L.D. 1541

DATE: 5.31.05 (Filing No. S-292)

HEALTH AND HUMAN SERVICES

Reported by:

Reproduced and distributed under the direction of the Secretary of the Senate.

STATE OF MAINE
SENATE
122ND LEGISLATURE
FIRST SPECIAL SESSION

COMMITTEE AMENDMENT "A" to S.P. 536, L.D. 1541, Bill, "An Act Pertaining to Disclosure of Prescription Drug Prices"

Amend the bill in the 4th paragraph after the title in the 2nd line (page 1, line 15 in L.D.) by striking out the following: "advance of the first reporting deadline of April 2005" and inserting in its place the following: 'order to amend the law as close as possible in time to the first reporting date'

Further amend the bill by striking out everything after the enacting clause and before the emergency clause and inserting in its place the following:

'**Sec. 1. 22 MRSA §2698-B, sub-§1,** as enacted by PL 2003, c. 667, §1 and affected by §2, is amended to read:

1. Quarterly report. A manufacturer of prescription drugs dispensed in this State under a health program directed or administered by the State shall, on a quarterly basis, report by National Drug Code the following pharmaceutical pricing criteria to the commissioner for each of its drugs:

~~A.--The-average-wholesale-price;~~

~~B.--The-wholesale-acquisition-cost;~~

COMMITTEE AMENDMENT

C. The average manufacturer price as defined in 42 United States Code, Section 1396r-8(k); and

D. The best price as defined in Section 1927 of the Social Security Act, 42 United States Code, Section 1396r-8(c)(1)(C) as in effect on January 1, 2005.

The pricing information required under this subsection is for drugs defined under the Medicaid drug rebate program.

Sec. 2. 22 MRSA §2698-B, sub-§2, as enacted by PL 2003, c. 667, §1 and affected by §2, is repealed.

Sec. 3. 22 MRSA §2698-B, sub-§§3, 4 and 5, as enacted by PL 2003, c. 667, §1 and affected by §2, are amended to read:

3. Description of methodology. When reporting the ~~average wholesale price,~~ wholesale acquisition cost, average manufacturer price and best price, a manufacturer of prescription drugs dispensed in this State shall also include a ~~detailed description of the methodologies by which the prices were calculated~~ summary of its methodology. The department may accept the standards of the national drug rebate agreement entered into by the federal Department of Health and Human Services and Section 1927 of the Social Security Act, 42 United States Code, Section 1396r-8(c)(1)(C) for reporting pricing methodology or may adopt its own standards by rule.

4. Certification. When a manufacturer of prescription drugs dispensed in this State reports the ~~average wholesale price, wholesale acquisition cost,~~ average manufacturer price or best price, the ~~president or~~ chief executive officer or chief officer of the manufacturer or an employee of the manufacturer in a position that reports directly to the chief executive officer or chief financial officer who has been delegated authority to sign shall certify to the department, on a form provided by the commissioner, that the reported prices are accurate as of the date they are submitted.

5. Confidentiality. Except as provided in this subsection, all information provided to the commissioner by a manufacturer of prescription drugs under this section is confidential and may not be disclosed by any person or by the department to any person without the consent of the manufacturer. Disclosure may be made by the department to an entity providing services to the department under this section and such a disclosure does not change the confidential status of the information. The information may be used by the entity only for the work that is authorized or approved by the department. Disclosure may be

ordered by a court for good cause shown or made in a court filing under seal unless or until otherwise ordered by a court. Nothing in this subsection limits the Attorney General's use of civil investigative demand authority under the Maine Unfair Trade Practices Act to investigate violations of this section.

Sec. 4. 22 MRSA §2698-B, sub-§8 is enacted to read:

8. 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.'

SUMMARY

This amendment replaces the bill. It clarifies details of the reporting of prescription drug pricing, including the methodology of pricing and certification requirements. It maintains current law on confidentiality, extending confidentiality explicitly to information disclosed to an entity under contract to the Department of Health and Human Services and restricting use of disclosed information to the purposes for which it was disclosed. The amendment directs the department to adopt routine technical rules to implement actual price disclosure and certification.

FISCAL NOTE REQUIRED
(See attached)

Approved: 05/26/05 mac

122nd MAINE LEGISLATURE

LD 1541 **LR 1702(02)**

An Act Pertaining to Disclosure of Prescription Drug Prices

Fiscal Note for Bill as Amended by Committee Amendment "A"
Committee: Health and Human Services
Fiscal Note Required: Yes

Fiscal Note

Minor cost increase - General Fund

Fiscal Detail and Notes

Any additional costs to the Department of Health and Human Services can be absorbed by the department utilizing existing budgetary resources.