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An Act Requiring Heavy Metal-free Immunizing Agents

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

Sec. 1. 22 MRSA §1066 is enacted to read:

§ 1066. Immunizing agents containing heavy metals

1. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "Label" means written information on outside packaging or bulk packaging; descriptive information, instructions on separate pages or brochures provided with a product; and written information that appears on individual vials or dispensing units.

B. "Trace amount" means one microgram or less per dose.

2. Prohibition. Except as provided in subsection 4, beginning January 1, 2008, a person may not sell, market, offer or otherwise provide an immunizing agent for use by health care practitioners in this State if the immunizing agent contains more than a trace amount of a heavy metal, including mercury or thimerosal.

3. Labeling. Except as provided in subsection 4, beginning January 1, 2008, a person may not sell, market, offer or otherwise provide an immunizing agent to any health care practitioner in this State unless the immunizing agent is clearly labeled in accordance with this subsection.

A. All labels must clearly indicate whether the immunizing agent contains a heavy metal, including mercury or thimerosal, or is free of heavy metals. An immunizing agent that contains a heavy metal, including mercury or thimerosal, even if only a trace amount, must be clearly labeled with the words "contains a heavy metal," "contains mercury" or "contains thimerosal."

B. An immunizing agent with more than a trace amount of a heavy metal, including mercury or thimerosal, must be labeled as unsuitable for a person in this State.

C. A sticker, such as that commonly used to identify special information on a prescription medication, with text in a font size no smaller than 10 points affixed to an existing label is acceptable labeling.

4. Exemption. The commissioner may allow the use of an immunizing agent otherwise prohibited under this section if the commissioner finds that an exemption is necessary to protect the public health in response to an actual or potential bioterrorist incident or other public health emergency, including an epidemic or shortage of supply of an immunizing agent that would prevent a person from receiving the needed immunizing agent.

A. An exemption under this subsection is limited to 12 months, renewable once per incident or emergency.

B. Upon issuing an exemption or a renewal of an exemption under this subsection, the commissioner shall provide notice of the findings justifying the exemption or renewal within 48 hours to the Legislature and within 7 days to parties who have filed with the commissioner's office a request for notification.

Sec. 2. Development of plan. The Department of Health and Human Services shall develop a plan to ensure that all immunizing agents administered in the State are free of heavy metals, including mercury and thimerosal, including trace amounts of a heavy metal, including mercury or thimerosal, as defined in the Maine Revised Statutes, Title 22, section 1066, subsection 1, paragraph B. In designing the plan, the department shall consider methods to eliminate all heavy metals, including mercury and thimerosal, from immunizing agents, including, but not limited to, requiring the use of single-dose immunizing agents.

SUMMARY

Beginning January 1, 2008, this bill prohibits the use of more than trace amounts of a heavy metal, including mercury or thimerosal, in any immunizing agent for administration to a person in this State. It imposes requirements for labeling and written information packaged with the immunizing agent. It provides for an exemption if the Commissioner of Health and Human Services determines that an immunizing agent containing more than a trace amount is necessary due to an actual or potential bioterrorist incident or public health emergency. The bill also directs the Department of Health and Human Services to develop a plan to ensure that all immunizing agents are free of heavy metals, including mercury and thimerosal, including considering the requirement of the use of single-dose immunizing agents.