SENATE BILL 459

J1, J2, F5 5lr3037 CF HB 420

By: Senator Gile

Introduced and read first time: January 21, 2025

Assigned to: Finance and Education, Energy, and the Environment

Committee Report: Favorable

Senate action: Adopted

Read second time: February 11, 2025

CHAPTER

-	A TAT	AOID	•
1	AN	\mathbf{ACT}	concerning
-	,	1101	COLLCCIALITY

2 Education and Health - Emergency Use Epinephrine - Alterations

- FOR the purpose of altering the defined term "auto-injectable epinephrine" to be "emergency use epinephrine" and to include certain drug delivery devices and products; altering the name of the Emergency Use Auto-Injectable Epinephrine Program to be the Emergency Use Epinephrine Program; and generally relating to
- 7 emergency use epinephrine.
- 8 BY repealing and reenacting, with amendments,
- 9 Article Education
- 10 Section 7–426.2, 7–426.3, and 9.5–117(a)(3) and (f)
- 11 Annotated Code of Maryland
- 12 (2022 Replacement Volume and 2024 Supplement)
- 13 BY repealing and reenacting, without amendments,
- 14 Article Education
- 15 Section 9.5–117(a)(1)
- 16 Annotated Code of Maryland
- 17 (2022 Replacement Volume and 2024 Supplement)
- 18 BY repealing and reenacting, with amendments.
- 19 Article Health General
- 20 Section 13–702, 13–704(e), 13–705, 13–706(a), 13–707(a) and (b), and 13–708(b); and
- 21 13–7A–01, 13–7A–02, 13–7A–03(a)(5), 13–7A–06, 13–7A–07(a) and (b),

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

<u>Underlining</u> indicates amendments to bill.

Strike out indicates matter stricken from the bill by amendment or deleted from the law by amendment.



1 2 3	13–7A–08(b), and 13–7A–09 to be under the amended subtitle "Subtitle 7A. Emergency Use Epinephrine Program" Annotated Code of Maryland						
4	(2023 Replacement Volume and 2024 Supplement)						
5 6 7 8 9	BY repealing and reenacting, without amendments, Article – Health Occupations Section 14–5F–01(a) and 14–5F–04.1(a)(1) Annotated Code of Maryland (2021 Replacement Volume and 2024 Supplement)						
10 11 12 13 14	Article – Health Occupations Section 14–5F–01(c) Annotated Code of Maryland						
15 16 17 18 19	Article – Health Occupations Section 14–5F–01(d) through (g), 14–5F–04.1(d)(1), and 14–5F–14(a)(5) Annotated Code of Maryland						
20 21 22 23 24	BY adding to Article – Health Occupations Section 14–5F–01(g) Annotated Code of Maryland (2021 Replacement Volume and 2024 Supplement)						
25 26	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:						
27	Article - Education						
28	7–426.2.						
29	(a) (1) In this section the following words have the meanings indicated.						
30 31	(2) "Anaphylaxis" means a sudden, severe, and potentially life—threatening allergic reaction that occurs when an individual is exposed to an allergen.						
32 33 34 35	(3) ["Auto—injectable] "EMERGENCY USE epinephrine" means a portable, disposable drug delivery device OR PRODUCT APPROVED BY THE FEDERAL FOOD AND DRUG ADMINISTRATION that contains a premeasured single dose of epinephrine that is used to treat anaphylaxis in an emergency situation.						

- 1 (b) Each county board shall establish a policy for public schools within its 2 jurisdiction to authorize the school nurse and other school personnel to administer 3 [auto-injectable] EMERGENCY USE epinephrine, if available, to a student who is determined to be or perceived to be in anaphylaxis, regardless of whether the student:
- 5 (1) Has been identified as having an anaphylactic allergy, as defined in 6 7-426.1 of this subtitle; or
- 7 (2) Has a prescription for epinephrine as prescribed by an authorized 8 licensed health care practitioner under the Health Occupations Article.
- 9 (c) The policy established under subsection (b) of this section shall include:
- 10 (1) Training for school personnel on how to recognize the symptoms of 11 anaphylaxis;
- 12 (2) Procedures for the emergency administration of [auto-injectable] 13 EMERGENCY USE epinephrine;
- 14 (3) The proper follow–up emergency procedures;
- 15 (4) A provision authorizing a school nurse to obtain and store at a public 16 school [auto-injectable] **EMERGENCY USE** epinephrine to be used in an emergency 17 situation; and
- 18 (5) A requirement that each public school develop and implement a method for notifying the parents or guardians of students of the school's policy under this section at the beginning of each school year.
- 21 (d) Except for any willful or grossly negligent act, a school nurse or other school 22 personnel who respond in good faith to the anaphylactic reaction of a child in accordance 23 with this section may not be held personally liable for any act or omission in the course of 24 responding to the reaction.
- 25 (e) (1) Each public school shall submit, on the form that the Department 26 requires, a report to the Department on each incident at the school or at a related school 27 event that required the use of [auto-injectable] EMERGENCY USE epinephrine.
- 28 (2) The Department shall develop and disseminate a standard form to 29 report each incident requiring the use of [auto-injectable] **EMERGENCY USE** epinephrine 30 at a public school.
- 31 7–426.3.
- 32 (a) (1) In this section the following words have the meanings indicated.

- 1 (2) "Anaphylaxis" means a sudden, severe, and potentially life—threatening allergic reaction that occurs when an individual is exposed to an allergen.
- 3 (3) ["Auto-injectable] "EMERGENCY USE epinephrine" means a portable, 4 disposable drug delivery device OR PRODUCT APPROVED BY THE FEDERAL FOOD AND 5 DRUG ADMINISTRATION that contains a premeasured single dose of epinephrine that is 6 used to treat anaphylaxis in an emergency situation.
- 7 (4) "School personnel" means individuals who are employed by a nonpublic 8 school, including part—time employees, teachers and substitute teachers employed by the 9 school for at least 7 days each school year, a school nurse, registered nurse case manager, 10 delegating nurse, and administrative staff.
- 11 (b) Each nonpublic school in the State may establish a policy authorizing school 12 personnel to administer [auto-injectable] **EMERGENCY USE** epinephrine, if available, to a 13 student who is determined to be or perceived to be in anaphylaxis, regardless of whether 14 the student:
- 15 (1) Has been identified as having an anaphylactic allergy, as defined in \S 16 7-426.1 of this subtitle; or
- 17 (2) Has a prescription for epinephrine as prescribed by an authorized licensed health care practitioner under the Health Occupations Article.
- 19 (c) The policy established under subsection (b) of this section shall include:
- 20 (1) Training for school personnel on how to recognize the signs and symptoms of anaphylaxis by a licensed health care practitioner who is authorized to 22 administer [auto-injectable] EMERGENCY USE epinephrine and who has been trained in 23 an established protocol on how to recognize the signs and symptoms of anaphylaxis;
- 24 (2) Procedures for the emergency administration of [auto-injectable] 25 EMERGENCY USE epinephrine;
 - (3) The proper follow–up emergency procedures;
- 27 (4) A provision authorizing a school nurse or other licensed health care 28 practitioner to obtain, and [,] school personnel to store, at a nonpublic school 29 [auto-injectable] EMERGENCY USE epinephrine to be used in an emergency situation;
- 30 (5) A requirement that the nonpublic school develop and implement a method for notifying the parents or guardians of students of the school's policy under this section at the beginning of each school year; and

- 1 (6) An ongoing process for oversight and monitoring by a licensed health 2 care practitioner of the implementation of the policy established under subsection (b) of this 3 section.
 - (d) Except for any willful or grossly negligent act, school personnel who respond in good faith to the anaphylactic reaction of a child in accordance with this section may not be held personally liable for any act or omission in the course of responding to the reaction.
- 7 9.5–117.

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- 8 (a) (1) In this section the following words have the meanings indicated.
- 9 (3) ["Auto-injectable] "EMERGENCY USE epinephrine" has the meaning 10 stated in § 7–426.2 of this article.
- 11 (f) Except for any willfully or grossly negligent act, a child care provider or an 12 employee of a child care provider who responds in good faith to the anaphylactic reaction 13 of a child in accordance with the guidelines implemented under this section or by use of 14 [auto-injectable] EMERGENCY USE epinephrine is immune from civil liability for any act 15 or omission in the course of responding to the reaction.

16 Article - Health - General

- 17 13–702.
- 18 (a) In this subtitle the following words have the meanings indicated.
- 19 (b) "Agent" means an individual who:
- 20 (1) Is at least 18 years of age;
- 21 (2) Has successfully completed, at the expense of an applicant, an 22 educational training program approved by the Department; and
- 23 (3) Is appointed by a certificate holder to administer [auto-injectable] 24 **EMERGENCY USE** epinephrine in accordance with the provisions of this subtitle.
- 25 (c) "Anaphylaxis" means a sudden, severe, and potentially life—threatening 26 allergic reaction that occurs when an individual is exposed to an allergen.
- [(d) "Auto-injectable epinephrine" means a portable, disposable drug delivery device that contains a premeasured single dose of epinephrine that is used to treat anaphylaxis in an emergency situation.]
- 30 **[(e)] (D)** "Certificate" means a certificate or an endorsement on the operating 31 certificate of a youth camp issued by the Department to an individual who operates a youth

- camp under Title 14, Subtitle 4 of this article to obtain, store, and administer [auto-injectable] EMERGENCY USE epinephrine.
- 3 [(f)] (E) "Certificate holder" means an individual who is authorized by the 4 Department to obtain, store, and administer [auto-injectable] EMERGENCY USE 5 epinephrine to be used in an emergency situation.
- 6 (F) "EMERGENCY USE EPINEPHRINE" MEANS A PORTABLE, DISPOSABLE
 7 DRUG DELIVERY DEVICE OR PRODUCT APPROVED BY THE FEDERAL FOOD AND
 8 DRUG ADMINISTRATION THAT CONTAINS A PREMEASURED SINGLE DOSE OF
 9 EPINEPHRINE THAT IS USED TO TREAT ANAPHYLAXIS IN AN EMERGENCY SITUATION.
- 10 (g) "Program" means the Emergency and Allergy Treatment Program.
- 11 (h) "Registered nurse practitioner" has the meaning stated in § 8–101 of the 12 Health Occupations Article.
- 13 (i) "Youth camp" has the meaning stated in § 14–401 of this article.
- 14 13–704.
- 15 (e) An applicant shall have a written policy that includes:
- 16 (1) Authorization for the certificate holder or agent to administer 17 [auto-injectable] **EMERGENCY USE** epinephrine, if available, to an individual who has 18 been determined to be or is believed to be experiencing anaphylaxis, whether or not the 19 individual:
- 20 (i) Has previously been known to have experienced anaphylaxis; or
- 21 (ii) Has a prescription for epinephrine prescribed by an authorized 22 health care practitioner licensed under the Health Occupations Article;
- 23 (2) A requirement that youth camp personnel complete training on how to 24 recognize the symptoms of anaphylaxis;
- 25 (3) Procedures for the emergency administration of [auto-injectable] 26 EMERGENCY USE epinephrine;
- 27 (4) Procedures for proper emergency follow–up;
- 28 (5) Authorization for a certificate holder to obtain and store 29 [auto-injectable] **EMERGENCY USE** epinephrine to be used in an emergency; and

- 1 (6) A requirement that each certificate holder implement a method for notifying the parent or guardian of a camper of the youth camp's policy under this section before the camper's attendance.
- 4 13–705.
- 5 (a) (1) A registered nurse practitioner or a physician licensed to practice 6 medicine in the State may prescribe [auto-injectable] **EMERGENCY USE** epinephrine in 7 the name of a certificate holder.
- 8 (2) A registered nurse practitioner, a pharmacist licensed to practice 9 pharmacy in the State, or a physician may dispense [auto-injectable] **EMERGENCY USE** 10 epinephrine under a prescription issued to a certificate holder.
- 11 (b) A certificate holder may:
- 12 (1) On presentment of a certificate, receive from any registered nurse 13 practitioner or any physician licensed to practice medicine in the State a prescription for 14 [auto-injectable] EMERGENCY USE epinephrine and the necessary paraphernalia for the 15 administration of [auto-injectable] EMERGENCY USE epinephrine; and
- 16 (2) Possess and store prescribed [auto-injectable] EMERGENCY USE 17 epinephrine and the necessary paraphernalia for the administration of [auto-injectable] 18 EMERGENCY USE epinephrine.
 - (c) In an emergency situation when registered nurse practitioner, physician, or emergency medical services are not immediately available, a certificate holder or agent may administer [auto-injectable] **EMERGENCY USE** epinephrine to an individual who is experiencing or believed in good faith by the certificate holder or agent to be experiencing anaphylaxis.
- 24 13–706.

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- 25 (a) A certificate holder shall submit to the Department, on a form required by the Department, a report of each incident that occurs while the youth camp is in session that required the administration of [auto-injectable] EMERGENCY USE epinephrine.
- 28 13-707.
- 29 (a) A cause of action may not arise against a certificate holder or agent authorized under this subtitle for any act or omission when the certificate holder or agent is acting in good faith while administering [auto-injectable] EMERGENCY USE epinephrine to an individual experiencing or believed by the certificate holder or agent to be experiencing anaphylaxis, except where the conduct of the certificate holder or agent amounts to gross negligence, willful or wanton misconduct, or intentionally tortious conduct.

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- 1 (b) (1) A cause of action may not arise against any physician for any act or 2 omission when the physician in good faith prescribes or dispenses [auto-injectable] 3 EMERGENCY USE epinephrine and the necessary paraphernalia for the administration of [auto-injectable] EMERGENCY USE epinephrine to a person certified by the Department under this subtitle.
 - (2) A cause of action may not arise against any pharmacist for any act or omission when the pharmacist in good faith dispenses [auto-injectable] EMERGENCY USE epinephrine and the necessary paraphernalia for the administration of [auto-injectable] EMERGENCY USE epinephrine to a person certified by the Department under this subtitle.
- 10 (3) A cause of action may not arise against any nurse practitioner for any act or omission when the nurse practitioner in good faith prescribes or dispenses 12 [auto-injectable] EMERGENCY USE epinephrine and the necessary paraphernalia for the 13 administration of [auto-injectable] EMERGENCY USE epinephrine to a person certified by 14 the Department under this subtitle.
- 15 13-708.
- 16 (b) An individual may not be held civilly liable in any action arising from or in 17 connection with the administration of [auto-injectable] **EMERGENCY USE** epinephrine by 18 the individual solely because the individual did not possess a certificate issued under this 19 subtitle.
- Subtitle 7A. Emergency Use [Auto-Injectable] Epinephrine Program.
- 21 13–7A–01.
- 22 (a) In this subtitle the following words have the meanings indicated.
- 23 (b) "Agent" means an individual who:
- 24 (1) Is at least 18 years of age;
- 25 (2) Has successfully completed, at the expense of the participating facility, 26 an educational training program approved by the Department under § 13–7A–03 of this 27 subtitle; and
- 28 (3) Is designated by a certificate holder to administer [auto-injectable] 29 **EMERGENCY USE** epinephrine in accordance with the provisions of this subtitle.
- 30 (c) "Anaphylaxis" means a sudden, severe, and potentially life—threatening 31 allergic reaction that occurs when an individual is exposed to an allergen.

- [(d) "Auto-injectable epinephrine" means a portable, disposable drug delivery device that contains a premeasured single dose of epinephrine that is used to treat anaphylaxis in an emergency situation.]
- 4 **[(e)] (D)** "Certificate" means a certificate issued by the Department to an 5 individual to obtain, store, and administer [auto-injectable] **EMERGENCY USE** 6 epinephrine.
- 7 **[(f)] (E)** "Certificate holder" means an individual who is authorized by the 8 Department to obtain, store, and administer [auto-injectable] **EMERGENCY USE** 9 epinephrine to be used in an emergency situation.
- [(g)] **(F)** "Eligible institution" means an institution of higher education that has a food service facility or a recreation and wellness facility on the premises and that is authorized under this subtitle to obtain and store [auto-injectable] **EMERGENCY USE** epinephrine.
- 14 (G) "EMERGENCY USE EPINEPHRINE" MEANS A PORTABLE, DISPOSABLE
 15 DRUG DELIVERY DEVICE OR PRODUCT APPROVED BY THE FEDERAL FOOD AND
 16 DRUG ADMINISTRATION THAT CONTAINS A PREMEASURED SINGLE DOSE OF
 17 EPINEPHRINE THAT IS USED TO TREAT ANAPHYLAXIS IN AN EMERGENCY SITUATION.
- 18 (h) "Food service facility" has the meaning indicated in § 21–301 of this article.
- 19 (i) "Participating facility" means a recreation or wellness facility at an eligible 20 institution or a food service facility, including a food service facility at an eligible 21 institution, in the State that voluntarily participates in the Program.
- 22 (j) "Program" means the Emergency Use [Auto-Injectable] Epinephrine 23 Program established under § 13–7A–02 of this subtitle.
- 24 13–7A–02.
- 25 (a) There is an Emergency Use [Auto-Injectable] Epinephrine Program.
- 26 (b) The purpose of the Program is to authorize individuals employed by a participating facility to obtain and store [auto-injectable] EMERGENCY USE epinephrine and administer [auto-injectable] EMERGENCY USE epinephrine to individuals who are experiencing or are believed to be experiencing anaphylaxis when a physician or emergency medical services are not immediately available.
- 31 (c) (1) Subject to paragraph (4) of this subsection, each participating facility 32 may obtain:

- 1 A prescription for a supply of [auto-injectable] EMERGENCY 2 USE epinephrine from a licensed physician as provided in § 13–7A–06 of this subtitle; and 3 A supply of [auto-injectable] EMERGENCY USE epinephrine 4 from a licensed pharmacist or a licensed physician as provided in § 13-7A-06 of this 5 subtitle. 6 Each participating facility shall store a supply of [auto-injectable] (2)7 **EMERGENCY USE** epinephrine obtained under paragraph (1)(ii) of this subsection: 8 In accordance with the manufacturer's instructions; and (i) 9 In a location that is readily accessible to employees or affiliated (ii) 10 individuals in an emergency situation. Each participating facility shall designate the employees who are 11 (3)12 certificate holders or designated affiliated individuals who are certificate holders who will be responsible for the storage, maintenance, and control of the supply of [auto-injectable] 13 EMERGENCY USE epinephrine. 14 15 A participating facility may not obtain or store [auto-injectable] 16 EMERGENCY USE epinephrine unless the participating facility has at least two employees 17 or designated affiliated individuals who are certificate holders. 18 Each participating facility shall maintain a copy of the certificate issued (5)19 to an employee or a designated affiliated individual under § 13–7A–05 of this subtitle. 20 13-7A-03. 21(a) The Department shall: 22 Develop a method by which certificate holders may submit a report to (5)23the Department about each incident that occurred on the premises of a participating facility 24that involved the administration of [auto-injectable] EMERGENCY USE epinephrine by a 25certificate holder or an agent; and 26 13-7A-06.
- 27 (a) (1) A physician licensed to practice medicine in the State may prescribe 28 [auto-injectable] **EMERGENCY USE** epinephrine in the name of a certificate holder.
- 29 (2) A pharmacist licensed to practice pharmacy in the State or a physician 30 may dispense [auto-injectable] **EMERGENCY USE** epinephrine under a prescription issued 31 to a certificate holder.
 - (b) A certificate holder may:

- 1 (1) On presentment of a certificate, receive from any physician licensed to practice medicine in the State a prescription for [auto-injectable] EMERGENCY USE epinephrine and the necessary paraphernalia for the administration of [auto-injectable] EMERGENCY USE epinephrine; and
- 5 (2) Possess and store prescribed [auto-injectable] EMERGENCY USE 6 epinephrine and the necessary paraphernalia for the administration of [auto-injectable] 7 EMERGENCY USE epinephrine.
- 8 (c) In an emergency situation when a physician or emergency medical services 9 are not immediately available, a certificate holder or an agent may administer 10 [auto-injectable] EMERGENCY USE epinephrine to an individual who is experiencing or is 11 believed in good faith by the certificate holder or agent to be experiencing anaphylaxis.
- 12 13–7A–07.
- 13 (a) Except as provided in paragraph (2) of this subsection, a cause of action (1) 14 may not arise against a certificate holder for any act or omission if the certificate holder or 15 agent is acting in good faith while administering [auto-injectable] EMERGENCY USE 16 epinephrine to an individual who is experiencing or believed by the certificate holder or 17 agent to be experiencing anaphylaxis except where the conduct of the certificate holder or 18 agent amounts to gross negligence, willful or wanton misconduct, or intentionally tortious 19 conduct.
- 20 (2) The provisions of paragraph (1) of this subsection do not apply if a certificate holder or participating facility that makes available, or a certificate holder who administers, [auto-injectable] EMERGENCY USE epinephrine to an individual who is experiencing or is believed by the certificate holder or participating facility to be experiencing anaphylaxis:
- 25 (i) Fails to follow standards and procedures for storage and 26 administration of [auto-injectable] EMERGENCY USE epinephrine; or
- 27 (ii) Administers [auto-injectable] EMERGENCY USE epinephrine 28 that is beyond the manufacturer's expiration date.
- (b) (1) A cause of action may not arise against any physician for any act or omission if the physician in good faith prescribes or dispenses [auto-injectable] EMERGENCY USE epinephrine and the necessary paraphernalia for the administration of [auto-injectable] EMERGENCY USE epinephrine to a certificate holder or participating facility under this subtitle.
- 34 (2) A cause of action may not arise against any pharmacist for any act or 35 omission if the pharmacist in good faith dispenses [auto-injectable] **EMERGENCY USE** 36 epinephrine and the necessary paraphernalia for the administration of [auto-injectable]

- EMERGENCY USE epinephrine to a certificate holder or a participating facility under this subtitle.
 13-7A-08.
- 4 (b) An individual may not be held civilly liable in any action arising from or in connection with the administration of [auto-injectable] **EMERGENCY USE** epinephrine by the individual solely because the individual did not possess a certificate issued under this subtitle.
- 8 13–7A–09.
- A certificate holder shall submit to the Department, in the manner required under § 13–7A–03 of this subtitle, a report of each incident that occurred on the premises of a participating facility that involved the administration of [auto-injectable] EMERGENCY USE epinephrine by a certificate holder or an agent.

13 Article - Health Occupations

- 14 14-5F-01.
- 15 (a) In this subtitle the following words have the meanings indicated.
- [(c) "Auto-injectable epinephrine" means a portable, disposable drug delivery device that contains a premeasured single dose of epinephrine that is used to treat anaphylaxis in an emergency situation.]
- 19 [(d)] (C) "Board" means the State Board of Physicians.
- [(e)] (D) "Committee" means the Naturopathic Medicine Advisory Committee.
- [(f)] (E) "Council" means the Naturopathic Doctors Formulary Council.
- [(g)] **(F)** (1) "Device" means a device used in the diagnosis, treatment, or prevention of disease.
- 24 (2) "Device" does not include:
- 25 (i) Any surgical or dental instrument;
- 26 (ii) Any physical therapy equipment;
- 27 (iii) Any X–ray apparatus; or
- 28 (iv) Any component part or accessory of any of the items listed in 29 items (i) through (iii) of this paragraph.

1 2 3 4	DRUG AD	IVERY MINIS	Y DEVI STRATI	NCY USE EPINEPHRINE" MEANS A PORTABLE, DISPOSABLE ICE OR PRODUCT APPROVED BY THE FEDERAL FOOD AND ON THAT CONTAINS A PREMEASURED SINGLE DOSE OF USED TO TREAT ANAPHYLAXIS IN AN EMERGENCY SITUATION.		
5	14–5F–04.1					
6	(a)	(1)	Ther	e is a Naturopathic Doctors Formulary Council within the Board.		
7	(d)	(1)	The f	formulary adopted by the Board shall include:		
8			(i)	Nonprescription drugs and devices;		
9 10	epinephrine	; and	(ii)	Prescription oxygen and [auto-injectable] EMERGENCY USE		
11			(iii)	Prescription diaphragms and cervical caps for contraception.		
12	14–5F–14.					
13 14 15	(a) A license authorizes a licensee, consistent with naturopathic education and training and competence demonstrated by passing the naturopathic physician licensing examination, to:					
16		(5)	Adm	inister [auto-injectable] EMERGENCY USE epinephrine;		
17 18	SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect June 1, 2025.					
	Approved:			Consequence		
				Governor.		
	President of the Senate.					
				Speaker of the House of Delegates		