J1 (5lr1518)

## ENROLLED BILL

-- Finance/Health and Government Operations --

Introduced by Senators Teitelbaum, Astle, Della, Dyson, Exum, Gladden, Haines, Hollinger, Hooper, Kelley, Lawlah, Middleton, Pipkin, and Ruben

	Read and Examined by Proofreaders:						
		Proofreader					
	ed with the Great Seal and presented to the Governor, for his approval thisday of at o'clock,M.	Proofreader					
		President					
	CHAPTER						
1 A	AN ACT concerning						
2 3	<u>Task Force on the Establishment of a Prescription Drug Repository</u> Program						
4 F 5	FOR the purpose of <del>requiring Medbank of Maryland, Inc., in collaboration with the</del> State Board of Pharmacy, to establish a Prescription Drug Repository Program						
6	to accept and dispense prescription drugs donated for the purpose of dispensing						
7	to certain individuals; providing that the Program may only accept and dispense						
8	drugs in certain unit dose packaging; providing for a certain exception;						
9	prohibiting the Program from accepting or dispensing drugs that bear a certain						
10	expiration date or may be adulterated; authorizing any person to donate						
11	prescription drugs to the Program; specifying that drugs may only be donated to						
12	certain entities that participate in the Program; requiring an entity that seeks						
13	to participate in the Program to apply to Medbank of Maryland, Inc. in the form						
14	and manner required; specifying the persons who can receive drugs donated						
15	through the Program; requiring a drug donated through the Program to be						

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1	dispense	ed throug	<del>sh a presc</del>	ription issued by an authorized prescriber; requiring			
2		entity that accepts donated drugs to comply with certain laws and conduct a					
3	certain inspection; authorizing an entity to charge a handling fee to individuals						
4	receiving donated drugs; prohibiting drugs donated to the Program from being						
5	resold; prohibiting for certain matters a certain person who acts in good faith						
6				ain prosecution, liability, or disciplinary action;			
7	requiring	<del>g Medba</del>	<del>nk of Ma</del>	ryland, Inc. to establish certain requirements,			
8				n or before a certain date; defining certain terms;			
9	establish	ning a Ta	isk Force	on the Establishment of a Prescription Drug			
10	Reposito	ory Prog	ram; prov	riding for the composition, chair, staffing, and duties of			
11	the Task	Force; 1	requiring	the Task Force to submit a report to the Governor and			
12				or before a certain date; providing for the termination			
13				relating to a Task Force on the Establishment of a			
14				ory Program.			
	1		C 1				
15	BY adding t	$\Theta$					
16			General				
17	Section						
18			of Maryl	and			
19			•	ne and 2004 Supplement)			
	(2000 11	-pracein		and 2001 Supplement)			
20	SECTIO	N 1. BF	IT ENA	CTED BY THE GENERAL ASSEMBLY OF			
				of Maryland read as follows:			
		,		<del></del>			
22				Article - Health - General			
23	<del>15 124.3.</del>						
24	<del>(A)</del>	<del>(1)</del>	IN THI	S SECTION THE FOLLOWING WORDS HAVE THE MEANINGS			
25	INDICATE	D <del>.</del>					
26		<del>(2)</del>	"HEAL	TH CARE FACILITY" MEANS:			
27			<b>(I</b> )	A HOSDITAL.			
27			<del>(I)</del>	A HOSPITAL;			
28			<del>(II)</del>	A HOSPICE CARE PROGRAM;			
20			(11)	A HOOF ICE CARE I ROOKAM,			
29			<del>(III)</del>	A NURSING HOME:			
			(111)	THURSHU HOME,			
30			<del>(IV)</del>	A HOME HEALTH AGENCY:			
-			(11)	THOME HERETH HOLIVOT,			
31			<del>(V)</del>	AN INTERMEDIATE CARE FACILITY FOR THE MENTALLY			
	RETARDEI	<u></u> -	( • )	THE HEALTH OF THE THORDER TO THE MELLINEST			
2ر	KL17 HKDEI	,					
33			<del>(VI)</del>	A FACILITY THAT PROVIDES TREATMENT OR OTHER SERVICES			
	EOD INDIA	IDLIAI		HAVE MENTAL DISORDERS; OR			
J4	TOR HADIA	1DU/AL	<del>o wnu i</del>	TAY D MIDITAL DISCRUDENS, OK			

(VII) AN ASSISTED LIVING PROGRAM.

- "HEALTH CARE PRACTITIONER" MEANS AN INDIVIDUAL LICENSED 1 2 OR CERTIFIED UNDER THIS ARTICLE TO PROVIDE HEALTH CARE. "NONPROFIT CLINIC" MEANS A PUBLIC OR PRIVATE NONPROFIT 4 ORGANIZATION THAT PROVIDES PRIMARY OR SPECIALTY OUTPATIENT HEALTH CARE 5 SERVICES TO INDIGENT AND UNINSURED INDIVIDUALS FOR FREE OR AT REDUCED 6 COST. "PRESCRIPTION DRUG" HAS THE MEANING STATED IN § 21-201 OF <del>(5)</del> 7 8 THIS ARTICLE. 9 "PROGRAM" MEANS THE PRESCRIPTION DRUG REPOSITORY <del>(6)</del> 10 PROGRAM. (B) MEDBANK OF MARYLAND, INC., IN COLLABORATION WITH THE STATE 12 BOARD OF PHARMACY, SHALL ESTABLISH A PRESCRIPTION DRUG REPOSITORY 13 PROGRAM TO ACCEPT AND DISPENSE PRESCRIPTION DRUGS DONATED FOR THE 14 PURPOSE OF DISPENSING TO INDIVIDUALS WHO ARE RESIDENTS OF THE STATE AND 15 MEET ELIGIBILITY REQUIREMENTS ESTABLISHED FOR THE PROGRAM. <del>(C)</del> EXCEPT AS PROVIDED IN PARAGRAPH (2) OF THIS SUBSECTION, THE 16 17 PROGRAM MAY ONLY ACCEPT AND DISPENSE DRUGS IN THEIR ORIGINAL UNOPENED. 18 SEALED, AND TAMPER EVIDENT UNIT DOSE PACKAGING. 19 (2)THE PROGRAM MAY ACCEPT AND DISPENSE DRUGS PACKAGED IN 20 SINGLE UNIT DOSES WHEN THE OUTSIDE PACKAGING IS OPENED IF THE SINGLE 21 UNIT DOSE PACKAGING IS UNDISTURBED. THE PROGRAM MAY NOT ACCEPT OR DISPENSE DRUGS THAT: 22 (3)BEAR AN EXPIRATION DATE THAT IS LESS THAN 6 MONTHS 23 24 FROM THE DATE THE DRUG IS DONATED; OR
- MAY BE ADULTERATED ACCORDING TO THE STANDARDS OF § 25 (II)
- 26 21 216 OF THIS ARTICLE.
- ANY PERSON, INCLUDING AN INDIVIDUAL, A DRUG MANUFACTURER, 2.7 <del>(D)</del> <del>(1)</del>
- 28 OR A HEALTH CARE FACILITY, MAY DONATE PRESCRIPTION DRUGS TO THE
- 29 PROGRAM.
- 30 (2)DRUGS MAY ONLY BE DONATED AT A PHARMACY, HOSPITAL, OR
- 31 NONPROFIT CLINIC THAT PARTICIPATES IN THE PROGRAM.
- 32 <del>(E)</del> <del>(1)</del> A PHARMACY, HOSPITAL, OR NONPROFIT CLINIC SEEKING TO
- 33 PARTICIPATE IN THE PROGRAM SHALL APPLY IN THE FORM AND MANNER REQUIRED
- 34 BY MEDBANK OF MARYLAND, INC.
- 35 A PHARMACY, HOSPITAL, OR NONPROFIT CLINIC THAT PARTICIPATES
- 36 IN THE PROGRAM MAY ONLY DISPENSE DRUGS DONATED THROUGH THE PROGRAM

1 TO INDIVIDUALS WHO ARE RESIDENTS OF THE STATE AND MEET THE ELIGIBILITY

2 STANDARDS ESTABLISHED BY MEDBANK OF MARYLAND, INC. A DRUG DONATED THROUGH THE PROGRAM MAY ONLY BE 4 DISPENSED ON A PRESCRIPTION ISSUED BY AN AUTHORIZED PRESCRIBER. <del>(4)</del> A PHARMACY, HOSPITAL, OR NONPROFIT CLINIC THAT ACCEPTS 6 DONATED DRUGS SHALL: <del>(I)</del> COMPLY WITH ALL APPLICABLE FEDERAL LAWS AND LAWS OF 8 THIS STATE PERTAINING TO STORAGE AND DISTRIBUTION OF DANGEROUS DRUGS: 9 AND 10 <del>(II)</del> INSPECT ALL DRUGS BEFORE DISPENSING TO DETERMINE 11 THAT THE DRUGS ARE NOT ADULTERATED. <del>(5)</del> THE PHARMACY, HOSPITAL, OR NONPROFIT CLINIC MAY CHARGE 12 13 INDIVIDUALS RECEIVING DONATED DRUGS A HANDLING FEE ESTABLISHED IN 14 ACCORDANCE WITH REQUIREMENTS ESTABLISHED BY MEDBANK OF MARYLAND, 15 <del>INC.</del> 16 (6)DRUGS DONATED TO THE PROGRAM MAY NOT BE RESOLD. THIS SUBSECTION APPLIES TO: 17 <del>(E)</del> (1)18 (I)**MEDBANK OF MARYLAND, INC.**; 19 (II)THE STATE BOARD OF PHARMACY: 20 (III)THE SECRETARY OF HEALTH AND MENTAL HYGIENE; 21 (IV)ANY PERSON THAT DONATES DRUGS TO THE PROGRAM; AND 22 <del>(V)</del> ANY PHARMACY, HOSPITAL, NONPROFIT CLINIC, OR HEALTH 23 CARE PRACTITIONER THAT ACCEPTS OR DISPENSES DRUGS UNDER THE PROGRAM. FOR MATTERS RELATED TO DONATING, ACCEPTING, OR DISPENSING 24 25 DRUGS UNDER THE PROGRAM, A PERSON DESCRIBED IN PARAGRAPH (1) OF THIS 26 SUBSECTION THAT ACTS IN GOOD FAITH MAY NOT BE SUBJECT TO: 27 <del>(I)</del> **CRIMINAL PROSECUTION**; 28 (II)LIABILITY IN TORT OR OTHER CIVIL ACTION FOR INJURY. 29 DEATH, OR LOSS TO PERSON OR PROPERTY: OR  $\frac{(III)}{(III)}$ 30 DISCIPLINARY ACTION BY A PROFESSIONAL LICENSING BOARD. A DRUG MANUFACTURER ACTING IN GOOD FAITH MAY NOT BE 31 32 SUBJECT TO CRIMINAL PROSECUTION OR LIABILITY IN TORT OR OTHER CIVIL 33 ACTION FOR INJURY, DEATH, OR LOSS TO PERSON OR PROPERTY FOR MATTERS 34 RELATED TO THE DONATION, ACCEPTANCE, OR DISPENSING OF A DRUG

- **UNOFFICIAL COPY OF SENATE BILL 441** 5 1 MANUFACTURED BY THE DRUG MANUFACTURER THAT IS DONATED BY ANY PERSON 2 UNDER THE PROGRAM, INCLUDING LIABILITY FOR FAILURE TO TRANSFER OR 3 COMMUNICATE PRODUCT OR CONSUMER INFORMATION OR THE EXPIRATION DATE 4 OF THE DONATED DRUG. ON OR BEFORE OCTOBER 1, 2006, AND IN CONSULTATION WITH THE <del>(G)</del> 6 STATE BOARD OF PHARMACY AND THE SECRETARY, MEDBANK OF MARYLAND, INC. 7 SHALL ESTABLISH REQUIREMENTS FOR THE PROGRAM. 8 (2)THE REQUIREMENTS SHALL INCLUDE: PARTICIPATION REQUIREMENTS FOR PHARMACIES, 9 <del>(I)</del> 10 HOSPITALS, AND NONPROFIT CLINICS TO ACCEPT AND DISPENSE DONATED DRUGS 11 UNDER THE PROGRAM: 12 <del>(II)</del> STANDARDS AND PROCEDURES FOR ACCEPTING. SAFELY 13 STORING, AND DISPENSING DONATED DRUGS; STANDARDS AND PROCEDURES FOR INSPECTING DONATED 14  $\frac{(III)}{(III)}$ 15 DRUGS TO DETERMINE THAT: THE ORIGINAL UNIT DOSE PACKAGING IS SEALED AND 16 1 17 TAMPER EVIDENT; AND 18 <del>2.</del> THE DRUGS ARE UNADULTERATED, SAFE, AND SUITABLE 19 FOR DISPENSING: (IV) ELIGIBILITY STANDARDS BASED ON ECONOMIC NEED FOR 20 21 INDIVIDUALS TO RECEIVE DRUGS: <del>(V)</del> A MEANS, SUCH AS AN IDENTIFICATION CARD, BY WHICH AN 22 23 INDIVIDUAL WHO IS ELIGIBLE TO RECEIVE DONATED DRUGS MAY DEMONSTRATE 24 ELIGIBILITY TO THE PHARMACY, HOSPITAL, OR NONPROFIT CLINIC DISPENSING THE 25 DRUGS; (VI)A FORM THAT AN INDIVIDUAL RECEIVING A DRUG FROM THE 26 27 PROGRAM MUST SIGN BEFORE RECEIVING THE DRUG TO CONFIRM THAT THE 28 INDIVIDUAL UNDERSTANDS THE IMMUNITY PROVISIONS OF THE PROGRAM:
- A FORMULA TO DETERMINE THE AMOUNT OF A HANDLING FEE 29 (VII)
- 30 THAT PHARMACIES, HOSPITALS, AND NONPROFIT CLINICS MAY CHARGE TO DRUG
- 31 RECIPIENTS TO COVER RESTOCKING AND DISPENSING COSTS:
- 32 <del>(VIII)</del> 1. A LIST OF DRUGS THAT THE REPOSITORY WILL ACCEPT:
- 33 A LIST OF DRUGS THAT THE REPOSITORY WILL NOT
- 34 ACCEPT. INCLUDING A STATEMENT AS TO WHY THE DRUG IS INELIGIBLE FOR
- 35 DONATION; AND

		-		3. FOR AN INDIVIDUAL DONOR, A FORM EACH DONOR MUSDONOR IS THE OWNER OF THE DRUGS AND INTENDS TO HEM TO THE PROGRAM; AND			
4 5	MARYLAND	<del>), INC. (</del>	` /	ANY OTHER STANDARDS AND PROCEDURES MEDBANK OF ERS APPROPRIATE.			
6 7	(a) There is a Task Force on the Establishment of a Prescription Drug Repository Program.						
8	<u>(b)</u>	The Tasl	K Force c	onsists of the following members:			
9 10	of the Senate		two men	nbers of the Senate of Maryland, appointed by the President			
11 12	the House;	<u>(2)</u>	two men	nbers of the House of Delegates, appointed by the Speaker of			
13 14	designee;	(3)	the Secre	etary of Health and Mental Hygiene, or the Secretary's			
15 16	Executive Di			utive Director of the State Board of Pharmacy, or the			
19	Executive Di	rector's c	<del>lesignee;</del>	utive Director of the Maryland Health Insurance Plan, or the and one representative of the Board of Directors for the lan, as determined by the Chairman of the Board of			
21 22	•			esentative of the State Board of Pharmacy, as determined by ed of Pharmacy;			
23 24	Mental Hygie		the follo	wing two members, appointed by the Secretary of Health and			
25 26				one representative of the Maryland Medical Assistance Program and Mental Hygiene; and			
27 28	<u>Department</u> of	of Health	<u>(ii)</u> and Mer	one representative of the Office of Health Care Quality in the ntal Hygiene; and			
29	!	<u>(6)</u>	the follo	wing six eight members, appointed by the Governor:			
30			<u>(i)</u>	one representative of the American Cancer Society;			
31			<u>(ii)</u>	one hospital representative;			
32			(iii)	one nursing home representative;			
33			<u>(iv)</u>	one representative of a community health center;			

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1	<u>(v)</u>	one pharmacy representative; and	
2	<u>(vi)</u>	one representative of the Medbank Program;	
3	<u>(vii)</u>	one representative of the pharmaceutical industry; and	
4 5 <i>Pharmacy</i> .	<u>(viii)</u>	one representative of the University of Maryland School of	
6 <u>(c)</u>	The members shall elect a chair from among the members.		
7 <u>(d)</u> 8 <u>Task Force.</u>	The Department of Health and Mental Hygiene shall provide staff for the		
9 <u>(e)</u>	A member of th	e Task Force may not receive compensation.	
10 <u>(f)</u>	The Task Force shall:		
11 12 <u>Prescription</u>	11 (1) study and make recommendations regarding the establishment of a 12 Prescription Drug Repository Program in the State, including:		
13	<u>(i)</u>	types of drugs that may be donated to the Program;	
14	<u>(ii)</u>	types of drugs that may not be donated to the Program;	
15	(iii)	who may donate drugs to the Program;	
16	<u>(iv)</u>	entities that may receive drugs for distribution;	
17 18 <u>donated dru</u>	<u>(v)</u>	standards and procedures for accepting, storing, and dispensing	
19 20 <u>donated dru</u>	<u>(vi)</u>	eligibility requirements for individuals wishing to receive	
21	(vii)	standards and procedures for inspecting donated drugs;	
22	(viii)	the appropriate entity to operate the Program;	
23	<u>(ix)</u>	<u>liability issues;</u>	
24	<u>(x)</u>	fees; and	
25 26 <u>Drug Repos</u>	(xi) sitory Program; ar	any other matter relating to the establishment of a Prescription and	
27 (2) report its findings and recommendations to the Governor and, in 28 accordance with § 2-1246 of the State Government Article, the General Assembly, on 29 or before January 1, 2006.			

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- 1 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take
- 2 effect October July 1, 2005. It shall remain effective for a period of 1 year and, at the
- 3 end of June 30, 2006, with no further action required by the General Assembly, this
- 4 Act shall be abrogated and of no further force and effect.