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By: Senator Collins

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CHAPTER_____

1 AN ACT concerning

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Licensed Physical Therapists and, Licensed Physical Therapist Assistants<u>,</u> <u>and Licensed Chiropractors with Physical Therapy Privileges</u> - Scope of Practice - Topical Pharmaceutical Agents

5 FOR the purpose of authorizing licensed physical therapists and, licensed physical

- 6 therapist assistants, and licensed chiropractors with physical therapy privileges
- 7 to apply to the skin of a patient certain topical pharmaceutical agents in a
- 8 certain manner and in accordance with certain standards; including within the
- 9 practice of physical therapy the procurement of a topical pharmaceutical agent,
- 10 but excluding that procurement from the practice of limited physical therapy;
- 11 providing that this Act may not be construed to authorize certain physical
- 12 therapy licensees to prescribe or to dispense topical pharmaceutical agents;
- 13 requiring the procurement of a topical pharmaceutical agent to be made from a
- 14 certain distribution permit holder; specifying certain requirements concerning15 the use of a topical pharmaceutical agent by certain physical therapy licensees;
- 16 providing that the State Pharmacy Act does not prohibit certain physical
- 17 therapy licensees from applying a topical pharmaceutical agent in accordance
- 18 with certain requirements; authorizing certain distribution permit holders to
- 19 distribute a prescription drug or device to a licensed physical therapist under
- 20 certain conditions; requiring the State Board of Physical Therapy Examiners, in
- 21 consultation and conjunction with the State Board of Pharmacy and the Board
- 22 of Physician Quality Assurance, to adopt certain regulations and lists; defining
- 23 a certain term; and generally relating to certain physical therapy licensees and
- 24 topical pharmaceutical agents.
- 25 BY repealing and reenacting, without amendments,
- 26 Article Health Occupations
- 27 Section 1-101 (a) and (d)

- 2 (1994 Replacement Volume and 1997 Supplement)
- 3 BY repealing and reenacting, with amendments,
- 4 Article Health Occupations
- 5 Section <u>3-307</u>, 12-102, 12-602, and 13-101
- 6 Annotated Code of Maryland
- 7 (1994 Replacement Volume and 1997 Supplement)
- 8 BY adding to
- 9 Article Health Occupations
- 10 Section 13-310.1
- 11 Annotated Code of Maryland
- 12 (1994 Replacement Volume and 1997 Supplement)

13 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF

14 MARYLAND, That the Laws of Maryland read as follows:

15		Article - Health Occupations
16	1-101.	
17	(a)	In this article the following words have the meanings indicated.
18	(d)	"Department" means the Department of Health and Mental Hygiene.
19	<u>3-307.</u>	
20 21	(a) licensee to p	Except as otherwise provided in this section, a license authorizes the practice chiropractic while the license is effective.
22 23 24		[A] EXCEPT AS OTHERWISE PROVIDED IN SUBSECTION (D) OF THIS A license that includes the right to practice physical therapy authorizes the practice chiropractic and physical therapy while the license is effective.
25 26	(c) certificate.	A license does not authorize a licensee to execute or file a birth or death
27 28	<u>(D)</u> THE FOLL	(1) IN THIS SUBSECTION, "TOPICAL PHARMACEUTICAL AGENTS" MEANS OWING PRESCRIPTION DRUGS:
29		(I) <u>ANESTHETIC AGENTS; AND</u>
30		(II) <u>ANTI-INFLAMMATORY AGENTS.</u>
31 32	PROCURE	(2) <u>A CHIROPRACTOR WITH PHYSICAL THERAPY PRIVILEGES MAY</u> AND APPLY TO THE SKIN TOPICAL PHARMACEUTICAL AGENTS TO THE

<u>SAME EXTENT AS A PHYSICAL THERAPIST UNDER § 13-310.1 OF THIS ARTICLE IF THE</u> <u>CHIROPRACTOR:</u>

3 (I) COMPLIES WITH THE PROCUREMENT REQUIREMENTS OF TITLE 4 12 OF THIS ARTICLE; AND

5(II)APPLIES TO THE SKIN TOPICAL PHARMACEUTICAL AGENTS IN6ACCORDANCE WITH GENERALLY ACCEPTED PRACTICES AND THE EDUCATIONAL7TECHNIQUES IN USE AT SCHOOLS ACCREDITED BY THE COUNCIL ON CHIROPRACTIC8EDUCATION.

9(E)THIS SECTION MAY NOT BE CONSTRUED TO AUTHORIZE A LICENSED10CHIROPRACTOR WITH PHYSICAL THERAPY PRIVILEGES TO PRESCRIBE FOR THE USE11OF A PATIENT, OR TO DISPENSE TO A PATIENT, A TOPICAL PHARMACEUTICAL AGENT.1212-102.

13 (a) (1) In this section the following terms have the meanings indicated.

14 (2) "In the public interest" means the dispensing of drugs or devices by a
15 licensed dentist, physician, or podiatrist to a patient when a pharmacy is not
16 conveniently available to the patient.

17 (3) "Personally preparing and dispensing" means that the licensed 18 dentist, physician, or podiatrist:

19(i)Is physically present on the premises where the prescription is20 filled; and

21(ii)Performs a final check of the prescription before it is provided to22the patient.

(b) This title does not limit the right of an individual to practice a healthoccupation that the individual is authorized to practice under this article.

25 (c) This title does not prohibit:

26 (1) A licensed veterinarian from personally preparing and dispensing the 27 veterinarian's prescriptions;

28 (2) A licensed dentist, physician, or podiatrist from personally preparing 29 and dispensing the dentist's, physician's, or podiatrist's prescriptions when:

30

(i) The dentist, physician, or podiatrist:

Has applied to the board of licensure in this State which
 licensed the dentist, physician, or podiatrist;

33
34 the dispensing of prescription drugs or devices by the dentist, physician, or podiatrist
35 is in the public interest; and

 prescription drugs or dev dispense starter dosages of 		Has received a written permit from that board to dispense at a written permit is not required in order to hout charge;	
4 (ii 5 patient of the prescribing		son for whom the drugs or devices are prescribed is a cian, or podiatrist;	
6 (ii 7 financial interest in a pha		tist, physician, or podiatrist does not have a substantial	
8 (iv	() The den	tist, physician, or podiatrist:	
9 10 this title;	1.	Complies with the labeling requirements of § 12-505 of	
 11 12 on the patient's chart; 	2.	Records the dispensing of the prescription drug or device	
1314 the dentist's, physician's,	3. , or podiatrist's	Allows the Division of Drug Control to enter and inspect office at all reasonable hours;	
 Except for starter dosages or samples without charge, provides the patient with a written prescription, maintains prescription files in accordance with § 12-403(b)(13) of this title, and maintains a separate file for Schedule II prescriptions; 			
 19 20 pharmacy IN ACCORD. 	5. ANCE WITH	Does not direct patients to a single pharmacist or § 12-403(b)(8) of this title; and	
2122 pharmacist or pharmacy	6. ; or	Does not receive remuneration for referring patients to a	
23 (3) A	hospital-based	clinic from dispensing prescriptions to its patients.	
24 (d) This title do	oes not prohibi	t:	
25 (1) A licensed veterinarian from personally dispensing a drug or device 26 sample to a patient of the veterinarian; or			
 27 (2) A licensed dentist, licensed physician, or licensed podiatrist from 28 personally dispensing a drug or device sample to a patient of the licensed dentist, 29 licensed physician, or licensed podiatrist if: 			
30 (i) 31 12-505 of this title;	The san	ple complies with the labeling requirements of §	
32 (ii) No char	ge is made for the sample; and	
33 (ii34 patient's chart.	i) The aut	horized prescriber enters an appropriate record in the	

(e) (1) This title does not prohibit a dentist, physician, or podiatrist from a dministering a prescription drug or device in the course of treating a patient.				
3 (2) For the purposes of paragraph (1) of this subsection, "administering" 4 means the direct introduction of a single dosage of a drug or device at a given time, 5 whether by injection or other means, and whether in liquid, tablet, capsule, or other 6 form.				
7 (f) (1) This title does not prohibit a dentist, physician, or podiatrist from 8 personally dispensing a starter dosage of a prescription drug or device to a patient of 9 the dentist, physician, or podiatrist, provided that:				
10(i)The starter dosage complies with the labeling requirements of §1112-505 of this title;				
12 (ii) No charge is made for the starter dosage; and				
13(iii)The dentist, physician, or podiatrist enters an appropriate14 record on the patient's chart.				
15 (2) For the purposes of paragraph (1) of this subsection, "starter dosage" 16 means an amount of drug or device sufficient to begin therapy:				
17 (i) Of short duration of 72 hours or less; or				
18 (ii) Prior to obtaining a larger quantity of the drug or device to 19 complete the therapy.				
20 (g) This title does not prohibit a dentist, physician, or podiatrist from 21 dispensing a prescription drug or device in the course of treating a patient:				
22 (1) At a medical facility or clinic that specializes in the treatment of 23 medical cases reimbursable through workers' compensation insurance;				
24 (2) At a medical facility or clinic that is operated on a nonprofit basis;				
25 (3) At a health center that operates on a campus of an institution of 26 higher education; or				
27(4)At a public health facility, a medical facility under contract with a28State or local health department, or a facility funded with public funds.				
 (H) THIS TITLE DOES NOT PROHIBIT A LICENSED PHYSICAL THERAPIST OR A LICENSED PHYSICAL THERAPIST ASSISTANT FROM APPLYING TO THE SKIN A TOPICAL PHARMACEUTICAL AGENT IN THE COURSE OF TREATING A PATIENT IN ACCORDANCE WITH TITLE 13 OF THIS ARTICLE <u>OR A LICENSED CHIROPRACTOR WITH</u> PHYSICAL THERAPY PRIVILEGES FROM APPLYING TO THE SKIN A TOPICAL PHARMACEUTICAL AGENT IN THE COURSE OF TREATING A PATIENT IN ACCORDANCE WITH TITLE 3 OF THIS ARTICLE. 				

36 [(h)] (I) This title does not limit the right of a general merchant to sell:

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1	(1)	Any nonprescription drug or device;	
2	(2)	Any commonly used household or domestic remedy; or	
3 4 otherwise.	(3)	Any farm remedy or ingredient for a spraying solution, in bulk or	
5 [(i)] 6 provisions o 7 shall:	(J) f this sec	A dentist, physician, or podiatrist who fails to comply with the tion governing the dispensing of prescription drugs or devices	
8	(1)	Have the dispensing permit revoked; and	
9 10 12-602.	(2)	Be subject to disciplinary actions by the appropriate licensing board.	
11 (a)	(1)	In this section, the following words have the meanings indicated.	
12 13 section to d 14 distributor,	(2) istribute jobber, n	"Distribution permit" means a permit issued by the Board under this prescription drugs or devices into, out of, or within the State as a nanufacturer, or wholesaler, wherever located.	
15 (3) "Prescription drugs or devices" means any drug or device that, 16 because of its toxicity or other potential for harmful effect, the method of its use, or 17 the collateral measures necessary for its use, is required by federal law to bear a 18 cautionary label warning against dispensing without a prescription or is designated 19 by the Department as not safe for use except under the supervision of a practitioner 20 licensed to administer drugs or devices of this nature.			
21 (b)	This see	ction does not affect any person while distributing:	
22	(1)	Feed for livestock or poultry;	
23	(2)	Fertilizers;	
24	(3)	Fungicides;	
25	(4)	Insecticide;	
26	(5)	Land plaster;	

Devices, drugs, or supplies of any kind for the treatment, care, or cure

27

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(6)

(7)

29 (8)30 of farm animals.

Lime;

Seeds; or

 (c) A person shall hold a distribution permit issued by the Board before the person may distribute prescription drugs or devices as a distributor, jobber, manufacturer, or wholesaler. 				
4 (d) To qua	o qualify for a distribution permit, an applicant shall:			
5 (1) Satisfy the Board that the applicant will distribute prescription 6 drugs or devices in compliance with the restrictions specified in subsection (e) of this 7 section; and				
8 (2) 9 of this section.				
10 (e) A distr 11 only:				
12 (1)	To the following persons:			
13	(i) An authorized prescriber;			
14	(ii) A pharmacy permit holder;			
15	(iii) A distribution permit holder; [or]			
16 17 SPECIFIED IN § 13	(IV) A LICENSED PHYSICAL THERAPIST UNDER THE CONDITIONS 3-310.1 OF THIS ARTICLE; OR			
18 19 <u>PRIVILEGES UND</u>	(V) <u>A LICENSED CHIROPRACTOR WITH PHYSICAL THERAPY</u> DER THE CONDITIONS SET FORTH IN § 3-307 OF THIS ARTICLE; OR			
20	[(iv)] (\forall) (VI) Any other person approved by the Board; and			
21 (2) 22 section.	In compliance with any rules and regulations adopted under this			
23 (f) To app	ly for a distribution permit, an applicant shall:			
24 (1) 25 provides; and	Submit an application to the Board on the form that the Board			
26 (2)	Pay to the Board an application fee set by the Board.			
27 (g) The Board shall issue a distribution permit to any applicant who meets the 28 requirements of this section.				

29 (h) A distribution permit issued under this section authorizes the distribution 30 permit holder to distribute prescription drugs or devices as a distributor, jobber,

31 manufacturer, or wholesaler while the distribution permit is effective.

	regulations regarding the distribution of prescription drugs or devices including			
4 (1) 5 issuance or renewal	(1) Qualifications and information required from an applicant seeking issuance or renewal of a distribution permit;			
1 1 0	Minimum requirements for the receipt, storage, and handling evices, security precautions, quality control, recordkeeping, ritten procedures, policy, and responsibilities of personnel;	of		
	The education and experience of personnel employed in positi referenced in paragraph (2) of this subsection and generally ag out those duties that are subject to State licensure is subtitle; and	ons		
	Disciplinary action to be taken against a permit holder who is guilty or nolo contendere to a violation of State, federal, or lo ates regulations promulgated by the Board under this section.	cal		
16(j)(1)17date, unless the distr18subsection.	A distribution permit expires on the December 31 after its effect oution permit is renewed for a 1-year term as provided in this	ctive		
	At least 1 month before a distribution permit expires, the Boar n permit holder, by first-class mail to the last known address o holder, a renewal notice that contains a statement of:			
22	(i) The date on which the current distribution permit exp	vires;		
2324 the Board for the ren25 expires; and	(ii) The date by which the renewal application must be rewal to be issued and mailed before the distribution permit	ceived by		
26	(iii) The amount of the renewal fee.			
27 (3)28 periodically may rer29 holder:	Before a distribution permit expires, a distribution permit hold w it for an additional 1-year term, if the distribution permit	er		
30	(i) Otherwise is entitled to a distribution permit;			
31	(ii) Pays to the Board a renewal fee set by the Board; and	l		
3233 Board requires.	(iii) Submits to the Board a renewal application on the for	m that the		
34 (4)	The Board shall renew the distribution permit of each distribut	tion		

35 permit holder who meets the requirements of this section and any regulation adopted 36 under this section.

1 (k) Each distribution permit shall be displayed conspicuously in the place for 2 which it is issued.

3 (l) A distribution permit is not transferable.

4 (m) Subject to any other restriction provided by law, a person may not 5 purchase or obtain any prescription drugs or devices unless the drug or device is 6 obtained from a distribution permit holder, a licensed pharmacist, or an authorized 7 prescriber.

8 (n) A person may not violate any rule or regulation adopted under this section.

9 (o) A distribution permit is void on conviction of the distribution permit holder 10 for any violation of:

11 (1) This section; or

12 (2) Any rule or regulation adopted by the Board under this section.

13 13-101.

14 (a) In this title the following words have the meanings indicated.

15 (b) "Board" means the State Board of Physical Therapy Examiners.

16 (c) "License" means, unless the context requires otherwise, a license issued by 17 the Board to practice:

18 (1) Physical therapy; or

19 (2) Limited physical therapy.

20 (d) "Licensed physical therapist" means, unless the context requires
21 otherwise, a physical therapist who is licensed by the Board to practice physical
22 therapy.

(e) "Licensed physical therapist assistant" means, unless the context requires
otherwise, a physical therapist assistant who is licensed by the Board to practice
limited physical therapy.

(f) "Physical therapist" means an individual, licensed by the State Board of
Physical Therapy Examiners, who practices physical therapy and who has passed the
national physical therapy licensing examination administered or accepted by the
Board.

30 (g) "Physical therapist assistant" means an individual who practices limited
31 physical therapy and who has passed the national physical therapy licensing
32 examination administered or accepted by the Board.

33 (h) (1) "Practice limited physical therapy" means to practice the health
 34 specialty concerned with:

1	(i)	The prevention of disability in individuals; and	
23 acquired disability.	(ii)	The physical rehabilitation of individuals with a congenital or	
4 (2) 5 paragraph (3) of this	e limited physical therapy" includes, except as provided in on,] SUBSECTION:		
		[administering] ADMINISTERING treatment with therapeutic mechanical devices, or therapeutic agents that use the operties of air, water, electricity, sound, or radiant	
10 11 ACCORDANCE W	(II) ITH § 13	APPLYING TO THE SKIN TOPICAL PHARMACEUTICAL AGENTS IN -310.1 OF THIS TITLE.	
12 (3)	"Practio	e limited physical therapy" does not include:	
13(i)Performing and interpreting tests and measurements of14neuromuscular and musculoskeletal functions to aid treatment;			
15 16 [or]	(ii)	Planning treatment programs that are based on test findings;	
17 18 OR	(III)	THE PROCUREMENT OF A TOPICAL PHARMACEUTICAL AGENT;	
19	[(iii)]	(IV) Using:	
20		1. X rays;	
21		2. Radioactive substances; or	
22		3. Electricity for cauterization or surgery.	
23 (i) (1) 24 concerned with:	"Practio	e physical therapy" means to practice the health specialty	
25	(i)	The prevention of disability in individuals; and	
2627 acquired disability.	(ii)	The physical rehabilitation of individuals with a congenital or	
28 (2)	"Practio	e physical therapy" includes:	
29 30 individuals;	(i)	Performing an evaluation of the physical therapy needs of	
31 (ii) Performing and interpreting tests and measurements of 32 neuromuscular and musculoskeletal functions to aid treatment;			

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1 2 [and]		(iii)	Planning treatment programs that are based on test findings;	
5 devices, or	therapeut	tic agents	Except as provided in paragraph (3) of this subsection, therapeutic exercise, therapeutic massage, mechanical that use the physical, chemical, or other properties of or radiant energy; AND	
7 8 PHARMAG	CEUTICA	(V) AL AGEN	PROCURING AND APPLYING TO THE SKIN A TOPICAL NT IN ACCORDANCE WITH § 13-310.1 OF THIS TITLE.	
9	(3)	"Practi	ce physical therapy" does not include using:	
10		(i)	X rays;	
11		(ii)	Radioactive substances; or	
12		(iii)	Electricity for cauterization or surgery.	
13 (j) 14 limited by		"Restricted license" means a license issued by the Board under and as 13-314 of this title to practice physical therapy.		
15 (k) 16 limited by	5 (k) "Temporary license" means a license issued by the Board under and as 6 limited by § 13-313 of this title to practice:			
17	(1)	Physica	al therapy; or	
18	(2)	Limite	d physical therapy.	
19 13-310.1.				
	21 PHYSICAL THERAPIST OR PHYSICAL THERAPIST ASSISTANT TO PRESCRIBE FOR THE 22 USE OF A PATIENT, OR TO DISPENSE TO A PATIENT, A TOPICAL PHARMACEUTICAL			
24 (B) 25 FOLLOW	24 (B) IN THIS SECTION, "TOPICAL PHARMACEUTICAL AGENT" MEANS THE 25 FOLLOWING PRESCRIPTION DRUGS:			
26	(1)	AN AN	VTIBACTERIAL AGENT;	
27	(2)	A DEB	BRIDING AGENT;	
28	(3)	AN AN	NESTHETIC AGENT; AND	
29	(4)	AN AN	TI-INFLAMMATORY AGENT.	
30 (C) 31 THERAPI 32 AGENT O		STANT N	ENSED PHYSICAL THERAPIST OR LICENSED PHYSICAL MAY APPLY TO THE SKIN A TOPICAL PHARMACEUTICAL	

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1	(I)	DIRECT APPLICATION;		
2	(II)	IONTOPHORESIS; OR		
3	(III)	PHONOPHORESIS.		
6 AGENT IN ACCO 7 EDUCATIONAL T	 4 (2) A LICENSED PHYSICAL THERAPIST OR LICENSED PHYSICAL 5 THERAPIST ASSISTANT SHALL APPLY TO THE SKIN A TOPICAL PHARMACEUTICAL 6 AGENT IN ACCORDANCE WITH GENERALLY ACCEPTED PRACTICES AND THE 7 EDUCATIONAL TECHNIQUES IN USE AT SCHOOLS ACCREDITED BY THE COMMISSION 8 ON ACCREDITATION IN PHYSICAL THERAPY EDUCATION. 			
10 SHALL BE OBTA	9 (D) A TOPICAL PHARMACEUTICAL AGENT PROCURED UNDER THIS SECTION 10 SHALL BE OBTAINED FROM A PERSON THAT HOLDS A DISTRIBUTION PERMIT ISSUED 11 UNDER § 12-602 OF THIS ARTICLE.			
13 LICENSED PHYS	12 (E) TO USE A TOPICAL PHARMACEUTICAL AGENT UNDER THIS SECTION, A 13 LICENSED PHYSICAL THERAPIST OR A LICENSED PHYSICAL THERAPIST ASSISTANT 14 SHALL ENSURE THAT THE ORIGINAL LABEL OF THE MANUFACTURER:			
15 (1)	IS AFI	FIXED TO THE TOPICAL PHARMACEUTICAL AGENT; AND		
16 (2)	INCLU	JDES:		
17	(I)	THE NAME OF THE MANUFACTURER;		
18 19 AGENT;	(II)	THE NAME AND STRENGTH OF THE TOPICAL PHARMACEUTICAL		
20	(III)	THE LOT NUMBER; AND		
21 22 AGENT.	(IV)	THE EXPIRATION DATE OF THE TOPICAL PHARMACEUTICAL		
23 (F) A LIC 24 ASSISTANT:	ENSED I	PHYSICAL THERAPIST OR A LICENSED PHYSICAL THERAPIST		
		L HAVE APPROPRIATE DOCUMENTATION IN THE PATIENT'S CERNING THE APPLICATION OF A TOPICAL PHARMACEUTICAL		
	O ENTEF THE LICE	L ALLOW THE OFFICE OF DRUG CONTROL OF THE & AND INSPECT THE OFFICE OF THE LICENSED PHYSICAL ENSED PHYSICAL THERAPIST ASSISTANT AT ALL		
		PHYSICAL THERAPIST OR A LICENSED PHYSICAL THERAPIST TOPICAL PHARMACEUTICAL AGENTS:		
34 <u>(1)</u> 35 <u>APPLICATION IS</u>		NTREATING A PATIENT REFERRED BY A PHYSICIAN IF THE TENT WITH THE REFERRAL; AND		

1(2)WHEN TREATING A PATIENT WHO WAS NOT REFERRED BY A2PHYSICIAN IF THE APPLICATION IS CONSISTENT WITH THE EVALUATION OF THE3PATIENT'S TREATMENT NEEDS.

4 (H) IN CONJUNCTION WITH THE STATE BOARD OF PHARMACY AND THE
5 BOARD OF PHYSICIAN QUALITY ASSURANCE, THE BOARD SHALL DEVELOP A LIST OF
6 TOPICAL PHARMACEUTICAL AGENTS THAT A LICENSED PHYSICAL THERAPIST, A
7 LICENSED PHYSICAL THERAPIST ASSISTANT, OR A LICENSED CHIROPRACTOR WITH
8 PHYSICAL THERAPY PRIVILEGES MAY PROCURE.

9 (G) (I) IN CONSULTATION WITH THE STATE BOARD OF PHARMACY <u>AND THE</u>
10 <u>BOARD OF PHYSICIAN QUALITY ASSURANCE</u>, THE BOARD SHALL ADOPT
11 REGULATIONS CONCERNING THE STORAGE <u>AND USE</u> OF TOPICAL PHARMACEUTICAL
12 AGENTS PROCURED UNDER THIS SECTION.

13 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect 14 October 1, 1998.