L.D. 719

Date: (Filing No. H-)

HEALTH AND HUMAN SERVICES

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STATE OF MAINE

HOUSE OF REPRESENTATIVES

125TH LEGISLATURE

FIRST REGULAR SESSION

COMMITTEE AMENDMENT " " to H.P. 530, L.D. 719, Bill, "An Act To Make Certain Prescription Drug Disclosure Laws Consistent with Federal Law"

Amend the bill in section 1 in paragraph C by striking out all of subparagraph (3) (page 1, line 13 in L.D.) and inserting the following:

'(3) Prescription drug price disclosure under section 2698-B;'

Amend the bill by striking out all of section 4.

Amend the bill in section 5 in §2700-A in subsection 1 by striking out all of paragraph A and inserting the following:

'A. "Clinical trial" means a clinical investigation as defined by the federal Food and Drug Administration that involves any trial to test the safety or efficacy of a drug or biological product with one or more human subjects and that is intended to be submitted to, or held for inspection by, the federal Food and Drug Administration as part of an application for a research or marketing permit.'

Amend the bill in section 5 in §2700-A by inserting after subsection 3 the following:

'**3-A. Clinical trial information.** The department shall post on its publicly accessible website links to clinical trial information available to the public through the United States Department of Health and Human Services and other sources.'

Amend the bill in section 5 in §2700-A by striking out all of subsection 4 and inserting the following:

'**4. Fees.** Beginning April 1, 2006, each manufacturer of prescription drugs that are provided to Maine residents through the MaineCare program under section 3174-G or the elderly low-cost drug program under section 254-D shall pay a fee of $1,000 per calendar year to the State. Fees collected under this subsection must be used to cover the cost of overseeing implementation of this section, including but not limited to maintaining links to publicly accessible websites to which manufacturers are posting clinical trial information under subsection ~~3~~ 3-A and other relevant sites, ~~assessing whether and the extent to which Maine residents have been harmed by the use of a particular drug and~~

~~undertaking the public education initiative under subsection 5~~ and the prescription drug academic detailing program under section 2685. One half of the annual revenues from this subsection must be allocated to and used for the academic detailing program under section 2685. Revenues received under this subsection, with the exception of funding designated for the academic detailing program under section 2685, must be deposited into an Other Special Revenue Funds account to be used for the purposes of this subsection.'

Amend the bill in section 5 in §2700-A by striking out all of subsections 6 and 7 and inserting the following:

'**6. Penalties.** A violation of this section is a violation of the Maine Unfair Trade Practices Act. Each day a manufacturer is in violation of this chapter is considered a separate violation.

7. Rulemaking. The department may adopt rules to implement this section. Rules adopted pursuant to this subsection are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.'

Amend the bill by adding after section 5 the following:

'**Sec. 6. Report.** By January 15, 2012 the Department of Health and Human Services shall report to the Joint Standing Committee on Health and Human Services regarding:

1. The mechanism that is being used to reimburse pharmacies for prescription drugs reimbursed under the MaineCare program;

2. The mechanism for reimbursement being considered by the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services for use in the future;

3. Options for ensuring transparency and accurate reporting in reimbursement for prescription drugs under the MaineCare program and for ensuring that Maine receives the maximum rebates allowed by federal law.

Sec. 7. Appropriations and allocations. The following appropriations and allocations are made.

HEALTH AND HUMAN SERVICES, DEPARTMENT OF (FORMERLY DHS)

Bureau of Medical Services 0129

Initiative: Reduces funding as a result of reductions in the drug marketing program and fees, partially offset by the restoration of the fee for the drug academic detailing program.

OTHER SPECIAL REVENUE FUNDS	**2011-12**	**2012-13**
All Other	($96,000)	($96,000)
OTHER SPECIAL REVENUE FUNDS TOTAL	($96,000)	($96,000)

'

Amend the bill by relettering or renumbering any nonconsecutive Part letter or section number to read consecutively.

SUMMARY

This amendment is the minority report of the committee. It does not repeal a section of current law on prescription drug pricing, restores the $500 fee per manufacturer that supports the academic detailing program, requires the Department of Health and Human Services to post website links to clinical trial information and retains provisions regarding penalties and rulemaking. The amendment also adds an appropriations and allocations section.

FISCAL NOTE REQUIRED

(See attached)