## MAINE STATE LEGISLATURE

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### STATE OF MAINE

 $128^{\text{TH}}$  Legislature First Special, Second Regular and Second Special Sessions



Summaries of bills, adopted amendments and laws enacted or finally passed

## JOINT STANDING COMMITTEE ON LABOR, COMMERCE, RESEARCH AND ECONOMIC DEVELOPMENT

October 2018

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## STATE OF MAINE

 $128^{\text{th}}\,Legislature$  First Special, Second Regular and Second Special Sessions



# LEGISLATIVE DIGEST OF BILL SUMMARIES AND ENACTED LAWS

This *Legislative Digest of Bill Summaries and Enacted Laws* contain summaries of all LDs and adopted amendments and all laws enacted or finally passed during the First Special, Second Regular and Second Special Sessions of the 128<sup>th</sup> Maine Legislature.

The *Digest* is arranged alphabetically by committee and within each committee by Legislative Document (LD) number. The committee report(s), prime sponsor and lead co-sponsor(s), if designated, are listed below each LD title. All adopted amendments are summarized and listed by paper number. A subject index is included with each committee. An appendix provides a summary of relevant session statistics.

Final action on each LD is noted to the right of the LD title. The following describes the various final actions.

CARRIED OVER carried over to a subsequent session of the Legislature
CON RES XXX
CONF CMTE UNABLE TO AGREE
DIED BETWEEN HOUSES
DIED IN CONCURRENCE defeated in each house, but on different motions; legislation died
DIED ON ADJOURNMENT action incomplete when session ended; legislation died
EMERGENCYenacted law takes effect sooner than 90 days after session adjournment
FAILED, EMERGENCY ENACTMENT or FINAL PASSAGEemergency failed to receive required 2/3 vote
FAILED, ENACTMENT or FINAL PASSAGE failed to receive final majority vote
FAILED, MANDATE ENACTMENTlegislation proposing local mandate failed required 2/3 vote
HELD BY GOVERNOR Governor has not signed; final disposition to be determined at subsequent session
LEAVE TO WITHDRAWsponsor's request to withdraw legislation granted
NOT PROPERLY BEFORE THE BODYruled out of order by the presiding officer; legislation died
INDEF PP indefinitely postponed; legislation died
ONTP, ACCEPTED, MAJORITY, MINORITY or REPORT X ought-not-to-pass report accepted; legislation died
P&S XXX
PUBLIC XXX chapter # of enacted public law
RESOLVE XXX
VETO SUSTAINEDLegislature failed to override Governor's veto

The effective dates for non-emergency legislation enacted in the First Special, Second Regular or Second Special Sessions of the 128<sup>th</sup> Legislature are: Monday, February 5, 2018; Wednesday, August 1, 2018; and Thursday, December 13, 2018, respectively. The effective date for legislation enacted as an emergency measure may be found in the enacted law summary for that legislation.

#### Joint Standing Committee on Labor, Commerce, Research and Economic Development

This bill was carried over in committee from the First Regular Session to the Second Regular Session of the 128th Legislature.

This bill is a concept draft pursuant to Joint Rule 208 that proposes to enact measures to support small manufacturers in the State.

LD 1280

#### An Act To Require Drug Manufacturers To Comply with Federal Law

**PUBLIC 434** 

Sponsor(s)	Committee Report	Amendments Adopted
JACKSON T	OTP-AM	S-153
GATTINE D	ONTP	S-297 JACKSON T
		S-309 JACKSON T

This bill was reported out of committee in the First Regular Session of the 128th Legislature and then carried over to the Second Regular Session on the Special Appropriations Table by joint order S.P. 601. This bill was again carried over, still on the Special Appropriations Table, from the Second Regular Session to the Second Special Session by joint order S.P. 748.

The bill amends the Maine Pharmacy Act to require that a drug distributed in this State must be made available for sale in this State to an "eligible product developer," which is defined as a person seeking to develop an application for the approval of the drug under the Federal Food, Drug, and Cosmetic Act or the licensing of a biological product under the federal Public Health Service Act. It establishes disciplinary actions for noncompliance and further authorizes the Attorney General to bring an action for injunctive relief to enforce the bill's requirements.

#### Committee Amendment "A" (S-153)

This amendment, which is the majority report of the committee, clarifies that the bill's requirement that a drug distributed in this State be made available for sale to an eligible product developer applies only to manufacturers and wholesalers of drugs licensed in this State under the Maine Pharmacy Act. The sale must be made at the fair market price and the licensed manufacturer or wholesaler may not impose any restriction on the sale that would block or delay the eligible product developer's application in a manner inconsistent with Section 505-1(f)(8) of the Federal Food, Drug, and Cosmetic Act, 21 United States Code, Section 355-1(f)(8) (2016).

The amendment further provides that if the Attorney General prevails in an enforcement action, the court must order the defendant to reimburse the State for the costs of prosecuting the action, including reasonable attorney's fees.

#### Senate Amendment "C" To Committee Amendment "A" (S-299)

This amendment requires a drug manufacturer or wholesaler to make a drug available for sale at a price no greater than the wholesale acquisition cost rather than at the fair market price as provided in Committee Amendment "A" and adds an intent section.

This amendment was not adopted.

#### Senate Amendment "B" To Committee Amendment "A" (S-297)

The bill, as amended by Committee Amendment "A," requires that a drug distributed in this State be made available for sale to an eligible product developer by a manufacturer or wholesaler of drugs licensed in this State under the Maine Pharmacy Act. This amendment provides that a manufacturer or wholesaler is not liable for injuries alleged to have been caused by the failure to include adequate safety warnings on a product's label or by a defect in the product's design if that product was not manufactured or sold by that manufacturer or wholesaler.

#### Senate Amendment "A" To Committee Amendment "A" (S-295)

#### Joint Standing Committee on Labor, Commerce, Research and Economic Development

This amendment amends Committee Amendment "A" to authorize the Attorney General to accept private funds, including, but not limited to, funds from corporations, private foundations and individuals, to defend the constitutionality of the requirements placed on manufacturers and wholesalers in the bill, as amended.

This amendment was not adopted.

#### Senate Amendment "D" To Committee Amendment "A" (S-309)

This amendment requires a drug manufacturer or wholesaler to make a drug available for sale to an eligible product developer at a price no greater than the wholesale acquisition cost rather than at the fair market price as provided in Committee Amendment "A" and limits the price charged to customers for a drug manufactured by the eligible product developer to no more than that wholesale acquisition cost. This amendment also adds an intent section.

#### **Enacted Law Summary**

Public Law 2017, chapter 434 requires that drug manufacturers and wholesalers licensed in this State under the Maine Pharmacy Act make a drug that is distributed in this State available for sale in this State to a person, known as an "eligible product developer," that seeks to develop an application for the approval of a drug under the Federal Food, Drug, and Cosmetic Act or the licensing of a biological product under the federal Public Health Service Act. The licensed drug manufacturer or wholesaler must make the drug available at a price no greater than the wholesale acquisition cost and without any restriction that would block or delay the eligible product developer's application for federal approval in a manner that is inconsistent with the Federal Food, Drug, and Cosmetic Act.

An eligible product developer who purchases a drug from a licensed drug manufacturer or wholesaler at a price no greater than the wholesale acquisition cost for that drug in accordance with this Act must sell the drug manufacturered by that eligible product developer to consumers in this state at an equal or lesser price.

A licensed drug manufacturer or wholesaler who makes products distributed in this State available to an eligible product developer as required by this Act is not liable for injuries alleged to have been caused by the failure to include adequate safety warnings on a product's lable or by a defect in the product's design if that product was not manufacturer or sold by that manufacturer or wholesaler.

Entities licensed under the Maine Pharmacy Act that fail to comply with the requirements of this Act are subject both to administrative discipline and to suits for injunctive relief brought by the Attorney General. If the Attorney General prevails in an enforcement action, the court must order the defendant to reimburse the State for the costs of prosecuting the action, including reasonable attorney's fees.

# LD 1308 Resolve, To Expedite the Processing of Applications for Certification under the Work Opportunity Tax Credit

Died On Adjournment

Sponsor(s)	<u>Committee Report</u>	Amendments Adopted
TALBOT ROSS R	OTP-AM	H-118
WOODSOME D	ONTP	

This bill was reported out of committee in the First Regular Session of the 128th Legislature and then carried over to the Second Regular Session on the Special Appropriations Table by joint order S.P. 601. This bill was again carried over, still on the Special Appropriations Table, from the Second Regular Session to the Second Special Session by joint order S.P. 748.

This bill is a concept draft pursuant to Joint Rule 208.

This bill proposes to implement programs to facilitate the transition of persons from rehabilitation for drug or