

MAINE STATE LEGISLATURE

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Date: 5/31/13

(Filing No. H-299)

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LABOR, COMMERCE, RESEARCH AND ECONOMIC DEVELOPMENT

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**STATE OF MAINE
HOUSE OF REPRESENTATIVES
126TH LEGISLATURE
FIRST REGULAR SESSION**

COMMITTEE AMENDMENT "A" to H.P. 934, L.D. 1315, Bill, "An Act To Ensure the Safety of Compounded Drugs"

Amend the bill by striking out the title and substituting the following:

'Resolve, Directing the Commissioner of Professional and Financial Regulation To Convene a Stakeholder Group To Review Changes in Federal and State Regulations and Rules Governing Compounding Pharmacies'

Amend the bill by striking out everything after the title and before the summary and inserting the following:

'Sec. 1. Commissioner of Professional and Financial Regulation directed to convene stakeholder group. Resolved: That the Commissioner of Professional and Financial Regulation shall convene a stakeholder group to review the proposed changes in federal and state safety and inspection regulations and rules governing sterile and nonsterile compounding pharmacies and identify any remaining gaps in the regulatory process that need to be addressed by state regulatory agencies in order to protect public health and safety. The Commissioner of Professional and Financial Regulation shall invite participation from the following stakeholders: the Department of Professional and Financial Regulation, Maine Board of Pharmacy; the division of licensing and regulatory services and the Maine Center for Disease Control and Prevention within the Department of Health and Human Services; and other interested parties from the medical and pharmaceutical communities; and be it further

Sec. 2. Report. Resolved: That the Commissioner of Professional and Financial Regulation shall submit a report on the study described in section 1 and any recommended legislation to the Joint Standing Committee on Labor, Commerce, Research and Economic Development by February 28, 2014. The joint standing committee is authorized to submit a bill to the Second Regular Session of the 126th Legislature related to the subject matter of the report.'

COMMITTEE AMENDMENT

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SUMMARY

This amendment replaces the bill with a resolve that directs the Commissioner of Professional and Financial Regulation to convene a stakeholder group to review the proposed changes in federal and state safety and inspection regulations and rules governing sterile and nonsterile compounding pharmacies and identify any remaining gaps in the regulatory process that need to be addressed by state regulatory agencies in order to protect public health and safety. It directs the Commissioner of Professional and Financial Regulation to invite participation from the following stakeholders: the Department of Professional and Financial Regulation, Maine Board of Pharmacy; the division of licensing and regulatory services and the Maine Center for Disease Control and Prevention within the Department of Health and Human Services; and other interested parties from the medical and pharmaceutical communities. It also requires the Commissioner of Professional and Financial Regulation to submit a report on the study and authorizes the Joint Standing Committee on Labor, Commerce, Research and Economic Development to submit a bill to the Second Regular Session of the 126th Legislature related to the subject matter of the report.

FISCAL NOTE REQUIRED
(See attached)



126th MAINE LEGISLATURE

LD 1315

LR 172(02)

An Act To Ensure the Safety of Compounded Drugs

Fiscal Note for Bill as Amended by Committee Amendment *A' (H-299)*
Committee: Labor, Commerce, Research and Economic Development

Fiscal Note Required: Yes

Fiscal Note

Minor cost increase - General Fund
Minor cost increase - Other Special Revenue Funds

Fiscal Detail and Notes

Additional costs to the Department of Professional and Financial Regulation to convene a stakeholder group to conduct the required review and submit the required report can be absorbed within existing budgeted resources. Additional costs to the Department of Health and Human Services to participate are expected to be minor and can be absorbed within existing budgeted resources.