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)

Prescription Drug Academic Detailing N026

Initiative: Provides a base allocation 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 the Maine Revised Statutes, Title 22, section 2700-A, subsection 4.

OTHER SPECIAL REVENUE FUNDS	**2007-08**	**2008-09**
All Other	$500	$500
OTHER SPECIAL REVENUE FUNDS TOTAL	$500	$500

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SUMMARY

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

FISCAL NOTE REQUIRED
(See attached)