HOUSE BILL 1030

J2 (7lr2476)

ENROLLED BILL

— Health and Government Operations/Education, Health, and Environmental Affairs —
Introduced by Delegate Montgomery Delegates Montgomery, Hammen,
Benson, Bromwell, Costa, Elliott, Hubbard, Kach, Kipke, Kullen,
McDonough, Mizeur, Morhaim, Nathan-Pulliam, Oaks, Pena-Melnyk,
Pendergrass, Riley, V. Turner, and Weldon

Read and	Examined by Proo	freaders:	
		P	roofreader.
		P	roofreader.
Sealed with the Great Seal and	presented to the	Governor, for his app	proval this
day of	at	o'clock, _	M.
			Speaker.
	CHAPTER		
AN ACT concerning			
State Board of Pharmacy Wholesale Distributor Pern	Requirements		
FOR the purpose of altering the repermit to include a certain requiring a certain pedigree State; requiring the State l	n inspection and for prescription d	the posting of a cer rugs or devices distrib	tain bond; uted in the

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

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

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

Italics indicate opposite chamber/conference committee amendments.



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41 42 certain pedigree and inspection requirements; defining a certain term; and generally relating to permit requirements for wholesale drug distribution.

FOR the purpose of requiring a wholesale distributor to hold a permit issued by the State Board of Pharmacy before the wholesale distributor engages in the wholesale distribution of prescription drugs or devices in the State; requiring certain entities to hold a wholesale distributor permit; providing that certain requirements for obtaining a permit do not apply to a manufacturer who distributes certain prescription drugs; requiring a permit to be displayed in a certain manner; providing that a permit is not transferable; prohibiting a person from purchasing or obtaining a prescription drug or device unless it is purchased or obtained from certain persons; authorizing the Board to grant a certain deemed status to certain wholesale distributors and to issue a permit to certain wholesale distributors by reciprocity; establishing certain requirements and procedures for applying for a permit; prohibiting the Board from issuing a permit unless the Board or its designee takes certain actions; establishing requirements for certain criminal history records checks and a certain surety bond: requiring the Board to provide a certain notification to an applicant within a certain period of time; providing for the expiration and renewal of a permit; authorizing the Board to deny, suspend, or revoke a permit under certain circumstances; requiring the Board to adopt regulations that require certain inspections; authorizing the Board to adopt regulations establishing certain requirements; prohibiting the disclosure of certain information provided by a wholesale distributor, except to certain entities for certain purposes; establishing certain procedures for returns or exchanges of prescription drugs; authorizing a wholesale distributor to supply or deliver prescription drugs only to certain persons; providing for certain exceptions; prohibiting a wholesale distributor from accepting payment or allowing the use of certain credit for a certain purpose; prohibiting a wholesale distributor from operating out of a residence: requiring a pedigree for certain prescription drug distributions: requiring certain entities to be authorized distributors of record for a certain purpose; establishing certain penalties for a certain violation of certain provisions of this Act; requiring the Board to adopt certain regulations on or before a certain date; requiring the Board to provide a certain report to the Governor and certain legislative committees on or before a certain date each year; repealing certain provisions of law relating to permits for the distribution of prescription drugs or devices; requiring the Secretary of Health and Mental Hygiene, in conjunction with the Board, to convene a certain workgroup to recommend to the Board a certain date for implementing electronic track and trace pedigree technology; requiring the Board to establish a certain date for implementation of electronic track and trace pedigree technology; requiring the Board to submit certain reports to certain legislative committees on or before certain dates; defining certain terms; making conforming changes; and

1 2	generally relating to permit and pedigree requirements for wholesale drug distributors.
3	BY repealing and reenacting, with amendments,
4	Article – Health Occupations
5	Section 12–601
6	Annotated Code of Maryland
7	(2005 Replacement Volume and 2006 Supplement)
8	BY repealing and reenacting, with amendments,
9	Article – Health Occupations
10	Section 12–602
11	Annotated Code of Maryland
12	(2005 Replacement Volume and 2006 Supplement)
13	BY adding to
14	<u>Article – Health Occupations</u>
15	Section 12–6C–01 through 12–6C–13 to be under the new subtitle "Subtitle 6C.
16	Wholesale Distributor Permitting and Prescription Drug Integrity Act"
17	Annotated Code of Maryland
18	(2005 Replacement Volume and 2006 Supplement)
19	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF
20	MARYLAND, That the Laws of Maryland read as follows:
21	Article - Health Occupations
22	<u>12–601.</u>
23 24 25	(a) Subject to the hearing provisions of § 12–315 of this title, for a violation of this subtitle, SUBTITLE 6C OF THIS TITLE , or any regulation adopted under [§ 12–602 of this subtitle] SUBTITLE 6C OF THIS TITLE , the Board may:
26	(1) Deny a permit to an applicant;
27	(2) Reprimand a permit holder;
28	(3) Place a permit holder on probation; or
29	(4) Suspend or revoke a permit.

1	(<u>b)</u>		rson aggrieved by a final action of the Board under this subtitle OR
2 3			THIS TITLE may not appeal to the Secretary or the Board of Review provided under Title 10, Subtitle 2 of the State Government Article.
3	but may ap	pear as	s provided under Title 10, Subtitle 2 of the State Government Article.
4	12-602.		
5	(a)	(1)	In this section the following words have the meanings indicated.
6		(2)	"Distribution permit" means a permit issued by the Board under
7	this section	to dis	tribute prescription drugs or devices into, out of, or within the State
8	as a distrib	utor, j e	obber, manufacturer, or wholesaler, wherever located.
9		(3)	"PEDIGREE" MEANS A DOCUMENT OR ELECTRONIC FILE
10	CONTAINI	NG IN	FORMATION THAT RECORDS EACH DISTRIBUTION OF A
11	PRESCRIP'	FION I	DRUG OR DEVICE.
10		F(0)]	
12	41 4 1		(4) "Prescription drugs or devices" means any drug or device
13	•		s toxicity or other potential for harmful effect, the method of its use,
14			neasures necessary for its use, is required by federal law to bear a
15			varning against dispensing without a prescription or is designated by
16			as not safe for use except under the supervision of a practitioner
17	licensed to	admın	ister drugs or devices of this nature.
18	(la)	This	section does not affect any person while distributing:
19		(1)	Feed for livestock or poultry;
20		(2)	Fertilizers;
21		(3)	Fungicides;
22		(4)	Insecticide;
23		(5)	Land plaster;
24		(6)	Lime;
25		(7)	Seeds; or
26		<u>(8)</u>	Devices, drugs, or supplies of any kind for the treatment, care, or
27	cure of farn	anim	
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1	(e)	A pe	rson sl	nall hold a distribution permit issued by the Board before the
2	person ma	y dis	tribute	prescription drugs or devices as a distributor, jobber,
3	manufactu i	er, or	wholes	aler.
4	(d)	To q	ialify f	for a distribution permit, an applicant shall:
5		(1)		fy the Board that the applicant will distribute prescription
6	drugs or de	vices i	n com	pliance with the restrictions specified in subsection (e) of this
7	section; [an	d]		
8		(2)	SUB	MIT EVIDENCE OF AN INSPECTION PERFORMED:
9			(I)	BY THE BOARD OR AN APPROVED AGENT OF THE
10	BOARD FO	R EAC	H FAC	ILITY OPERATED BY THE APPLICANT; AND
11			(II)	IN ACCORDANCE WITH REGULATIONS ADOPTED BY THE
12	BOARD; AN	ID		
13		[(2)]	(3)	Comply with any pertinent regulations adopted under
14	subsection ((i) of th	ris sect	ion.
15	(e)	A dis	stributi	ion permit holder may distribute prescription drugs or devices
16	only:			
17		(1)	To th	ne following persons:
18			(i)	An authorized prescriber;
19			(ii)	A pharmacy permit holder;
20			(iii)	A distribution permit holder; or
21			(iv)	Any other person approved by the Board; [and]
22		(2)	IF T	HE DISTRIBUTED PRESCRIPTION DRUGS OR DEVICES ARE
23	ACCOMPA	VIED-	BY	A PEDIGREE ESTABLISHED IN ACCORDANCE WITH
24	REGULATI	ONS A	DOPTI	ED BY THE BOARD; AND
25		[(2)]	(3)	In compliance with any rules and regulations adopted under
26	this section	.		

1	(f) To apply for a distribution permit, an applicant shall:
2	(1) Submit an application to the Board on the form that the Board
3	provides; [and]
4	(2) SUBMIT TO THE BOARD, IN ACCORDANCE WITH REGULATIONS
5	ADOPTED BY THE BOARD, A BOND OF AT LEAST \$100,000, OR OTHER
6	EQUIVALENT MEANS OF SECURITY ACCEPTABLE TO THE BOARD, SUCH AS AN
7	IRREVOCABLE LETTER OF CREDIT OR A DEPOSIT IN A TRUST ACCOUNT OR
8	FINANCIAL INSTITUTION, PAYABLE TO AN ACCOUNT ESTABLISHED BY THE
9	BOARD; AND
10	[(2)] (3) Pay to the Board an application fee set by the Board.
11	(g) The Board shall issue a distribution permit to any applicant who meets
12	the requirements of this section.
13	(h) A distribution permit issued under this section authorizes the
14	distribution permit holder to distribute prescription drugs or devices as a distributor,
15	jobber, manufacturer, or wholesaler while the distribution permit is effective.
16	(i) To protect the public health and safety, the Board:
17	(1) [may]-MAY-adopt rules and regulations regarding the distribution
18	of prescription drugs or devices including regulations regarding:
19	[(1)] (I) Qualifications and information required from an applicant
20	seeking issuance or renewal of a distribution permit;
21	[(2)] (H) Minimum requirements for the receipt, storage, and
22	handling of prescription drugs or devices, security precautions, quality control, record
23	keeping, and establishment of written procedures, policy, and responsibilities of
24	personnel;
25	[(3)] (III) The education and experience of personnel employed in
26	positions responsible for duties referenced in [paragraph (2)] ITEM (II) of this
27	[subsection] ITEM and generally responsible for carrying out those duties that are
28	subject to State licensure requirements under this subtitle; and
29	[(4)] (IV) Disciplinary action to be taken against a permit holder who
30	is convicted of or pleads guilty or nolo contendere to a violation of State, federal, or

1	local drug laws o	who violates regulations promulgated by the Board under the	is
2	section; AND		
3	(2)	SHALL ADOPT REGULATIONS SPECIFYING:	
4		(I) PEDIGREE REQUIREMENTS; AND	
5		(H) ROUTINE INSPECTION REQUIREMENTS.	
6 7 8	(j) (1) date, unless the d subsection.	A distribution permit expires on the December 31 after its effective stribution permit is renewed for a 1-year term as provided in the	
9 10 11 12		At least 1 month before a distribution permit expires, the Boar distribution permit holder, by first-class mail to the last know ribution permit holder, a renewal notice that contains a statemen	/n
13		(i) The date on which the current distribution permit expires;	
14 15 16	by the Board for to expires; and	(ii) The date by which the renewal application must be received ne renewal to be issued and mailed before the distribution perm	
17		(iii) The amount of the renewal fee.	
18 19 20	(3) periodically may holder:	Before a distribution permit expires, a distribution permit holdenew it for an additional 1-year term, if the distribution perm	
21		(i) Otherwise is entitled to a distribution permit;	
22		(ii) Pays to the Board a renewal fee set by the Board; and	
23 24	the Board requires	(iii) Submits to the Board a renewal application on the form the	at
25 26 27	(4) permit holder who under this section.	The Board shall renew the distribution permit of each distribution meets the requirements of this section and any regulation adopted	

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
9	section.
10	(o) A distribution permit is void on conviction of the distribution permit
11	holder for any violation of:
12	(1) This section; or
13	(2) Any rule or regulation adopted by the Board under this section.
1.4	Cupant e CC Who ecal e Digrepipinos Departmento AND Decopionion
14	SUBTITLE 6C. WHOLESALE DISTRIBUTOR PERMITTING AND PRESCRIPTION DRIVE INVESTMENT ACT
15	DRUG INTEGRITY ACT.
16	<u>12-6C-01.</u>
17	(A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS
18	INDICATED.
10	INDICATED:
19	(B) "AUTHENTICATE" MEANS TO AFFIRMATIVELY VERIFY, BEFORE ANY
20	WHOLESALE DISTRIBUTION OF A PRESCRIPTION DRUG OCCURS, THAT EACH
21	TRANSACTION LISTED ON THE PEDIGREE FOR THE PRESCRIPTION DRUG HAS
22	OCCURRED.
23	(C) "AUTHORIZED DISTRIBUTOR OF RECORD" MEANS A WHOLESALE
24	DISTRIBUTOR WITH WHOM A MANUFACTURER HAS ESTABLISHED AN ONGOING
25	RELATIONSHIP TO DISTRIBUTE THE MANUFACTURER'S PRESCRIPTION DRUG.
26	(D) "CO-LICENSED PARTNER" MEANS A PERSON IN A RELATIONSHIP IN
27	WHICH TWO OR MORE PERSONS HAVE THE RIGHT TO ENGAGE IN THE
28	MANUFACTURING OR MARKETING OF A PRESCRIPTION DRUG, CONSISTENT WITH

1	THE U.S. FOOD AND DRUG ADMINISTRATION'S IMPLEMENTATION OF THE
2	FEDERAL PRESCRIPTION DRUG MARKETING ACT.
3 4	(E) "CO-LICENSED PRODUCT" MEANS A PRODUCT OF CO-LICENSED PARTNERS.
5	(F) "DESIGNATED REPRESENTATIVE" MEANS AN INDIVIDUAL WHO:
6	(1) IS DESIGNATED BY A WHOLESALE DISTRIBUTOR;
7	(2) SERVES AS THE PRIMARY CONTACT OF THE WHOLESALE
8	DISTRIBUTOR WITH THE BOARD; AND
9	(3) IS ACTIVELY INVOLVED IN AND AWARE OF THE DAILY
10	OPERATION OF THE WHOLESALE DISTRIBUTOR.
11	(G) "DROP SHIPMENT" MEANS THE SALE OF A PRESCRIPTION DRUG:
12	(1) TO A WHOLESALE DISTRIBUTOR BY:
13	(I) THE MANUFACTURER OF THE PRESCRIPTION DRUG; OR
14	(II) THE MANUFACTURER'S CO-LICENSED PARTNER, THIRD
15	PARTY LOGISTICS PROVIDER, OR MANUFACTURER'S EXCLUSIVE DISTRIBUTOR;
16	AND
17	(2) THROUGH WHICH:
18	(I) THE WHOLESALE DISTRIBUTOR OR A PHARMACY
19	WAREHOUSE TAKES TITLE TO BUT NOT PHYSICAL POSSESSION OF THE
20	PRESCRIPTION DRUG;
21	(II) THE WHOLESALE DISTRIBUTOR INVOICES THE
22	PHARMACY, PHARMACY WAREHOUSE, OR OTHER PERSON AUTHORIZED BY LAW
23	TO DISPENSE OR ADMINISTER THE PRESCRIPTION DRUG TO A PATIENT; AND
24	(III) THE PHARMACY, PHARMACY WAREHOUSE, OR OTHER
25	AUTHORIZED PERSON RECEIVES DELIVERY OF THE PRESCRIPTION DRUG
26	DIRECTLY FROM:

1	$\underline{1.} \qquad \underline{\mathbf{THE\ MANUFACTURER;}}\ \underline{\mathbf{OR}}$
2	2. The manufacturer's third party logistics
3	PROVIDER OR THE MANUFACTURER'S EXCLUSIVE DISTRIBUTOR; OR.
4	3. AN AUTHORIZED DISTRIBUTOR OF RECORD THAT
5 6	PURCHASED THE PRESCRIPTION DRUG DIRECTLY FROM THE MANUFACTURER, THE MANUFACTURER'S THIRD PARTY LOGISTICS PROVIDER, OR THE
7	MANUFACTURER'S EXCLUSIVE DISTRIBUTOR.
8	(H) "FACILITY" MEANS A FACILITY OF A WHOLESALE DISTRIBUTOR
9	WHERE PRESCRIPTION DRUGS ARE STORED, HANDLED, REPACKAGED, OR
10	OFFERED FOR SALE.
11	(I) "INTRACOMPANY SALES" MEANS A:
12	(1) TRANSACTION OR TRANSFER OF PRESCRIPTION DRUGS
13	BETWEEN A DIVISION, SUBSIDIARY, PARENT, OR AFFILIATED OR RELATED
14	COMPANY UNDER COMMON OWNERSHIP AND CONTROL OF A CORPORATE
15	ENTITY; OR
16	(2) Transaction or transfer of a co-licensed product
17	BETWEEN CO-LICENSED PARTNERS.
1,	BETWEEN CO BIELL WEED TANKET WAS
18	(J) "MANUFACTURER" MEANS A PERSON LICENSED OR APPROVED BY
19	THE U.S. FOOD AND DRUG ADMINISTRATION TO ENGAGE IN THE
20	MANUFACTURE OF PRESCRIPTION DRUGS OR PRESCRIPTION DEVICES,
21	CONSISTENT WITH THE DEFINITION OF "MANUFACTURER" UNDER THE U.S.
22	FOOD AND DRUG ADMINISTRATION'S REGULATIONS AND GUIDELINES
23	IMPLEMENTING THE PRESCRIPTION DRUG MARKETING ACT.
24	(K) "MANUFACTURER'S EXCLUSIVE DISTRIBUTOR" MEANS A PERSON
25	WHO:
26	(1) CONTRACTS WITH A MANUFACTURER TO PROVIDE OR
27	COORDINATE WAREHOUSING, DISTRIBUTION, OR OTHER SERVICES ON BEHALF
28	OF THE MANUFACTURER; AND

1	(2) Takes title to the manufacturer's prescription
2	DRUG, BUT DOES NOT HAVE GENERAL RESPONSIBILITY TO DIRECT THE SALE OR
3	DISPOSITION OF THE MANUFACTURER'S PRESCRIPTION DRUG.
4	(L) "NORMAL DISTRIBUTION CHANNEL" MEANS A CHAIN OF CUSTODY
5	FOR A PRESCRIPTION DRUG THAT, DIRECTLY OR BY DROP SHIPMENT, GOES:
_	(1) Enow.
6	(1) <u>From:</u>
7	(I) A MANUFACTURER OF THE PRESCRIPTION DRUG; OR
,	(I) IIIMINOTHETERATION OF THE TRANSPORT TO THE CAN CITY
8	(II) THE MANUFACTURER'S CO-LICENSED PARTNER, THIRD
9	PARTY LOGISTICS PROVIDER, OR MANUFACTURER'S EXCLUSIVE DISTRIBUTOR;
10	AND
11	(2) <u>To:</u>
10	(T) A DVI DVI CV OD OMVID DVICTOV DVDCOV
12	(I) A PHARMACY OR OTHER DESIGNATED PERSON
13 14	AUTHORIZED BY LAW TO DISPENSE OR ADMINISTER THE PRESCRIPTION DRUG
14	TO A PATIENT;
15	(II) A WHOLESALE DISTRIBUTOR TO A PHARMACY OR
16	OTHER DESIGNATED PERSON AUTHORIZED BY LAW TO DISPENSE OR
17	ADMINISTER THE PRESCRIPTION DRUG TO A PATIENT;
18	(III) A WHOLESALE DISTRIBUTOR TO A PHARMACY
19	WAREHOUSE TO THE PHARMACY WAREHOUSE'S INTRACOMPANY PHARMACY OR
20	OTHER DESIGNATED PERSON AUTHORIZED BY LAW TO DISPENSE OR
21	ADMINISTER THE PRESCRIPTION DRUG TO A PATIENT;
22	(IV) A DILADMACK WADELIOUGE TO THE DILADMACK
22	(IV) A PHARMACY WAREHOUSE TO THE PHARMACY
23 24	WAREHOUSE'S INTRACOMPANY PHARMACY OR OTHER DESIGNATED PERSON AUTHORIZED BY LAW TO DISPENSE OR ADMINISTER THE PRESCRIPTION DRUG
25	TO A PATIENT; OR
23	IOATAILENI, OL
26	(V) AN AUTHORIZED DISTRIBUTOR OF RECORD TO
27	ANOTHER AUTHORIZED DISTRIBUTOR OF RECORD SOLELY FOR DISTRIBUTION
28	TO AN OFFICE-BASED HEALTH CARE PRACTITIONER AUTHORIZED BY LAW TO
29	DISPENSE OR ADMINISTER THE PRESCRIPTION DRUG TO A PATIENT.

1	(M) "ONGOING RELATIONSHIP" MEANS A RELATIONSHIP THAT EXISTS
2	BETWEEN A WHOLESALE DISTRIBUTOR, INCLUDING ANY AFFILIATED GROUP OF
3	THE WHOLESALE DISTRIBUTOR, AS DEFINED IN § 1504 OF THE INTERNAL
4	REVENUE CODE, AND A MANUFACTURER WHEN THE WHOLESALE DISTRIBUTOR:
5	(1) HAS A WRITTEN AGREEMENT CURRENTLY IN EFFECT WITH
6	THE MANUFACTURER EVIDENCING THE ONGOING RELATIONSHIP; AND
7	(2) IS LISTED ON THE MANUFACTURER'S CURRENT LIST OF
8	AUTHORIZED DISTRIBUTORS OF RECORD.
0	AUTHORIZED DISTRIBUTORS OF RECORD.
9	(N) "PEDIGREE" MEANS A DOCUMENT OR ELECTRONIC FILE
10	CONTAINING INFORMATION THAT RECORDS EACH WHOLESALE DISTRIBUTION
11	OF A PRESCRIPTION DRUG.
12	(O) "PHARMACY WAREHOUSE" MEANS A PHYSICAL LOCATION FOR
13	STORAGE OF PRESCRIPTION DRUGS THAT:
14	(1) SERVES AS A CENTRAL WAREHOUSE; AND
1.5	(9) Depropaga nampa gorganan garang op mpanggupag on mun
15	(2) PERFORMS INTRACOMPANY SALES OR TRANSFERS OF THE
16	PRESCRIPTION DRUGS TO A GROUP OF PHARMACIES THAT ARE UNDER COMMON
17	OWNERSHIP AND CONTROL WITH THE PHARMACY WAREHOUSE.
18	(P) (1) "Prescription drug" means any drug required by
19	FEDERAL LAW OR REGULATION TO BE DISPENSED ONLY BY A PRESCRIPTION.
	<u> </u>
20	(2) "Prescription drug" includes:
21	(I) A BIOLOGICAL PRODUCT; AND
22	(II) FINISHED DOSAGE FORMS AND BULK DRUG
23	SUBSTANCES SUBJECT TO § 503(B) OF THE FEDERAL FOOD, DRUG, AND
24	COSMETIC ACT.
25	(9) "Description policy poec not include place And
2526	(3) "PRESCRIPTION DRUG" DOES NOT INCLUDE BLOOD AND BLOOD COMPONENTS INTENDED FOR TRANSFUSION OR BIOLOGICAL PRODUCTS
26 27	THAT ARE ALSO MEDICAL DEVICES.
<i>21</i>	I HAT ARE ALSO MEDICAL DEVICES.

1	(Q) "PRESCRIPTION DEVICE" MEANS ANY DEVICE REQUIRED BY
2	FEDERAL LAW OR REGULATION TO BE DISPENSED ONLY BY A PRESCRIPTION.
3	(R) (1) "REPACKAGE" MEANS TO REPACKAGE OR OTHERWISE
4	CHANGE THE CONTAINER, WRAPPER, OR LABELING OF A PRESCRIPTION DRUG
5	TO FURTHER THE DISTRIBUTION OF THE PRESCRIPTION DRUG.
	(9) (Propagitage) pong Nom Ingripp gitangng mo
6	(2) "REPACKAGE" DOES NOT INCLUDE CHANGES TO A
7 8	CONTAINER, WRAPPER, OR LABELING OF A PRESCRIPTION DRUG COMPLETED
8 9	BY THE PHARMACIST RESPONSIBLE FOR DISPENSING THE PRESCRIPTION DRUG TO A PATIENT.
9	IOAPAHENI.
10	(S) "REPACKAGER" MEANS A PERSON WHO REPACKAGES
11	PRESCRIPTION DRUGS.
	A TABLE CALLET TATE OF CALLET
12	(T) "THIRD PARTY LOGISTICS PROVIDER" MEANS A PERSON WHO:
13	(1) CONTRACTS WITH A MANUFACTURER TO PROVIDE OR
14	COORDINATE WAREHOUSING, DISTRIBUTION, OR OTHER SERVICES ON BEHALF
15	OF THE MANUFACTURER; BUT
16	(2) DOES NOT TAKE TITLE TO THE PRESCRIPTION DRUG OR HAVE
17	GENERAL RESPONSIBILITY TO DIRECT THE PRESCRIPTION DRUG'S SALE OR
18	DISPOSITION.
10	(II) (1) "WHO EGALE DISTRIBUTION" MEANS THE DISTRIBUTION OF
19	(U) (1) "WHOLESALE DISTRIBUTION" MEANS THE DISTRIBUTION OF
2021	PRESCRIPTION DRUGS OR PRESCRIPTION DEVICES TO PERSONS OTHER THAN A CONSUMER OR PATIENT.
21	CONSUMER OR PATIENT.
22	(2) "WHOLESALE DISTRIBUTION" DOES NOT INCLUDE:
	(=) Wildelessee Backwelless, Bolless, Carlotte
23	(I) INTRACOMPANY SALES;
	_
24	(II) THE SALE, PURCHASE, DISTRIBUTION, TRADE, OR
25	TRANSFER OF A PRESCRIPTION DRUG OR AN OFFER TO SELL, PURCHASE,
26	DISTRIBUTE, TRADE, OR TRANSFER A PRESCRIPTION DRUG FOR EMERGENCY
27	MEDICAL REASONS;
28	(III) THE DISTRIBUTION OF SAMPLES OF A PRESCRIPTION
29	DRUG BY A MANUFACTURER'S REPRESENTATIVE;

1	(IV) PRESCRIPTION DRUG RETURNS CONDUCTED BY A
2	HOSPITAL, HEALTH CARE ENTITY, OR CHARITABLE INSTITUTION IN
3	ACCORDANCE WITH 21 CFR § 203.23;
4	(V) THE SALE OF MINIMAL QUANTITIES OF PRESCRIPTION
5	DRUGS BY RETAIL PHARMACIES TO LICENSED HEALTH CARE PRACTITIONERS
6	FOR OFFICE USE;
7	(VII) THE CALE DIRECTION OF TRADE OF A PRECEDITION
7 8	(VI) THE SALE, PURCHASE, OR TRADE OF A PRESCRIPTION DRUG, AN OFFER TO SELL, PURCHASE, OR TRADE A PRESCRIPTION DRUG, OR
9	THE DISPENSING OF A PRESCRIPTION DRUG IN ACCORDANCE WITH A
10	PRESCRIPTION;
10	PRESCRIPTION;
11	(VII) THE SALE, TRANSFER, MERGER, OR CONSOLIDATION OF
12	ALL OR PART OF THE BUSINESS OF A PHARMACY TO OR WITH ANOTHER
13	PHARMACY, WHETHER ACCOMPLISHED AS A PURCHASE AND SALE OF STOCK OR
14	BUSINESS ASSETS;
15	(VIII) THE SALE, PURCHASE, DISTRIBUTION, TRADE, OR
16	TRANSFER OF A PRESCRIPTION DRUG FROM ONE AUTHORIZED DISTRIBUTOR OF
17	RECORD TO ONE ADDITIONAL AUTHORIZED DISTRIBUTOR OF RECORD IF:
10	1
18	1. THE MANUFACTURER HAS STATED IN WRITING TO
19	THE RECEIVING AUTHORIZED DISTRIBUTOR OF RECORD THAT THE
20	MANUFACTURER IS UNABLE TO SUPPLY THE PRESCRIPTION DRUG; AND
21	2. The supplying authorized distributor of
22	RECORD STATES IN WRITING THAT THE PRESCRIPTION DRUG BEING SUPPLIED
23	HAD UNTIL THAT TIME BEEN EXCLUSIVELY IN THE NORMAL DISTRIBUTION
24	CHANNEL;
	<u></u>
25	(IX) THE DELIVERY OF, OR OFFER TO DELIVER, A
26	PRESCRIPTION DRUG BY A COMMON CARRIER SOLELY IN THE COMMON
27	CARRIER'S USUAL COURSE OF BUSINESS OF TRANSPORTING PRESCRIPTION
28	DRUGS, IF THE COMMON CARRIER DOES NOT STORE, WAREHOUSE, OR TAKE
29	LEGAL OWNERSHIP OF THE PRESCRIPTION DRUG; OR
30	(X) THE SALE OR TRANSFER FROM A RETAIL PHARMACY OR
31	PHARMACY WAREHOUSE OF EXPIRED, DAMAGED, RETURNED, OR RECALLED

1	PRESCRIPTION DRUGS TO THE ORIGINAL MANUFACTURER OR TO A THIRD
2	PARTY RETURNS PROCESSOR.
3	(v) (1) "WHOLESALE DISTRIBUTOR" MEANS A PERSON THAT IS
<i>3</i>	ENGAGED IN THE WHOLESALE DISTRIBUTION OF PRESCRIPTION DRUGS OR
5	PRESCRIPTION DEVICES.
5	I RESORTI TION DEVICES.
6	(2) "WHOLESALE DISTRIBUTOR" INCLUDES:
7	(I) A MANUFACTURER;
8	(II) A REPACKAGER;
9	(III) AN OWN-LABEL DISTRIBUTOR;
10	(IV) A PRIVATE-LABEL DISTRIBUTOR;
11	(V) A JOBBER;
12	(VI) A BROKER;
13	(VII) A WAREHOUSE, INCLUDING A MANUFACTURER'S OR
14	DISTRIBUTOR'S WAREHOUSE;
15	(VIII) A MANUFACTURER'S EXCLUSIVE DISTRIBUTOR OR AN
16	AUTHORIZED DISTRIBUTOR OF RECORD;
17	(IX) A DRUG WHOLESALER OR DISTRIBUTOR;
18	(X) AN INDEPENDENT WHOLESALE DRUG TRADER;
19	(XI) A THIRD PARTY LOGISTICS PROVIDER;
20	(XII) A RETAIL PHARMACY THAT CONDUCTS WHOLESALE
21	DISTRIBUTION, IF THE WHOLESALE DISTRIBUTION BUSINESS ACCOUNTS FOR
22	MORE THAN 5% OF THE RETAIL PHARMACY'S ANNUAL SALES; AND
	1101W 111W OI THE IMPLIES I MANUAL TO THE TOTAL OF THE OF THE
23	(XIII) A PHARMACY WAREHOUSE THAT CONDUCTS
24	WHOLESALE DISTRIBUTION.

1 2 3 4	(W) "WHOLESALE DISTRIBUTOR PERMIT" MEANS A PERMIT ISSUED BY THE BOARD UNDER THIS SUBTITLE TO DISTRIBUTE PRESCRIPTION DRUGS OR PRESCRIPTION DEVICES INTO, OUT OF, OR WITHIN THE STATE AS A WHOLESALE DISTRIBUTOR.
5	12-6C-02.
6	THIS SUBTITLE DOES NOT AFFECT ANY PERSON WHILE DISTRIBUTING:
7	(1) FEED FOR LIVESTOCK OR POULTRY;
8	(2) FERTILIZERS;
9	(3) FUNGICIDES;
10	(4) INSECTICIDE;
11	(5) LAND PLASTER;
12	(6) LIME;
13	(7) SEEDS; OR
14 15	(8) DEVICES, DRUGS, OR SUPPLIES OF ANY KIND FOR THE TREATMENT, CARE, OR CURE OF FARM ANIMALS.
16	<u>12-6C-03.</u>
17 18 19	(A) A WHOLESALE DISTRIBUTOR SHALL HOLD A PERMIT ISSUED BY THE BOARD BEFORE THE WHOLESALE DISTRIBUTOR ENGAGES IN WHOLESALE DISTRIBUTION IN THE STATE.
20 21 22	(B) (1) A MANUFACTURER ENGAGED IN WHOLESALE DISTRIBUTION SHALL HOLD A WHOLESALE DISTRIBUTOR PERMIT ISSUED UNDER THIS SUBTITLE.
23 24 25	(2) NOTWITHSTANDING PARAGRAPH (1) OF THIS SUBSECTION, THE INFORMATION AND QUALIFICATION REQUIREMENTS FOR OBTAINING A PERMIT UNDER THIS SUBTITLE, BEYOND THAT REQUIRED BY FEDERAL LAW, DO

- 1 NOT APPLY TO A MANUFACTURER WHO DISTRIBUTES ITS OWN PRESCRIPTION
- 2 DRUGS APPROVED BY THE U.S. FOOD AND DRUG ADMINISTRATION.
- 3 (C) A MANUFACTURER'S EXCLUSIVE DISTRIBUTOR AND A THIRD-PARTY
- 4 <u>LOGISTICS PROVIDER SHALL HOLD A WHOLESALE DISTRIBUTOR PERMIT ISSUED</u>
- 5 UNDER THIS SUBTITLE.
- 6 (D) A WHOLESALE DISTRIBUTOR PERMIT SHALL BE DISPLAYED
- 7 CONSPICUOUSLY IN THE PLACE OF BUSINESS FOR WHICH THE PERMIT IS
- 8 ISSUED.
- 9 (E) A WHOLESALE DISTRIBUTOR PERMIT IS NOT TRANSFERABLE.
- 10 (F) SUBJECT TO ANY OTHER RESTRICTION PROVIDED BY LAW, A
- 11 PERSON MAY NOT PURCHASE OR OBTAIN A PRESCRIPTION DRUG OR
- 12 PRESCRIPTION DEVICE UNLESS THE PRESCRIPTION DRUG OR PRESCRIPTION
- 13 <u>DEVICE IS PURCHASED OR OBTAINED FROM A PERSON WHO HOLDS A</u>
- 14 WHOLESALE DISTRIBUTOR PERMIT, A LICENSED PHARMACIST, OR AN
- 15 **AUTHORIZED PRESCRIBER.**
- 16 **12–6C–04.**
- 17 (A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE
- 18 **MEANINGS INDICATED.**
- 19 (2) "ACCREDITATION ORGANIZATION" MEANS A PRIVATE ENTITY
- 20 THAT CONDUCTS INSPECTIONS AND SURVEYS OF WHOLESALE DISTRIBUTORS
- 21 BASED ON NATIONALLY RECOGNIZED AND DEVELOPED STANDARDS.
- 22 (3) "DEEMED STATUS" MEANS A STATUS UNDER WHICH A
- 23 WHOLESALE DISTRIBUTOR MAY BE EXEMPT FROM ROUTINE INSPECTIONS AND
- 24 OTHER PERMIT REQUIREMENTS OF THE BOARD.
- 25 (B) IF THE BOARD DETERMINES THAT THE STANDARDS OF AN
- 26 ACCREDITATION ORGANIZATION ARE EQUAL TO OR MORE STRINGENT THAN
- 27 STATE PERMIT REQUIREMENTS, THE BOARD MAY:
- 28 (1) ACCEPT THE ACCREDITATION OF A WHOLESALE DISTRIBUTOR
- 29 BY AN ACCREDITATION ORGANIZATION AS EVIDENCE THAT THE WHOLESALE
- 30 DISTRIBUTOR HAS MET STATE PERMIT REQUIREMENTS; AND

1		<u>(2)</u>	GRANT THE WHOLESALE DISTRIBUTOR DEEMED STATUS.
2	(C)	ТНЕ	BOARD MAY ISSUE A PERMIT BY RECIPROCITY TO A
3	WHOLESAL	E DIST	RIBUTOR WHO HOLDS A LICENSE OR PERMIT UNDER THE LAWS
4			TE IF THE BOARD DETERMINES THAT THE REQUIREMENTS OF
5			SUBSTANTIALLY EQUIVALENT TO THE REQUIREMENTS OF THIS
6	STATE.		
Ü			
7	(D)	THE	BOARD OR ITS DESIGNEE MAY INSPECT A WHOLESALE
8	DISTRIBUTO		HO IS ACCREDITED OR HAS BEEN ISSUED A PERMIT BY
9	RECIPROCI		
10		(1)	DETERMINE COMPLIANCE WITH ANY PERMIT REQUIREMENT
11	UNDER THI	S SUBT	TITLE; OR
12		<u>(2)</u>	INVESTIGATE A COMPLAINT.
13	<u>12-6C-05.</u>		
14	<u>(A)</u>	TO Al	PPLY FOR A WHOLESALE DISTRIBUTOR PERMIT, AN APPLICANT
15	SHALL:		
16		<u>(1)</u>	PAY TO THE BOARD AN APPLICATION FEE SET BY THE BOARD;
17	<u>AND</u>		
18		<u>(2)</u>	SUBMIT AN APPLICATION TO THE BOARD ON THE FORM THAT
19	THE BOARI	REQU	JIRES.
20	<u>(B)</u>	THE A	APPLICATION SHALL INCLUDE THE FOLLOWING:
		/ - 1	m
21			THE NAME, FULL BUSINESS ADDRESS, AND TELEPHONE
22	NUMBER OF	THE A	APPLICANT;
•		(2)	A.
23		<u>(2)</u>	ALL TRADE OR BUSINESS NAMES USED BY THE APPLICANT;
24		(9)	Appreciate were entrane and appreciate and apprecia
24	CONTRACT	(<u>3)</u>	ADDRESSES, TELEPHONE NUMBERS, AND THE NAMES OF
25	•		NS FOR THE FACILITY USED BY THE APPLICANT FOR THE
26	STORAGE, I	<u> IANDL</u>	ING, AND DISTRIBUTION OF PRESCRIPTION DRUGS;

1	(4) THE TYPE OF BUSINESS FORM UNDER WHICH THE APPLICANT
2	OPERATES, SUCH AS PARTNERSHIP, CORPORATION, OR SOLE PROPRIETORSHIP;
3	(5) THE NAME OF EACH OWNER AND OPERATOR OF THE
4	APPLICANT, INCLUDING:
5	(I) IF AN INDIVIDUAL, THE NAME OF THE INDIVIDUAL;
6	(II) IF A PARTNERSHIP, THE NAME OF THE PARTNERSHIP
7	AND OF EACH PARTNER;
8	(III) IF A CORPORATION, THE NAME OF THE CORPORATION
9	THE NAME AND TITLE OF EACH CORPORATE OFFICER AND DIRECTOR, AND THE
10	STATE OF INCORPORATION; AND
11	(IV) IF A SOLE PROPRIETORSHIP, THE FULL NAME OF THE
12	SOLE PROPRIETOR AND THE NAME OF THE SOLE PROPRIETOR'S BUSINESS
13	ENTITY;
14	(6) A LIST OF ALL LICENSES AND PERMITS ISSUED TO THE
15	APPLICANT BY ANY OTHER STATE THAT AUTHORIZES THE APPLICANT TO
16	PURCHASE OR POSSESS PRESCRIPTION DRUGS;
17	(7) FOR THE DESIGNATED REPRESENTATIVE AND THE
18	IMMEDIATE SUPERVISOR OF THE DESIGNATED REPRESENTATIVE AT THE
19	APPLICANT'S PLACE OF BUSINESS:
20	
20	(I) FINGERPRINTS NECESSARY TO CONDUCT A CRIMINAL
21	HISTORY RECORDS CHECK; AND
22	
22	(II) THE FOLLOWING:
23	1 Names
23	<u>1.</u> <u>Name;</u>
24	2. Places of residence for the past 7 years;
∠ →	i laces of itemperce for the last (leans,
25	3. DATE AND PLACE OF BIRTH;
4 3	DATE THE DI LACE OF DIREIT,

1	4. The name and address of each business
2	WHERE THE INDIVIDUAL WAS EMPLOYED DURING THE PAST 7 YEARS, AND THE
3	INDIVIDUAL'S JOB TITLE OR OFFICE HELD AT EACH BUSINESS;
4	5. A STATEMENT OF WHETHER, DURING THE PAST 7
5	YEARS, THE INDIVIDUAL HAS BEEN THE SUBJECT OF ANY PROCEEDING FOR THE
6	REVOCATION OF ANY PROFESSIONAL OR BUSINESS LICENSE OR ANY CRIMINAL
7	<u>VIOLATION AND, IF SO, THE NATURE AND DISPOSITION OF THE PROCEEDING;</u>
0	C A COLUMNIANO OF WHEMHED DIDING WHE DACK 7
8 9	6. A STATEMENT OF WHETHER, DURING THE PAST 7
	YEARS, THE INDIVIDUAL HAS BEEN ENJOINED, EITHER TEMPORARILY OR
10	PERMANENTLY, BY A COURT OF COMPETENT JURISDICTION FROM VIOLATING
11	ANY FEDERAL OR STATE LAW REGULATING THE POSSESSION, CONTROL, OR
12	DISTRIBUTION OF PRESCRIPTION DRUGS, TOGETHER WITH DETAILS
13	CONCERNING THE EVENT;
14	7. A DESCRIPTION OF ANY INVOLVEMENT,
15	INCLUDING ANY INVESTMENTS OTHER THAN THE OWNERSHIP OF STOCK IN A
16	PUBLICLY TRADED COMPANY OR MUTUAL FUND, BY THE INDIVIDUAL DURING
17	THE PAST 7 YEARS WITH ANY BUSINESS THAT MANUFACTURES, ADMINISTERS,
18	PRESCRIBES, DISTRIBUTES, OR STORES PRESCRIPTION DRUGS, AND ANY
19	LAWSUITS IN WHICH THE BUSINESS WAS NAMED AS A PARTY;
19	EAWSOITS IN WINCH THE BUSINESS WAS NAMED AS AT ALLTI,
20	8. A. A DESCRIPTION OF ANY MISDEMEANOR OR
21	FELONY OFFENSE OF WHICH THE INDIVIDUAL, AS AN ADULT, WAS FOUND
22	GUILTY, REGARDLESS OF WHETHER ADJUDICATION OF GUILT WAS WITHHELD
23	OR WHETHER THE INDIVIDUAL PLED GUILTY OR NOLO CONTENDERE; AND
24	B. IF THE INDIVIDUAL INDICATES THAT A CRIMINAL
25	CONVICTION IS UNDER APPEAL AND SUBMITS A COPY OF THE NOTICE OF
26	APPEAL, WITHIN 15 DAYS AFTER THE DISPOSITION OF THE APPEAL, A COPY OF
27	THE FINAL WRITTEN ORDER OF DISPOSITION; AND
28	9. A PHOTOGRAPH OF THE INDIVIDUAL TAKEN IN
29	THE PREVIOUS 180 DAYS.
30	(C) THE INFORMATION REQUIRED UNDER SUBSECTION (B) OF THIS
31	SECTION SHALL BE PROVIDED UNDER OATH.

1	(D) THE BOARD MAY NOT ISSUE A WHOLESALE DISTRIBUTOR PERMIT
2	TO AN APPLICANT UNLESS THE BOARD OR ITS DESIGNEE:
	(1)
3	(1) CONDUCTS A PHYSICAL INSPECTION OF THE APPLICANT'S
4	PLACE OF BUSINESS, INCLUDING ANY FACILITY OF THE APPLICANT;
5	(2) FINDS THAT THE PLACE OF BUSINESS AND FACILITY, IF ANY
6	MEETS THE BOARD'S REQUIREMENTS;
O	
7	(3) DETERMINES THAT THE DESIGNATED REPRESENTATIVE OF
8	THE APPLICANT MEETS THE FOLLOWING QUALIFICATIONS:
9	(I) IS AT LEAST 21 YEARS OF AGE;
10	(II) HAG DEEN EMPLOYED BUILDING BOD AT LEACT 9
l0	(II) HAS BEEN EMPLOYED FULL TIME FOR AT LEAST 3 YEARS IN A PHARMACY OR WITH A WHOLESALE DISTRIBUTOR IN A CAPACITY
11 12	RELATED TO THE DISPENSING AND DISTRIBUTION OF, AND RECORDKEEPING
13	RELATING TO, PRESCRIPTION DRUGS;
	AND THE POPULATION PROGRAM
14	(III) IS EMPLOYED BY THE APPLICANT FULL TIME IN A
15	MANAGERIAL LEVEL POSITION;
	, <u>-</u>
16	(IV) IS ACTIVELY INVOLVED IN AND AWARE OF THE DAILY
17	OPERATION OF THE WHOLESALE DISTRIBUTOR;
18	(V) IS PHYSICALLY PRESENT, EXCEPT FOR AN AUTHORIZED
19	ABSENCE SUCH AS SICK LEAVE OR VACATION LEAVE, AT THE FACILITY OF THE
20	APPLICANT DURING REGULAR BUSINESS HOURS;
21	(VI) IS SERVING AS A DESIGNATED REPRESENTATIVE FOR
22	ONLY ONE APPLICANT AT A TIME, OR FOR TWO OR MORE WHOLESALE
23	DISTRIBUTORS WHO ARE LOCATED IN THE SAME FACILITY AND ARE MEMBERS
24	OF AN AFFILIATED GROUP, AS DEFINED IN § 1504 OF THE INTERNAL REVENUE
25	CODE;
26	(VII) DOES NOT HAVE ANY CONVICTIONS FOR A VIOLATION
20 27	OF ANY FEDERAL, STATE, OR LOCAL LAWS RELATING TO WHOLESALE OR RETAIL
28	PRESCRIPTION DRUG DISTRIBUTION OR DISTRIBUTION OF CONTROLLED
29	SUBSTANCES; AND
-	

1	(VIII) DOES NOT HAVE ANY CONVICTIONS FOR A FELONY
2	UNDER FEDERAL, STATE, OR LOCAL LAWS; AND
3	(4) DETERMINES THAT THE IMMEDIATE SUPERVISOR OF THE
4	DESIGNATED REPRESENTATIVE OF THE APPLICANT MEETS THE FOLLOWING
5	QUALIFICATIONS:
6	$\underline{\text{(I)}}$ IS AT LEAST 21 YEARS OF AGE;
7	(II) HAS BEEN EMPLOYED FULL TIME FOR AT LEAST 3
8	YEARS IN A PHARMACY OR WITH A WHOLESALE DISTRIBUTOR IN A CAPACITY
9	RELATED TO THE DISPENSING AND DISTRIBUTION OF, AND RECORDKEEPING
10	RELATING TO, PRESCRIPTION DRUGS;
	, , , -
11	(III) IS EMPLOYED BY THE APPLICANT FULL TIME IN A
12	MANAGERIAL LEVEL POSITION;
10	(m) Is a sometime to the analysis of my
13	(IV) IS ACTIVELY INVOLVED IN AND AWARE OF THE DAILY
14	OPERATION OF THE WHOLESALE DISTRIBUTOR;
15	(V) DOES NOT HAVE ANY CONVICTIONS FOR A VIOLATION
16	OF ANY FEDERAL, STATE, OR LOCAL LAWS RELATING TO WHOLESALE OR RETAIL
17	PRESCRIPTION DRUG DISTRIBUTION OR DISTRIBUTION OF CONTROLLED
18	SUBSTANCES; AND
10	SUBSTANCES, AND
19	(VI) DOES NOT HAVE ANY CONVICTIONS FOR A FELONY
20	UNDER FEDERAL, STATE, OR LOCAL LAWS.
20	CHARLES THE DESIGNATION OF LOCAL MATTER
21	(E) (1) IN THIS SUBSECTION, "CENTRAL REPOSITORY" MEANS THE
22	CRIMINAL JUSTICE INFORMATION SYSTEM CENTRAL REPOSITORY OF THE
23	DEPARTMENT OF PUBLIC SAFETY AND CORRECTIONAL SERVICES.
24	(2) IN ACCORDANCE WITH THE REQUIREMENTS OF THIS
25	SUBSECTION, THE BOARD SHALL SUBMIT THE FINGERPRINTS PROVIDED WITH A
26	PERMIT APPLICATION TO THE CENTRAL REPOSITORY FOR A STATE AND
27	NATIONAL CRIMINAL HISTORY RECORDS CHECK OF THE DESIGNATED
28	REPRESENTATIVE AND THE IMMEDIATE SUPERVISOR OF THE DESIGNATED
29	REPRESENTATIVE.

1	(3) AS PART OF AN APPLICATION TO THE CENTRAL REPOSITORY
2	FOR A STATE AND NATIONAL CRIMINAL HISTORY RECORDS CHECK, THE BOARD
3	SHALL SUBMIT TO THE CENTRAL REPOSITORY:
4	(I) TWO COMPLETE SETS OF LEGIBLE FINGERPRINTS
5	TAKEN ON FORMS APPROVED BY THE DIRECTOR OF THE CENTRAL REPOSITORY
6	AND THE DIRECTOR OF THE FEDERAL BUREAU OF INVESTIGATION;
7	(II) THE FEE AUTHORIZED UNDER § 10–221(B)(7) OF THE
8	CRIMINAL PROCEDURE ARTICLE FOR ACCESS TO STATE CRIMINAL HISTORY
9	RECORDS; AND
10	(III) THE PROCESSING FEE REQUIRED BY THE FEDERAL
11	BUREAU OF INVESTIGATION FOR A NATIONAL CRIMINAL HISTORY RECORDS
12	CHECK.
1.2	(4) The accompanion water \$5 10 001 temporary 10 000 on the
13	(4) IN ACCORDANCE WITH §§ 10–201 THROUGH 10–228 OF THE
14	CRIMINAL PROCEDURE ARTICLE, THE CENTRAL REPOSITORY SHALL FORWARD
15	TO THE BOARD AND TO THE APPLICANT THE CRIMINAL HISTORY RECORD
16	INFORMATION OF THE APPLICANT.
17	(5) Information obtained from the Central Repository
18	UNDER THIS SUBSECTION:
10	CNDER THIS SCHEETION.
19	(I) SHALL BE CONFIDENTIAL;
.,	
20	(II) MAY NOT BE REDISSEMINATED; AND
21	(III) SHALL BE USED ONLY FOR THE PERMITTING PURPOSE
22	AUTHORIZED BY THIS SUBTITLE.
23	(6) THE SUBJECT OF A CRIMINAL HISTORY RECORDS CHECK
24	UNDER THIS SUBSECTION MAY CONTEST THE CONTENTS OF THE PRINTED
25	STATEMENT ISSUED BY THE CENTRAL REPOSITORY AS PROVIDED IN § 10–223
26	OF THE CRIMINAL PROCEDURE ARTICLE.
27	(F) (1) THIS SUBSECTION DOES NOT APPLY TO A PHARMACY
28	WAREHOUSE THAT IS NOT ENGAGED IN WHOLESALE DISTRIBUTION.

1	(2) AN APPLICANT FOR A WHOLESALE DISTRIBUTOR PERMIT
2	SHALL SUBMIT A SURETY BOND OF AT LEAST \$100,000, OR OTHER EQUIVALENT
3	MEANS OF SECURITY ACCEPTABLE TO THE STATE SUCH AS AN IRREVOCABLE
4	LETTER OF CREDIT OR A DEPOSIT IN A TRUST ACCOUNT OR FINANCIAL
5	INSTITUTION, PAYABLE TO AN ACCOUNT ESTABLISHED BY THE STATE UNDER
6	PARAGRAPH (6) OF THIS SUBSECTION.
7	(3) THE PURPOSE OF THE SURETY BOND IS TO SECURE PAYMENT
8	OF ANY FINES OR PENALTIES IMPOSED BY THE BOARD AND ANY FEES AND
9	COSTS INCURRED BY THE STATE RELATING TO THE PERMIT THAT:
	Object in the Company of the Company
10	(I) ARE AUTHORIZED UNDER STATE LAW; AND
	<u>(-)</u>
11	(II) ARE NOT PAID BY THE PERMIT HOLDER WITHIN 30 DAYS
12	AFTER THE FINES, PENALTIES, FEES, OR COSTS BECOME FINAL.
12	THE THE PHASES, I ENABLIES, PEES, OR COSTS BECOME PHASE.
13	(4) THE STATE MAY MAKE A CLAIM AGAINST THE SURETY BOND
14	OR OTHER SECURITY UNTIL 2 YEARS AFTER THE PERMIT HOLDER'S PERMIT
15	CEASES TO BE VALID.
1.0	(E) A CINCLE CURETY POND CHAIL COVER ALL DACHUTTEC
16	(5) A SINGLE SURETY BOND SHALL COVER ALL FACILITIES
17	OPERATED BY THE APPLICANT IN THE STATE.

- 18 (6) THE BOARD SHALL ESTABLISH AN ACCOUNT, SEPARATE
- 19 FROM ITS OTHER ACCOUNTS, IN WHICH TO DEPOSIT THE APPLICANT'S SURETY
- 20 **BOND OR OTHER SECURITY.**
- 21 (G) IF A WHOLESALE DISTRIBUTOR DISTRIBUTES PRESCRIPTION DRUGS 22 OR PRESCRIPTION DEVICES FROM MORE THAN ONE FACILITY, THE WHOLESALE 23 DISTRIBUTOR SHALL OBTAIN A PERMIT FOR EACH FACILITY.
- 24 (H) WITHIN 30 DAYS AFTER THE DATE THE BOARD RECEIVES A
 25 COMPLETED APPLICATION, INCLUDING THE RESULTS OF ALL REQUIRED
 26 CRIMINAL HISTORY RECORDS CHECKS, THE BOARD SHALL NOTIFY THE
 27 APPLICANT OF THE BOARD'S ACCEPTANCE OR REJECTION OF THE
 28 APPLICATION.
- 29 **12–6C–06.**

1	(A) A WHOLESALE DISTRIBUTOR PERMIT EXPIRES ON DECEMBER 3	31
2	AFTER ITS EFFECTIVE DATE, UNLESS THE WHOLESALE DISTRIBUTOR PERMIT	IS
3	RENEWED FOR AN ADDITIONAL 2-YEAR TERM AS PROVIDED IN THIS SECTION.	
4	(n) (1) Evenue as providing by parameter (0) on (0)	

- 4 (B) (1) EXCEPT AS PROVIDED IN PARAGRAPH (2) OF THIS
 5 SUBSECTION, AT LEAST 1 MONTH BEFORE A WHOLESALE DISTRIBUTOR PERMIT
 6 EXPIRES, THE BOARD SHALL SEND TO THE WHOLESALE DISTRIBUTOR PERMIT
 7 HOLDER A RENEWAL NOTICE BY FIRST-CLASS MAIL TO THE LAST KNOWN
 8 ADDRESS OF THE PERMIT HOLDER.
- 9 (2) IF REQUESTED BY A WHOLESALE DISTRIBUTOR PERMIT
 10 HOLDER, THE BOARD SHALL SEND TO THE PERMIT HOLDER, AT LEAST TWO
 11 TIMES WITHIN THE MONTH BEFORE A WHOLESALE DISTRIBUTOR PERMIT
 12 EXPIRES, A RENEWAL NOTICE BY ELECTRONIC MEANS TO THE LAST KNOWN
 13 ELECTRONIC ADDRESS OF THE PERMIT HOLDER.
- 14 (3) IF A RENEWAL NOTICE SENT BY ELECTRONIC MEANS UNDER
 15 PARAGRAPH (2) OF THIS SUBSECTION IS RETURNED TO THE BOARD AS
 16 UNDELIVERABLE, THE BOARD SHALL SEND TO THE WHOLESALE DISTRIBUTOR
 17 PERMIT HOLDER A RENEWAL NOTICE BY FIRST-CLASS MAIL TO THE LAST
 18 KNOWN ADDRESS OF THE PERMIT HOLDER.
- 19 (4) A RENEWAL NOTICE SENT UNDER THIS SUBSECTION SHALL 20 STATE:
- 21 <u>(I) THE DATE ON WHICH THE CURRENT WHOLESALE</u> 22 **DISTRIBUTOR PERMIT EXPIRES**;
- 23 (II) THE DATE BY WHICH THE RENEWAL APPLICATION MUST
 24 BE RECEIVED BY THE BOARD FOR THE RENEWAL TO BE ISSUED AND MAILED
 25 BEFORE THE CURRENT WHOLESALE DISTRIBUTOR PERMIT EXPIRES; AND
- 26 (III) THE AMOUNT OF THE RENEWAL FEE.
- 27 (5) BEFORE A WHOLESALE DISTRIBUTOR PERMIT EXPIRES, A
 28 WHOLESALE DISTRIBUTOR PERMIT HOLDER PERIODICALLY MAY RENEW IT FOR
 29 AN ADDITIONAL 2-YEAR TERM, IF THE WHOLESALE DISTRIBUTOR PERMIT
 30 HOLDER:

1	(I) OTHERWISE IS ENTITLED TO A WHOLESALE
2	DISTRIBUTOR PERMIT;
3	(II) PAYS TO THE BOARD A RENEWAL FEE SET BY THE
4	BOARD; AND
5	(III) SUBMITS TO THE BOARD A RENEWAL APPLICATION ON
6	THE FORM THAT THE BOARD REQUIRES.
7	(6) (I) THE RENEWAL APPLICATION FORM SHALL SET FORTH
8	THE INFORMATION THAT THE WHOLESALE DISTRIBUTOR PROVIDED UNDER §
9	12–6C–05 OF THIS SUBTITLE.
10	(II) WITHIN 30 DAYS AFTER RECEIVING THE FORM, THE
11	WHOLESALE DISTRIBUTOR SHALL IDENTIFY AND STATE UNDER OATH TO THE
12	BOARD ALL CHANGES OR CORRECTIONS TO THE INFORMATION THAT WAS
13	PROVIDED UNDER § 12–6C–05 OF THIS SUBTITLE.
14	(7) THE BOARD SHALL RENEW THE WHOLESALE DISTRIBUTOR
15	PERMIT OF A WHOLESALE DISTRIBUTOR PERMIT HOLDER WHO MEETS THE
16	REQUIREMENTS OF THIS SUBTITLE AND ANY REGULATIONS ADOPTED UNDER
10 17	THIS SUBTITLE.
1 /	THIS SUBTILLE.
18	(8) THE BOARD MAY DENY, SUSPEND, OR REVOKE THE PERMIT
19	OF A WHOLESALE DISTRIBUTOR IF THE BOARD DETERMINES THAT THE
20	WHOLESALE DISTRIBUTOR NO LONGER QUALIFIES FOR A PERMIT.
21	<u>12-6C-07.</u>
22	THE BOARD:
12	(1) SHALL ADOPT REGULATIONS THAT REQUIRE ROUTINE
23	
24	INSPECTIONS OF WHOLESALE DISTRIBUTOR FACILITIES; AND
25	(2) MAY ADOPT REGULATIONS ESTABLISHING:
26	(I) MINIMUM REQUIREMENTS FOR THE RECEIPT, STORAGE,
27	AND HANDLING OF PRESCRIPTION DRUGS OR PRESCRIPTION DEVICES,
28	SECURITY PRECAUTIONS, QUALITY CONTROL, RECORD KEEPING, AND
29	PROCEDURES, POLICY, AND RESPONSIBILITIES OF PERSONNEL; AND

- (II) EDUCATION AND EXPERIENCE REQUIREMENTS FOR 1 2 PERSONNEL EMPLOYED IN POSITIONS RESPONSIBLE FOR CARRYING OUT THE 3 **DUTIES:** 4 REFERENCED IN ITEM (I) OF THIS ITEM; OR 1. 5 2. RELATED TO STATE PERMIT REQUIREMENTS 6 UNDER THIS SUBTITLE. 7 12-6C-08. 8 INFORMATION PROVIDED BY A WHOLESALE DISTRIBUTOR OR AN 9 APPLICANT FOR A WHOLESALE DISTRIBUTOR PERMIT UNDER THIS SUBTITLE MAY NOT BE DISCLOSED TO ANY PERSON OR ENTITY EXCEPT A STATE 10 LICENSING OR PERMITTING AUTHORITY, STATE BOARD, OR GOVERNMENT 11 AGENCY THAT NEEDS THE INFORMATION FOR LICENSING, PERMITTING, 12 13 MONITORING, OR LAW ENFORCEMENT PURPOSES. 12-6C-09. 14 (A) 15 (1) A WHOLESALE DISTRIBUTOR SHALL RECEIVE PRESCRIPTION 16 DRUG RETURNS OR EXCHANGES FROM A PHARMACY OR PHARMACY WAREHOUSE ACCORDING TO THE TERMS AND CONDITIONS OF THE AGREEMENT BETWEEN 17 THE WHOLESALE DISTRIBUTOR AND THE PHARMACY OR PHARMACY 18 19 WAREHOUSE.
- 21 NONSALEABLE PRESCRIPTION DRUGS SHALL BE DISTRIBUTED BY THE 22 RECEIVING WHOLESALE DISTRIBUTOR ONLY TO EITHER THE ORIGINAL 23 MANUFACTURER OR A THIRD PARTY RETURNS PROCESSOR.

20

(2)

RETURNS OF EXPIRED, DAMAGED, RECALLED, OR OTHERWISE

24 (3) RETURNS OR EXCHANGES OF PRESCRIPTION DRUGS,
25 SALEABLE OR OTHERWISE, INCLUDING ANY REDISTRIBUTION BY A RECEIVING
26 WHOLESALER, ARE NOT SUBJECT TO THE PEDIGREE REQUIREMENTS OF
27 § 12-6C-10 OF THIS SUBTITLE IF THEY ARE EXEMPT FROM THE PEDIGREE
28 REQUIREMENT OF THE U.S. FOOD AND DRUG ADMINISTRATION'S CURRENTLY
29 APPLICABLE PRESCRIPTION DRUG MARKETING ACT GUIDELINES.

4 (II) ENSURING THAT THE RETURNS PROCE 5 AND DOES NOT PERMIT THE ENTRY OF ADULTERATED AND 6 PRODUCT. 7 (B) A WHOLESALE DISTRIBUTOR MAY SUPPLY PRESCRE 8 ONLY TO A PERSON AUTHORIZED BY LAW TO DISPENSE 9 PRESCRIPTION DRUGS. 10 (C) (1) EXCEPT AS PROVIDED IN PARAGRAPH 11 SUBSECTION, A WHOLESALE DISTRIBUTOR MAY DELIVER PRESCRIPTION 12 ONLY TO: 13 (I) THE PREMISES LISTED ON THE RECIPIT OR PERMIT; OR 14 OR PERMIT; OR 15 (II) AN AUTHORIZED PERSON OR AN A AUTHORIZED PERSON AT THE PREMISES OF THE WHOLESALE DISTRIBUTOR AND 16 AUTHORIZED PERSON AT THE PREMISES OF THE WHOLESALE DISTRIBUTOR AND 17 1. THE IDENTITY AND AUTHORIZA PERSON OR AGENT IS PROPERLY ESTABLISHED; AND 18 PERSON OR AGENT IS PROPERLY ESTABLISHED; AND 19 2. THIS METHOD OF DELIVERY IS ENTO MEET THE IMMEDIATE NEEDS OF A PARTICULAR PATAUTHORIZED PERSON. 21 (2) (1) PRESCRIPTION DRUGS MAY BE SUR HOSPITAL PHARMACY RECEIVING AREA IF A PHARMACY SIGNS, A DELIVERY, A RECEIPT SHOWING THE TYPE AND QUANTED PRESCRIPTION DRUG RECEIVED. 22 (II) ANY DISCREPANCY BETWEEN THE TYPE	1	(4) Wholesale distributors and pharmacies shall be
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29 QUANTITY OF THE PRESCRIPTION DRUG RECEIVED:		OF THE PRESCRIPTION DRUG INDICATED ON THE RECEIPT AND THE TYPE AND
	29	QUANTITY OF THE PRESCRIPTION DRUG RECEIVED:

1	1. SHALL BE REPORTED TO THE DELIVERING
2	WHOLESALE DISTRIBUTOR BY THE NEXT BUSINESS DAY AFTER THE DELIVERY
3	TO THE HOSPITAL PHARMACY RECEIVING AREA; AND
4	2. MAY BE REPORTED TO THE BOARD FOR
5	INVESTIGATION.
6	(D) (1) A WHOLESALE DISTRIBUTOR MAY NOT ACCEPT PAYMENT OR
7	ALLOW THE USE OF A PERSON'S CREDIT TO ESTABLISH AN ACCOUNT FOR THE
8	PURCHASE OF PRESCRIPTION DRUGS FROM ANY PERSON OTHER THAN THE
9	OWNER OF RECORD, THE CHIEF EXECUTIVE OFFICER, OR THE CHIEF FINANCIAL
10	OFFICER LISTED ON THE LICENSE OR PERMIT OF A PERSON LEGALLY
11	AUTHORIZED TO RECEIVE PRESCRIPTION DRUGS.
12	(2) ANY ACCOUNT ESTABLISHED FOR THE PURCHASE OF
13	PRESCRIPTION DRUGS SHALL BEAR THE NAME OF THE LICENSE OR PERMIT
14	HOLDER.
1.7	(E) A WITCHEST E DISTRIBUTION MAN NOT OPENATE OUT OF
15	(E) A WHOLESALE DISTRIBUTOR MAY NOT OPERATE OUT OF A
16	RESIDENCE.
17	12-6C-10.
1 /	12-00-10.
18	(A) A PERSON WHO IS ENGAGED IN THE WHOLESALE DISTRIBUTION OF
19	A PRESCRIPTION DRUG THAT LEAVES, OR HAS EVER LEFT, THE NORMAL
20	DISTRIBUTION CHANNEL SHALL PROVIDE, BEFORE EACH WHOLESALE
21	DISTRIBUTION OF THE PRESCRIPTION DRUG, A PEDIGREE TO THE PERSON WHO
22	RECEIVES THE PRESCRIPTION DRUG.
23	(B) A RETAIL PHARMACY OR PHARMACY WAREHOUSE SHALL COMPLY

27 (C) (1) TO BE CONSIDERED PART OF THE NORMAL DISTRIBUTION

WITH THE REQUIREMENTS OF THIS SECTION ONLY IF THE PHARMACY OR

PHARMACY WAREHOUSE ENGAGES IN THE WHOLESALE DISTRIBUTION OF A

- 28 <u>CHANNEL, A WHOLESALE DISTRIBUTOR, A MANUFACTURER'S EXCLUSIVE</u>
- 29 <u>DISTRIBUTOR, AND A MANUFACTURER'S THIRD PARTY LOGISTICS PROVIDER</u>
- 30 ALSO MUST BE AN AUTHORIZED DISTRIBUTOR OF RECORD.

PRESCRIPTION DRUG IN THE STATE.

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1	(2) NOTWITHSTANDING PARAGRAPH (1) OF THIS SUBSECTION, A
2	PHARMACY WAREHOUSE THAT IS NOT AN AUTHORIZED DISTRIBUTOR OF
3	RECORD SHALL BE CONSIDERED PART OF THE NORMAL DISTRIBUTION
4	CHANNEL.
_	(a) B
5	(D) EACH PERSON WHO ENGAGES IN THE WHOLESALE DISTRIBUTION OF
6	A PRESCRIPTION DRUG, INCLUDING REPACKAGERS BUT EXCLUDING THE
7	ORIGINAL MANUFACTURER OF THE FINISHED FORM OF THE PRESCRIPTION
8 9	DRUG, WHO IS PROVIDED A PEDIGREE FOR THE PRESCRIPTION DRUG AND
10	ATTEMPTS TO FURTHER DISTRIBUTE THE PRESCRIPTION DRUG, SHALL AUTHENTICATE, BEFORE ANY DISTRIBUTION OF THE PRESCRIPTION DRUG
11	OCCURS, THAT EACH TRANSACTION LISTED ON THE PEDIGREE HAS OCCURRED.
1.1	occurs, that each manuscrion hister on the replacement.
12	(E) THE PEDIGREE SHALL INCLUDE:
13	(1) ALL NECESSARY IDENTIFYING INFORMATION RELATING TO
14	EACH SALE IN THE CHAIN OF DISTRIBUTION OF THE PRESCRIPTION DRUG FROM
15	THE MANUFACTURER OR THE MANUFACTURER'S THIRD PARTY LOGISTICS
16	PROVIDER, CO-LICENSED PARTNER, OR MANUFACTURER'S EXCLUSIVE
17	DISTRIBUTOR, THROUGH ACQUISITION AND SALE BY ANY WHOLESALE
18	DISTRIBUTOR OR REPACKAGER, UNTIL FINAL SALE TO A PHARMACY OR OTHER
19	PERSON DISPENSING OR ADMINISTERING THE PRESCRIPTION DRUG
20	INCLUDING:
21	(I) THE NAME, ADDRESS, TELEPHONE NUMBER, AND IF
22	AVAILABLE, ELECTRONIC MAIL ADDRESS, OF EACH OWNER AND EACH
23	WHOLESALE DISTRIBUTOR OF THE PRESCRIPTION DRUG;
23	WITOELESTELE DISTRIBUTOR OF THE TRESCRET TION DRUG
24	(II) THE NAME AND ADDRESS OF EACH LOCATION FROM
25	WHICH THE PRESCRIPTION DRUG WAS SHIPPED, IF DIFFERENT FROM THE
26	OWNER'S;
27	(III) TRANSACTION DATES; AND
28	(IV) CERTIFICATION THAT EACH RECIPIENT HAS
29	AUTHENTICATED THE PEDIGREE;
30	(2) THE NAME OF THE PRESCRIPTION DRUG;
\mathcal{I}	(4) THE NAME OF THE FRESURIFIION DRUG;

1 2	(<u>3)</u> <u>DRUG</u> ;	THE DOSAGE FORM AND STRENGTH OF THE PRESCRIPTION
3	<u>(4)</u>	THE SIZE OF THE CONTAINER;
4	<u>(5)</u>	THE NUMBER OF CONTAINERS;
5	(6) PRESCRIPTION	THE LOT NUMBER AND NATIONAL DRUG CODE OF THE DRUG; AND
7 8	(7) DOSAGE FORM.	THE NAME OF THE MANUFACTURER OF THE FINISHED
9	<u>(F)</u> <u>EAC</u>	CH PEDIGREE FOR A PRESCRIPTION DRUG SHALL BE:
10 11	(1) DISTRIBUTOR F	MAINTAINED BY THE PURCHASER AND THE WHOLESALE OR 3 YEARS FROM THE DATE OF SALE OR TRANSFER; AND
12 13 14	-	AVAILABLE FOR INSPECTION OR USE WITHIN 5 BUSINESS QUEST OF THE BOARD, THE BOARD'S DESIGNEE, OR AN AW ENFORCEMENT OFFICER.
15	<u>12–6C–11.</u>	
16 17	·	ANY REGULATION ADOPTED UNDER THIS SUBTITLE, THE BOARD
18 19	MAY IMPOSE A (2)	FINE NOT TO EXCEED \$500,000. BEFORE THE BOARD IMPOSES A FINE, THE BOARD SHALL
-		APPROPRIATENESS OF THE FINE IN RELATION TO:
21		(I) THE SIZE OF THE WHOLESALE DISTRIBUTOR;
22 23	IS TO BE IMPOS	(II) THE GRAVITY OF THE VIOLATION FOR WHICH THE FINE ED;
24 25	AND	(III) THE GOOD FAITH OF THE WHOLESALE DISTRIBUTOR;
4 J	<u>WID</u>	

1 2	(IV) ANY PREVIOUS VIOLATIONS BY THE WHOLESALE DISTRIBUTOR.
3	(B) IN ADDITION TO THE PENALTY PROVIDED IN SUBSECTION (A) OF
4	THIS SECTION, THE BOARD ALSO MAY TAKE DISCIPLINARY ACTION AGAINST A
5	PERMIT HOLDER WHO IS CONVICTED OF OR PLEADS GUILTY OR NOLO
6	CONTENDERE TO A VIOLATION OF STATE, FEDERAL, OR LOCAL DRUG LAWS.
7	<u>12-6C-12.</u>
8	ON OR BEFORE JANUARY 1, 2008, THE BOARD SHALL ADOPT
9	REGULATIONS TO IMPLEMENT THIS SUBTITLE.
10	<u>12-6C-13.</u>
11	On or before January 1, 2008, and on or before January 1 of
12	EACH SUBSEQUENT YEAR, THE BOARD SHALL REPORT TO THE GOVERNOR AND,
13	IN ACCORDANCE WITH § 2–1246 OF THE STATE GOVERNMENT ARTICLE, TO THE
14	GENERAL ASSEMBLY ON THE IMPLEMENTATION OF THIS SUBTITLE.
15	SECTION 2. AND BE IT FURTHER ENACTED, That:
16	(a) The Secretary of Health and Mental Hygiene, in conjunction with the
17	State Board of Pharmacy, shall convene a workgroup of manufacturers, distributors,
18	and pharmacies that sell and distribute prescription drugs in the State to recommend
19	to the Board a target date for implementation of electronic track and trace pedigree
20	technology.
21	(b) The workgroup shall:
22	(1) survey the availability of electronic track and trace pedigree
23	technology across the entire prescription pharmaceutical supply chain;
2.4	
24	(2) determine when electronic track and trace pedigree technology will
2526	be universally available across the entire prescription pharmaceutical supply chain; and
20	and
27	(3) based on its determination of the universal availability of
28	electronic track and trace pedigree technology, make recommendations to the Board
29	for a target date, no sooner than July 1, 2010, for implementation of electronic track

1 2	and trace pedigree technology across the entire prescription pharmaceutical supply chain.
3 4 5	(c) Taking into consideration the recommendations of the workgroup, the Board shall establish a target date, no sooner than July 1, 2010, for implementation of electronic track and trace pedigree technology.
6 7 8	(d) In accordance with § 2–1246 of the State Government Article, the Board shall submit to the Senate Education, Health, and Environmental Affairs Committee and the House Health and Government Operations Committee:
9 10	(1) on or before January 1, 2009, a report with the recommendations of the workgroup; and
11 12	(2) on or before July 1, 2009, the target date for implementation of electronic track and trace pedigree technology established by the Board.
13 14	SECTION $\stackrel{2}{=}$ 3. AND BE IT FURTHER ENACTED, That this Act shall take effect July 1, 2007.
	Approved:
	Governor.
	Speaker of the House of Delegates.
	President of the Senate.