LAWS

OF THE

STATE OF MAINE

AS PASSED BY THE

ONE HUNDRED AND TWENTY-SECOND LEGISLATURE

FIRST REGULAR SESSION
December 1, 2004 to March 30, 2005

FIRST SPECIAL SESSION
April 4, 2005 to June 18, 2005

THE GENERAL EFFECTIVE DATE FOR
FIRST REGULAR SESSION
NON-EMERGENCY LAWS IS
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PUBLISHED BY THE REVISOR OF STATUTES
IN ACCORDANCE WITH MAINE REVISED STATUTES ANNOTATED,
TITLE 3, SECTION 163-A, SUBSECTION 4.

Penmor Lithographers
Lewiston, Maine
2005

rate and apart from records relating to any other transaction in which the licensee engages.

D. The bureau, upon application by the holder of a small distillery off-premises license whose distillery has produced distilled spirits in an amount that exceeds 50,000 gallons in one year, may renew that holder's small distillery off-premises license for only one additional year.

Emergency clause. In view of the emergency cited in the preamble, this Act takes effect when approved.

Effective June 14, 2005.

CHAPTER 391

H.P. 975 - L.D. 1411

An Act Regarding the Reporting of Hospital and Ambulatory Surgical Center Prices

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

Sec. 1. 22 MRSA §1718, as corrected by RR 2003, c. 1, §16, is amended by adding at the end a new paragraph to read:

The Maine Health Data Organization, established in chapter 1683, shall adopt rules to establish criteria for the services and procedures and to standardize the manner of listing prices by hospitals and ambulatory surgical centers under this section. Rules adopted pursuant to this paragraph are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

Sec. 2. 22 MRSA §8712, sub-§2, as enacted by PL 2003, c. 469, Pt. C, §29, is amended to read:

2. Average payments. At a minimum, the organization, with advice from the Maine Health Data Processing Center as authorized in Title 10, section 681, shall develop and produce annual reports on ~~prices charged~~ average private-payer payments for ~~the 15 most common~~ services provided by health care facilities and health care practitioners, excluding emergency services. For health care facilities, the reports must include, but are not limited to, the average ~~price charged~~ private-payer payments per service per facility and total number of services per facility.

See title page for effective date.

CHAPTER 392

H.P. 1141 - L.D. 1618

An Act Regarding Advertising by Drug Manufacturers and Disclosure of Clinical Trials

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

Sec. 1. 22 MRSA c. 605 is enacted to read:

CHAPTER 605

PRESCRIPTION DRUG ADVERTISING

§2700-A. Prohibitions and required disclosures

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

A. "Clinical trial" means a clinical investigation as defined by the federal Food and Drug Administration that involves any trial to test the safety or efficacy of a drug or biological product with one or more human subjects and that is intended to be submitted to, or held for inspection by, the federal Food and Drug Administration as part of an application for a research or marketing permit.

B. "Manufacturer of prescription drugs" or "manufacturer" means a manufacturer of prescription drugs or biological products or an affiliate of the manufacturer or a labeler that receives prescription drugs or biological products from a manufacturer or wholesaler and repackages those drugs or biological products for later retail sale and that has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 2027.20 (1999).

C. "Regulated advertisement" means the presentation to the general public of a commercial message regarding a prescription drug or biological product by a manufacturer of prescription drugs that is:

(1) Broadcast on television or radio from a station that is physically located in the State;

(2) Broadcast over the Internet from a location in the State; or

(3) Printed in magazines or newspapers that are printed, distributed or sold in the State.

2. Regulated advertisement requirement. Beginning October 15, 2005, a manufacturer may not present or cause to be presented in the State a regu-

lated advertisement, unless that advertisement meets the requirements concerning misbranded drugs and devices and prescription drug advertising of federal law and regulations under 21 United States Code, Sections 331 and 352(n) and 21 Code of Federal Regulations, Part 202 and state rules.

3. Disclosure of clinical trials of prescription drugs. Beginning October 15, 2005, a manufacturer or labeler of prescription drugs that is required to report marketing costs for prescription drugs pursuant to section 2698-A shall post, with regard to those prescription drugs, on the publicly accessible Internet website of the federal National Institutes of Health or its successor agency or another publicly accessible website the following information concerning any clinical trial that the manufacturer conducted or sponsored on or after October 15, 2002:

A. The name of the entity that conducted or is conducting the clinical trial;

B. A summary of the purpose of the clinical trial;

C. The dates during which the trial has taken place; and

D. Information concerning the results of the clinical trial, including potential or actual adverse effects of the drug.

In order to satisfy the requirements of this subsection, the publicly accessible website and manner of posting must be acceptable to the department.

4. Fees. Beginning April 1, 2006, each manufacturer of prescription drugs that are provided to Maine residents through the MaineCare program under section 3174-G or the elderly low-cost drug program under section 254 shall pay a fee of $1,000 per calendar year to the department. Fees collected under this subsection must be used to cover the cost of overseeing implementation of this section, including but not limited to maintaining links to publicly accessible websites to which manufacturers are posting clinical trial information under subsection 3 and other relevant sites, assessing whether and the extent to which Maine residents have been harmed by the use of a particular drug and undertaking the public education initiative under subsection 5. Revenues received under this subsection must be deposited into an Other Special Revenue Funds account to be used for the purposes of this subsection.

5. Public education initiative. The department shall undertake a public education initiative to inform residents of the State about clinical trials and drug safety information.

6. Penalties. A violation of this section is a violation of the Maine Unfair Trade Practices Act. Each day a manufacturer is in violation of this chapter is considered a separate violation.

7. 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.

Sec. 2. Report. By January 15, 2007, the Department of Health and Human Services shall report to the joint standing committee of the Legislature having jurisdiction over health and human services matters regarding compliance with the Maine Revised Statutes, Title 22, section 2700-A, the completeness and ease of public access to information provided by the drug manufacturers and the need for further action or legislation.

See title page for effective date.

CHAPTER 393

H.P. 1170 - L.D. 1659

An Act To Amend the Laws Governing Crimes against People Who Are Homeless

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

Sec. 1. 25 MRSA §2804-C, sub-§2-B is enacted to read:

2-B. Training regarding people who are homeless. The board shall include in the basic law enforcement training program a block of instruction aimed specifically at reducing barriers to reporting crimes against people who are homeless and dealing with the unique challenges posed by cases that involve victims or witnesses who are homeless.

Sec. 2. Required recertification law enforcement training. The Board of Trustees of the Maine Criminal Justice Academy shall include requirements in its next available schedule of recertification training for all law enforcement officers a block of instruction aimed specifically at reducing barriers to reporting crimes against people who are homeless and dealing with the unique challenges posed by cases that involve victims or witnesses who are homeless. The board shall thereafter determine quadrennially whether further training in the next available schedule of recertification training is necessary as a refresher or to incorporate improved procedures or practices demonstrated to reduce barriers to reporting crimes against people who are homeless and dealing with the unique challenges posed by cases that involve victims or witnesses who are homeless.