

MAINE STATE LEGISLATURE

The following document is provided by the
LAW AND LEGISLATIVE DIGITAL LIBRARY
at the Maine State Law and Legislative Reference Library
<http://legislature.maine.gov/lawlib>



Reproduced from scanned originals with text recognition applied
(searchable text may contain some errors and/or omissions)

R.O.S.

Date: 6/12/7

HEALTH AND HUMAN SERVICES

Reproduced and distributed under the direction of the Clerk of the House.

STATE OF MAINE
HOUSE OF REPRESENTATIVES
123RD LEGISLATURE
FIRST REGULAR SESSION

COMMITTEE AMENDMENT "A" to H.P. 638, L.D. 839, Bill, "An Act To Establish a Prescription Drug Academic Detailing Program"

Amend the bill in section 1 in §2685 by striking out all of subsection 3 (page 2, lines 6 to 13 in L.D.) and inserting the following:

3. Program components. Program components must include outreach and education regarding the therapeutic and cost-effective use of prescription drugs as issued in peer-reviewed scientific, medical and academic research publications and made available to prescribers and dispensers of drugs in the State, including through written information and through personal visits from program staff. To the extent possible, program components must also include information regarding clinical trials, pharmaceutical efficacy, adverse effects of drugs, evidence-based treatment options and drug marketing approaches that are intended to circumvent competition from generic and therapeutically equivalent drugs. Academic detailers shall observe standards of conduct in their educational materials and written and oral presentations as established by rules adopted by the department that are consistent with the following federal regulations regarding labeling and false and misleading advertising: the Food and Drug Administration labeling requirements of 21 Code of Federal Regulations, Part 201 (2007) and prescription drug advertising provisions of 21 Code of Federal Regulations, Part 202 (2007) and the Office of the Inspector General's Compliance Program Guidance for Pharmaceutical Manufacturers issued in April 2003, as amended. The rules must require academic detailers to disclose evidence-based information about the range and cost of appropriate drug treatment options and the health benefits and risks of all appropriate drugs.

Amend the bill by inserting after section 4 the following:

Sec. 5. Appropriations and allocations. The following appropriations and allocations are made.

HEALTH AND HUMAN SERVICES, DEPARTMENT OF (FORMERLY DHS)

COMMITTEE AMENDMENT

A. of S.

COMMITTEE AMENDMENT "A" to H.P. 638, L.D. 839

1 Prescription Drug Academic Detailing N026

2 Initiative: Provides a base allocation for the costs of the prescription drug academic
3 detailing program to be funded from a share of the fees collected from prescription drug
4 manufacturers under the Maine Revised Statutes, Title 22, section 2700-A, subsection 4.

5	OTHER SPECIAL REVENUE FUNDS	2007-08	2008-09
6	All Other	\$500	\$500
7			
8	OTHER SPECIAL REVENUE FUNDS TOTAL	\$500	\$500
9	,		

10 SUMMARY

11 This amendment is the majority report of the committee. The amendment clarifies
12 that the basis for academic detailing is peer-reviewed scientific, medical and academic
13 research publications. The amendment adds the requirement that academic detailers
14 observe standards of conduct consistent with certain federal Food and Drug
15 Administration and Office of the Inspector General requirements. The amendment
16 clarifies that the Department of Health and Human Services may adopt routine technical
17 rules to implement the prescription drug academic detailing program. The amendment
18 also adds an appropriations and allocations section.

19 FISCAL NOTE REQUIRED
20 (See attached)

COMMITTEE AMENDMENT



123rd MAINE LEGISLATURE

LD 839

LR 1964(02)

An Act To Establish a Prescription Drug Academic Detailing Program

Fiscal Note for Bill as Amended by Committee Amendment "A"

Committee: Health and Human Services

Fiscal Note Required: Yes

Fiscal Note

	2007-08	2008-09	Projections 2009-10	Projections 2010-11
Appropriations/Allocations				
Other Special Revenue Funds	\$500	\$500	\$500	\$500

Fiscal Detail and Notes

Provides a base allocation of \$500 in fiscal years 2007-08 and 2008-09 for the costs of the prescription drug academic detailing program to be funded from a share of the fees collected from prescription drug manufacturers under 22 MRSA §2700-A, sub-§-4. This base allocation assumes the Department of Health and Human Services will request by financial order increases in this allocation as needed and will transfer by journal voucher the revenue needed and available to fund the costs of this new program.