BILL ANALYSIS

LD 8 – An Act To Support Collection and Proper Disposal of Unwanted Drugs (Carney)

Bill summary and legislative history

This bill provides for the establishment of drug take-back stewardship programs. It requires certain drug manufacturers, as defined in the bill, to operate a drug take-back stewardship program to collect and dispose of certain drugs.

As noted by the sponsor, LD 8 is essentially identical to the committee amendment to LD 1460, a bill worked and voted unanimously by the ENR Committee during the 129th Legislature. That bill was not reported out of ENR before the early adjournment of the Second Regular Session of the 129th Legislature in March 2020 and it thus died upon the termination of that Legislature.

List of entities that submitted written testimony and/or spoke at the hearing¹

For – Department of Environmental Protection, Maine Public Health Association Maine Sheriff's Association, Maine Water Environment Association, Natural Resources Council of Maine, Product Stewardship Institute.

Against – Association for Accessible Medicines, Consumer Healthcare Products Association, Pharmaceutical Research and Manufacturers of America (PhRMA).

Neither for nor against – Animal Health Institute, ecomaine, Retail Association of Maine.

Issues, suggested amendments and other notes

1. DEP proposed amendments – DEP proposes amending the bill on page 6, lines 10-14 as follows (changes shaded):

When 2 or more manufacturers participate in a stewardship program or if multiple stewardship programs exist, the costs of implementing, administering and operating the program must be fairly and reasonably allocated between each participating manufacturer so that the share of the costs that is allocated to each manufacturer is reasonably related to the market share of covered drugs that the manufacturer sells in the State.

DEP also proposes amending the bill on page 8 by inserting at the bottom of that page a new paragraph 10(L) that reads:

L. An analysis of market share of covered drugs by manufacturers in the State and any other additional information required by the department for determining appropriate cost share.

2. Animal Health Institute proposed amendments – AHI proposes amending the definition of "covered drug" on page 1 (begins on line 30) to exclude from that definition the following:

- Drugs, medical devices, biologics or diagnostics approved or authorized by the Food and Drug Administration or United States Department of Agriculture for use in animals;
- Veterinary pesticide products approved by the Environmental Protection Agency for use in animals; and

¹ List does not include sponsor, co-sponsors or any individuals not associated with an agency, business or organization

• Medical products for animals required to be sterile or enclosed in packaging with tamper-resistant seals to protect public health.

3. FOAA review – because the bill proposes in new 38 MRSA §1612(7) (see page 6, lines 18-22) that any confidential information submitted to DEP as part of a plan under this law be maintained as confidential, 1 MRSA §434 requires that, if the proposal is supported by a majority of the committee, it must be submitted to the JUD Committee for a public records exception review.

For reference, LD 1460, as amended, contained this same proposed exception and was submitted to JUD for a FOAA review in July 2020. After conducting that review, JUD approved the proposed exception.

Requests made of analyst for work session

Senator Brenner requested information regarding the costs associated with the current drug takeback system in the State, which has a number of components.

- **Pharmacy take backs** costs associated with permanent pharmacy-based kiosks and the provision/sale of mail-back envelopes and drug destroyer type products. Depending on the particular pharmacy, some or all of these disposal options may be provided free or at a reduced cost to consumers (costs to pharmacy). Information provided by Retail Association of Maine.
- Law enforcement take backs costs associated with permanent law enforcement kiosks and biannual law enforcement-run take back days. Based on information provided by the Maine Sheriffs' Association and the U.S. Drug Enforcement Administration.
 - Costs associated with the installation and maintenance of most law enforcement kiosks are covered by DEA and/or pharmaceutical manufacturers/vendors.
 - DEA funds all costs associated with take back days <u>except law enforcement staff time</u> (e.g., boxes and bags for transporting collected drugs, advertising materials, trucks needed for transportation to disposal, disposal costs). Per DEA, these costs are estimated at \$60,000 per year (~\$30,000 per take back day).
 - Total county/municipal law enforcement staff time costs associated with the take back days is ~\$223,000 per year (based on an average annual cost to each sheriff's office of ~\$1,900 annually multiplied by 118 law enforcement agencies (county and municipal) that participated in the last take back day).