

# MAINE STATE LEGISLATURE

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# 122nd MAINE LEGISLATURE

## FIRST REGULAR SESSION-2005

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Legislative Document

No. 710

H.P. 505

House of Representatives, February 10, 2005

### An Act To Require Notice of Clinical Trials

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Reference to the Committee on Health and Human Services suggested and ordered printed.

*Millicent M. MacFarland*  
MILLICENT M. MacFARLAND  
Clerk

Presented by Representative MILLS of Farmington.  
Cosponsored by Representatives: DUDLEY of Portland, LERMAN of Augusta, Senator:  
President EDMONDS of Cumberland.

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

4 **Sec. 1. 34-B MRSA §3011** is enacted to read:

6 **§3011. Clinical trials**

8 Beginning January 1, 2006, a manufacturer of pharmaceutical  
10 drugs or a research organization or other health organization  
12 that sponsors a clinical trial of a pharmaceutical drug,  
14 treatment option or medical device and that enrolls as a  
16 participant in the trial a person who is receiving mental health  
18 treatment at a state mental health institute, as described in  
20 section 3201, at a community or specialty hospital if that  
22 treatment is fully or partially reimbursed with state funds, or  
at a juvenile or adult correctional facility shall notify the  
Executive Director of Dirigo Health established under Title 24-A,  
chapter 87 prior to beginning the clinical trial. The Executive  
Director of Dirigo Health shall report by February 1st each year  
to the joint standing committee of the Legislature having  
jurisdiction over health and human services matters regarding the  
notifications received for the prior calendar year under this  
section.

24 **SUMMARY**

26  
28 Beginning January 1, 2006, this bill requires a manufacturer  
30 of pharmaceutical drugs or a research organization or other  
32 health organization that sponsors a clinical trial of a  
34 pharmaceutical drug, treatment option or medical device and that  
36 enrolls as a participant in the trial a person who is receiving  
38 mental health treatment at a state mental health institute, as  
defined in the Maine Revised Statutes, Title 34-B, section 3201,  
at a community or specialty hospital if that treatment is fully  
or partially reimbursed with state funds, or at a juvenile or  
adult correctional facility to notify the Executive Director of  
Dirigo Health prior to beginning the clinical trial. The bill  
requires annual reports from the executive director regarding  
notifications of clinical trials.