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H.P. 543 House of Representatives, February 23, 2011

An Act To Expand Access to Clinical Trials

Received by the Clerk of the House on February 18, 2011. Referred to the Committee on Insurance and Financial Services pursuant to Joint Rule 308.2 and ordered printed pursuant to Joint Rule 401.

HEATHER J.R. PRIEST
Clerk

Presented by Representative STRANG BURGESS of Cumberland.
Cosponsored by Senator SAVIELLO of Franklin and
Representatives: BEAUDOIN of Biddeford, BEAULIEU of Auburn, DILL of Cape Elizabeth, FOSSEL of Alna, PETERSON of Rumford, RICHARDSON of Warren, SANBORN of Gorham, Senator: SULLIVAN of York.

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 24-A MRSA §4310, as amended by PL 2003, c. 517, Pt. B, §31, is further amended to read:

§4310. Access to clinical trials

1. Qualified enrollee. An enrollee is eligible for coverage for participation in an approved clinical trial if the enrollee meets the following conditions:

A. The enrollee has a ~~life-threatening illness for which no standard treatment is effective~~ medical condition for which an approved clinical trial that is approved by an institutional review board is available;

B. The enrollee is eligible to participate according to the clinical trial protocol with respect to treatment of such illness; and

~~C. The enrollee's participation in the trial offers meaningful potential for significant clinical benefit to the enrollee; and~~

D. The enrollee's referring physician has concluded that the enrollee's participation in such a trial would be appropriate based upon the satisfaction of the conditions in paragraphs A~~,~~ and B ~~and C~~.

2. Coverage. A carrier may not deny a qualified enrollee participation in an approved clinical trial or deny, limit or impose additional conditions on the coverage of routine patient costs for items and services furnished in connection with participation in the clinical trial. For the purposes of this section, "routine patient costs" does not include the costs of the tests or measurements conducted ~~primarily~~ exclusively for the purpose of the clinical trial involved.

3. Payment. A carrier shall provide payment for routine patient costs but is not required to pay for costs of items and services that are reasonably expected to be paid for by the sponsors of an approved clinical trial. In the case of covered items and services, the carrier shall pay participating providers at the agreed upon rate and pay nonparticipating providers at the same rate the carrier would pay for comparable services performed by participating providers.

4. Approved clinical trial. For the purposes of this section, "approved clinical trial" means a clinical research study or clinical investigation approved and funded by the federal Department of Health and Human Services, National Institutes of Health or a cooperative group ~~or,~~ center of the National Institutes of Health or a pharmaceutical manufacturer. It includes all phases of clinical trials, including translational trials and Phase I, Phase II and Phase III trials.

5. Application. The requirements of this section apply to all individual and group policies, contracts and certificates executed, delivered, issued for delivery, continued or renewed in this State. For purposes of this section, all contracts are deemed to be renewed no later than the next yearly anniversary of the contract date.

SUMMARY

This bill amends the Maine Insurance Code to include those with medical conditions for whom an approved clinical trial is available. It requires health insurance coverage of clinical trials by pharmaceutical manufacturers. It also clarifies that the law covers all phases of clinical trials, including translational trials as well as Phase I, Phase II and Phase III trials.