to the insured person than if such treatment was available in-network. The insurer or HMO may require that any routine tests or services required under the clinical trial be performed by contracted providers.

Routine patient care costs do not include:

1. the cost of an investigational new drug or device that is not FDA-approved;
2. the cost of a non-health-care service that an insured person may be required to receive as a result of the clinical trial;
3. facility, ancillary, professional services, and drug costs that are paid for by grants or funding for the clinical trial;
4. costs of services that are (a) inconsistent with widely accepted and established regional or national standards of care for a particular

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- diagnosis, or (b) performed specifically to meet the requirements of the clinical trials;
5. costs that would not be covered under the insured person's policy for non-investigational treatments, including items excluded from coverage under the person's insurance contract; and
 6. transportation, lodging, food, or any other expenses associated with travel to or from the clinical trial facility.

Health care providers, including hospitals and institutions, that provide routine patient care services approved for coverage cannot bill the insurer, HMO, or insured for any (1) services or costs that do not meet the definition of routine patient care services or (2) product or service for which the clinical trial sponsor is paying.

Payment to Out-of-Network Providers

An insurer or HMO must pay out-of-network providers the lesser of (1) the lowest contracted daily fee schedule or case rate it pays its Connecticut in-network providers for similar services or (2) actual charges. Out-of-network providers may not collect more than the total amount paid by the insurer or HMO and the insured's deductible and copayment.

Coverage Request Form

The act requires the Insurance Department to develop a standardized form that all providers must submit to the insurer or HMO when seeking to enroll an insured patient in a clinical trial for disabling or life-threatening chronic diseases, excluding cancer. (The law already requires this for cancer trials.) The department must develop the form in consultation with:

1. at least one state nonprofit research or advocacy organization related to the clinical trial's subject,
2. at least one national nonprofit research or advocacy organization related to the clinical trial's subject,
3. the Connecticut Association of Health Plans, and
4. Anthem Blue Cross of Connecticut.

An insurer or HMO must use the department's form unless it is exempt because its coverage is certified to be substantially the same as the act requires and it has the department's approval to use another form.

An insurer or HMO that receives a completed form from a provider requesting coverage for routine patient care costs for clinical trials must approve or deny the request within five business days or, if using independent experts to review clinical trial requests, 10 business days. The act removes the requirement under current law that requests for coverage of Phase III cancer prevention clinical trials be approved or denied within 14 business days.

Under existing law, the Insurance Department has to (1) develop a form for use with cancer clinical trials and (2) adopt regulations to implement the coverage request form requirements, which the act extends to other clinical trials.

Exemption from Requirements

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Insurers and HMOs must submit their coverage policies for clinical trials to the Insurance Department for evaluation and approval. The department must certify whether the coverage policy is substantially equivalent to the act's requirements. If it is, the insurer or HMO is exempt from the act's requirements.

An exempt insurer or HMO must annually report in writing to the department that there have been no changes to the coverage policy. If there have been changes, the insurer or HMO must resubmit the policy for the department's certification.

OFF-LABEL DRUGS

By law, individual and group health insurance policies that cover a prescription drug that is FDA-approved to treat a certain type of cancer must also cover the drug when it is used for another type of cancer (known as "off-label" drugs) if it is recognized as a cancer treatment in one of three sources.

The act requires coverage for off-label drug use for FDA-approved drugs to treat disabling or life-threatening chronic diseases. The drug must be recognized for the treatment of such a condition in the:

1. U.S. Pharmacopoeia Drug Information Guide for the Health Care Professional,
2. American Medical Association's Drug Evaluations, or
3. American Society of Hospital Pharmacists' American Hospital Formulary Service Drug Information.

The act specifies that it does not require coverage for experimental or investigational drugs or any drug that the FDA has determined to be contraindicated for the treatment of a specific disabling, or life-threatening chronic disease. This is already law with respect to cancer drugs.

OLR Tracking: ND:JR:PF:df