

**OFFICE OF POLICY AND LEGAL ANALYSIS**

Date: March 9, 2010  
To: Business, Research and Economic Development Committee  
From: Natalie Haynes, Esq., Legislative Analyst

**LD 1677 - An Act to Protect Minors from Pharmaceutical Marketing Practices**

**SUMMARY**

This bill prohibits the collection and use of personal information collected on the Internet from a minor who is at least 13 years of age and under 17 years of age for the purposes of pharmaceutical marketing in violation of rules adopted by the Attorney General. The bill requires the Attorney General to adopt rules consistent with the federal Children's Online Privacy Protection Act of 1998, 15 United States Code, Sections 6501 to 6506 (2007) and 16 Code of Federal Regulations, Part 312 (1999), which regulates the collection and use of personal information from children under 13 years of age on the Internet.

The rules, which are routine technical rules, must define "pharmaceutical marketing" in a manner that includes the business of advertising or otherwise promoting the sale of prescription and over-the-counter drugs, as regulated by the United States Food and Drug Administration, and ensures the adequate protection of the health and safety of minors who are at least 13 years of age and under 17 years of age. The bill establishes that a violation is an unfair trade practice as prohibited by the Maine Unfair Trade Practices Act.

**TESTIMONY**

<p><b>Proponents:</b></p> <ul style="list-style-type: none"><li>○ The proposed amendment to this bill specifically addresses the concerns of the JUD Committee in that the prohibited acts are narrowly tailored and not left to rulemaking.</li><li>○ The bill restricts personal information from being collected and then sold or shared to other entities for uses other than those allowed under HIPAA, and nothing in the bill would prohibit providing information on a one-time basis to a minor at the request of the minor, which addresses the constitutional rights of teens.</li><li>○ The bill remains focuses on prescription drug marketing, which also addresses the concerns of the JUD committee and reflects the hearing record and testimony in both BRED and JUD committee hearings.</li><li>○ The bill also has been clarified to apply to "knowing" violations and to residents of the State and also provides that prizes, gifts or other promotions may not be used to collect information beyond what is necessary to provide the prize or gift</li></ul>	<p><b>Opponents:</b></p> <ul style="list-style-type: none"><li>● Supportive of the repeal in Section 1 as soon as possible, as colleges, insurance provider and other entities are currently in violation of the law passed last year.</li><li>● Maine's current laws may need some clarification to deal with these concerns, but these laws should be sufficient to deal with the concerns raised by the bill.</li><li>● This bill, as amended, does address many of the major concerns brought up with the law enacted last year; however there is a lot of work going on at the federal level on these issues.</li><li>● The Federal Trade Commission is working on these issues.</li><li>● Parents could be better informed about privacy tools that are available for their children.</li><li>● Congress held detailed hearings on COPPA, and a bright line rule for kids below 12 was established as the best age category to regulate.</li></ul>
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to the minor.

- Regulation is lacking in this area; direct to consumer advertising for prescription drugs have been allowed by the FDA since 1997 and there are still no specific rules for marketing to kids and teens.
- There is no law that governs marketing to teens; direct to consumer marketing of pharmaceuticals is big business and kids are the next frontier.
- Marketing aimed at teens can be very effective, especially if targeted on the basis of personal, private information that this bill addresses.
- Children are vulnerable to marketing that targets body image and social position; drugs have serious side effects and the risks of taking these drugs are often poorly communicated in DTC advertising.
- There is a compelling state interest in protecting children and teens from health marketing uses of personal data collected from them without parental consent.
- Strongly support the repeal of Public Law c. 230 (section 1 of the bill).
- The amendment still raises concerns about retail pharmacy, which should not be captured by this bill, and the amendment should not contradict or conflict with HIPAA or Title 22.

- Very concerned that the amendment takes things out of context of the Internet and applies it to all media. This amendment will have implications for people that are not aware of the new changes; there is existing law in place to regulate these issues, and if there needs to be further amplification of the law then it should be done at federal level.
- The Food and Drug Administration is in the process of taking on rules to deal with marketing and promotion of products regulated over the Internet and new guidelines are expected this year.
- The amendment still contains a private right of action under the Unfair Trade Practices Act; this should be removed and it should only be enforceable by the AG.
- The definition of minor is inconsistent with COPPA.
- A prescription is required to get these drugs.
- There are unintended consequences of applying this law to all media.
- Sections 2 and 3 of the bill may negatively impact reproductive health care provider's ability to provide information about contraception to teens, and conflict with current Maine law and well established health care policy priorities.
- State level regulations of the Internet violate the Commerce Clause; if this bill is enacted, websites around the country would have to redesign their sites to comply with Maine law.

**NFNA**

- The amendment addresses many of the concerns the Office of the Attorney General had with the bill regarding the Commerce Clause and the First Amendment issues.
- The amendment has been narrowly tailored, but there still are free speech concerns that should be addressed.
- The private right of action increases the chances that more frivolous lawsuits could be filed.
- The bill should include an exception for the activities associated with the administration and management of health insurance benefits; the language should be clear to exclude activities related to HIPAA and the Maine Insurance Information and Privacy Act or purposes

permitted under Title 22.

- Why define minor as anything but someone under 18?
- Non-profits should be exempted clearly from this bill.

**Issues for Consideration:**

- The Maine Civil Liberties Union and the Center for Democracy and Technology have submitted additional comments regarding the proposed amendment to the bill (see attached).
- Senator Schneider's proposed amendment (attached).

**Requests for Information:**

- Request to the Attorney General's Office regarding complaints that their office may have received on this issue.
- Request for information on the FTC national Do Not Call Registry (see attached); request for information on promotional spending for prescription drugs (see attached report from the Congressional Budget Office); and request for information on the FDA's activity in this area (see attached FDA notice of public hearing and public comments on the promotion of FDA-regulated medical products using the Internet and social media tools).

**FISCAL IMPACT:**

- Not yet received.

**Proposed Amendment from Senator Schneider to LD 1677**

**(updated March 9, 2010)**

**An Act To Protect Minors from Pharmaceutical Prescription Drug Marketing Practices**

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 10 MRSA c. 1055, as amended, is repealed.

Sec. 2. 10 MRSA c. 1057 is enacted to read:

**CHAPTER 1057**

**PHARMACEUTICAL-PRESCRIPTION DRUG MARKETING TO MINORS**

**§ 9561. Unlawful pharmaceutical marketing of prescription drugs to minors**

1. **Definitions.** As used in this section, "minor" means a person who is at least 13 years of age and under 17 years of age. As used in this chapter, unless the context otherwise indicates, the following terms have the following meanings:

**A. Minor.** "Minor" means a person who is under 17 years of age and a resident of the State of Maine.

**B. Personal information.** "Personal information" means an individual's first name or first initial and last name in combination with a physical address, telephone number or other information sufficient to contact the minor.

**C. Marketing prescription drugs.** "Marketing prescription drugs" means the business, not including activity by or in support of non-profit organizations, of advertising or otherwise promoting the purchase of a prescription drug as regulated by the United States Food and Drug Administration pursuant to the Federal Food, Drug and Cosmetic Act, 21 United States Code, Chapter 9, but does not include (1) the collection, use and transfer of personal information for the purposes of treatment, payment, or health care operations, or any other purpose permitted under the federal Health Insurance Portability and Accountability Act of 1996, Public Law 104-91, as amended; (2) any purpose permitted under the Maine Insurance Information and Privacy Act, Title 24-A, sections 2201-2220; or (3) any purpose permitted under Title 22, chapter 401, sections 1711-C, 1711-E, or 1711-F. "Marketing prescription drugs" also does not include pharmacy reimbursement, formulary compliance, pharmacy file transfers in response to a patient request or as a result of the sale or purchase of a pharmacy, patient care management, utilization review by a health care practitioner or agent of a health care practitioner, or the patient's health plan or an agent of the patient's health plan, quality assurance, utilization review or peer review and health care research.

*remove  
"transfer"  
we  
"disclosure"  
from  
HIPAA*

2. **Prohibition; marketing prescription drugs to minors.** A person may not knowingly collect and use personal information collected on the Internet from a minor a person known to be a minor for the purposes of pharmaceutical marketing prescription drugs to that minor, except that a person may collect personal information from a minor

**Proposed Amendment from Senator Schneider to LD 1677**

**(updated March 9, 2010)**

for the purposes of responding directly to a specific request from that minor in violation of rules adopted by the Attorney General under subsection 3.

**2-A. Prohibition; prizes and contests.** A person involved in marketing prescription drugs is prohibited from conditioning the participation of a person known to be a minor in any game, the offering of a prize, contest, giveaway, or any other activity on the minor disclosing more personal information than is reasonably necessary to participate in such activity and is required to promptly delete any personal information once the minor's participation in the activity is completed. *similar*

~~**3. Rules.** In order to ensure the health and safety of minors, no later than one year after the effective date of this section, after issuing notice and receiving public comment, the Attorney General shall adopt rules governing the collection and use of personal information collected on the Internet from a minor for the purposes of pharmaceutical marketing prescription drugs. The rules must be consistent with and to the extent possible the same as those established under the federal Children's Online Privacy Protection Act of 1998, 15 United States Code, Sections 6501 to 6506 (2007) and 16 Code of Federal Regulations, Part 312 (1999). The rules must define "pharmaceutical marketing" "prescription drug marketing" in a manner that includes the business of advertising or otherwise promoting the sale of prescription and over the counter drugs as regulated by the United States Food and Drug Administration pursuant to the Federal Food, Drug and Cosmetic Act, 21 United States Code, Chapter 9, and that ensures the adequate protection of the health and safety of minors.~~

**4. 3. Unfair trade practice.** Violation of subsection 2 is an unfair trade practice as prohibited under Title 5, section 207. The Attorney General may establish procedures for receiving and investigating complaints of violations of subsection 2. *r 2.4*

*(creates private right of action)*

**SUMMARY**

This amendment maintains the repeal in the bill of Title 10, chapter 1055 on marketing and data collection practices. It changes the scope of the new chapter from pharmaceutical marketing to marketing prescription drugs to minors. It prohibits the knowing collection of personal information known to be a minor who is under 17 years of age and a resident of the State of Maine for the purposes of marketing prescription drugs to that minor, except that a person may collect personal information from a minor for the purposes of responding directly to a specific request from that minor. It also prohibits a person involved in marketing prescription drugs from conditioning the participation of a person known to be a minor in any game, the offering of a prize, contest, giveaway, or any other activity on the minor disclosing more personal information than is reasonably necessary to participate in such activity and requires that the information collected be promptly deleted once the minor's participation in the activity is completed.

It adds a new definition for personal information and marketing prescription drugs, as well amends the definition of minor. It removes any reference in the bill to rulemaking requirements for the Office of the Attorney General. It maintains the current

**Proposed Amendment from Senator Schneider to LD 1677**

**(updated March 9, 2010)**

language in the bill that establishes that a violation of this chapter is an unfair trade practice as prohibited by the Maine Unfair Trade Practices Act.