



**MARYLAND
BOARD OF PHARMACY
WHOLESALE DISTRIBUTOR PERMITTING
AND PRESCRIPTION DRUG INTEGRITY
ACT**

**ANNUAL REPORT TO THE GOVERNOR
AND
THE GENERAL ASSEMBLY**

January 1, 2008

**MARYLAND BOARD OF PHARMACY WHOLESALE DISTRIBUTOR
PERMITTING AND PRESCRIPTION DRUG INTEGRITY ACT**

ANNUAL REPORT

TABLE OF CONTENTS

BOARD MEMBERS.....3

EXECUTIVE SUMMARY.....4

INTRODUCTION AND DEVELOPMENT OF REGULATIONS.....6

IMPLEMENTATION OF NEW REGULATORY REQUIREMENTS.....7

WORKGROUP TRACK AND TRACE SURVEY PROGRESS.....7

CONCLUSION.....9

APPENDIX I.....10

APPENDIX II.....12

APPENDIX III.....15

APPENDIX IV.....34

Members of the Maryland Board of Pharmacy

Donald W. Taylor, President

David Chason, Secretary

Michael M. Souranis, Treasurer

Mayer Handelman

Rodney Taylor

Cynthia Anderson

Harry Finke, Jr.

Lynette Bradley-Baker

Lenna Israbian-Jamgochian

Reid A. Zimmer

Margie A. Bonnett

Alland Leandre

Board of Pharmacy Staff

LaVerne G. Naesea, Executive Director

Anna D. Jeffers, Legislation and Regulations Manager

EXECUTIVE SUMMARY

This is the first annual report on the implementation of the Wholesale Distributor Permitting and Prescription Drug Integrity Act (the “Act”) as required by Health Occupations Article, Subtitle 6C, Annotated Code of Maryland.

The purpose of this Act, Senate Bill 759, Chapter 352, is to impose additional requirements for persons applying to be licensed to distribute prescription drugs or devices into Maryland, including requiring a pedigree, or history of the distribution chain, for prescription drugs that are distributed in Maryland. As part of the 2007 Act, the Board of Pharmacy (the “Board”) is required to adopt regulations for its implementation by January 1, 2008. Additionally the Board was required by the Act to convene a Workgroup (Wholesale Distributor SB 759 Workgroup) to:

- (1) Survey the availability of electronic track and trace pedigree technology across the entire prescription pharmaceutical supply chain;
- (2) Determine when electronic track and trace pedigree technology will be universally available across the entire prescription pharmaceutical supply chain; and
- (3) Based on its determination of the universal availability of electronic track and trace pedigree technology, make recommendations to the Board for a target date, no sooner than July 1, 2010, for implementation of electronic track and trace pedigree technology across the entire prescription pharmaceutical supply chain.

The Board is also required to submit a report with the recommendations of the Workgroup to the Senate Education, Health, and Environmental Affairs Committee (EHE) and the House Health and Government Operations Committee (HGO) on or before January 1, 2009, and to establish a target date for implementation of electronic track and trace pedigree technology on or before July 1, 2009.

This report sets forth the status of implementation of requirements under the Act. The Workgroup consists of stakeholders that were involved in workgroups before HGO to negotiate the provisions of the legislation. Although not required by the Act, the Board initially asked the Workgroup to review the current wholesale distributor regulations and to recommend draft regulatory language for the Board’s consideration. The Workgroup recommendations were submitted to the Board on August 13, 2007. After review and consideration, the Board accepted the recommendations, with minor revisions, at its October 17, 2007 and November 14, 2007 Public Board Meetings. As of the date of this submission, proposed regulations are going through the regulatory review process at the Department of Health and Mental Hygiene (DHMH). Once effective, the Board will begin implementing the Act by licensing wholesale distributors under the new regulations.

The Workgroup will continue collecting information regarding electronic track and trace technology with the eventual plan of conducting a survey of the availability of electronic track and trace pedigree technology across the entire prescription pharmaceutical supply chain. The survey is anticipated to be completed and analyzed by the fall of 2008. Based on the findings, the Workgroup will determine the universal availability of electronic track and trace pedigree technology and make recommendations to the Board for implementation of electronic track and trace pedigree technology across the entire prescription pharmaceutical supply chain. As required by the Act, the target date will be after July 1, 2010.

Following receipt of the Workgroup recommendations, the Board will submit a report to EHE and HGO with the recommendations of the Workgroup no later than January 1, 2009. The Board will submit the target date for implementation of electronic track and trace pedigree technology to EHE and HGO on or before July 1, 2009.

INTRODUCTION AND DEVELOPMENT OF REGULATIONS

The Board chaired and staffed a workgroup of wholesale distributor stakeholders to review the current wholesale distributor regulations and recommend draft regulatory language. Several Workgroup participants were also part of the group that recommended bill provisions before HGO related to the passed legislation (listed in Appendix I). A website (*Google Group*) was set up as a convenient way for Workgroup participants and interested persons to review meeting information, meeting handouts, related materials and the progress of the Workgroup. A listing of persons that have accessed the Google Group website are listed in Appendix II.¹

The Workgroup met on June 11, 2007, July 9, 2007, August 13, 2007, September 10, 2007, November 19, 2007 and December 10, 2007. During the first three meetings the participants reviewed the existing Maryland regulations COMAR 10.34.22.01 - .09 Licensing of Wholesale Prescription Drug or Device Distributors and similar existing regulations from various states who have enacted similar legislation. The Workgroup also reviewed model wholesale distributor regulations received from the National Association of Boards of Pharmacy (NABP) and the Pharmaceutical Research and Manufacturers of America (PhRMA). At the August 13, 2007 Workgroup meeting, the Workgroup agreed on draft regulations to recommend to the Board (see Appendix III).

The Board accepted the Workgroup's recommended regulations with some minor revisions. The revisions included:

- Insuring that all requirements of the statute are incorporated in the regulations;
- Adding the definition of "Co-licensed Partner" from SB 759;
- Requiring additional contact information from applicants;
- Revising language regarding the designated representative to require documented training sufficient to ensure that the operations of the wholesale distributor are in compliance with applicable State and federal laws;
- Adding the wholesale distribution of prescription drugs or devices that were donated under the Prescription Drug Repository Program, Health-General Article, Title 15, Subtitle 6, Annotated Code of Maryland to the list of violations of the regulations;
- Requiring that if no storage requirements are established for a prescription drug or device, the drug or device shall be held at a controlled room temperature as defined in an official compendium as set forth by the United States Pharmacopeia/National Formulary (USP/NF) under 21 CFR §205.50(c);
- Rewording "shortages or losses" to "inventory losses;" and
- Requiring that wholesale distributors consider the factors listed in the regulations regarding what constitutes a significant inventory loss.

The Board approved the Workgroup's recommended regulations with the Board's revisions at the October 17, 2007 Public Board Meeting. At the November 14, 2007 Public Board Meeting, the Board approved adding language to clarify the routine inspection of wholesale distributors at the time of renewal. The proposed regulations were then submitted to the Department of Health and Mental

¹ Members of the "Google Group" are not necessarily members of the SB 759 Wholesale Distributor Workgroup. "Google Group" access is granted upon request to the Board.

Hygiene, Office of Regulation and Policy Coordination, for review and submission to the Maryland Register for publication (see Appendix IV). The proposal is anticipated to be published in January 2008. Since all the major stakeholders participated in the drafting on these regulations it is anticipated that there will be a limited number of comments received during the official 30 day comment period that follows publication.

IMPLEMENTATION OF NEW REGULATORY REQUIREMENTS

The Board will utilize the statute and the proposed regulations to develop new applications and permit processes. Once the regulations become effective in 2008, the program will be fully operational and the Board's Licensing Unit will begin implementing requirements for all new wholesale distributor permit applicants and for existing wholesale distributor permits upon renewal. One substantive change to be included in the new licensure process is requirements related to inspection of wholesale distributors located in Maryland. The Board has also begun to develop procedures and seek personnel resources to insure that the new system for inspections can be fully implemented following the effective date of the regulations.

WORKGROUP TRACK AND TRACE SURVEY PROGRESS

SB 759 also required the Board to convene a Workgroup to (1) survey the availability of electronic track and trace pedigree technology across the entire prescription pharmaceutical supply chain; (2) determine when electronic track and trace pedigree technology will be universally available across the entire prescription pharmaceutical supply chain; and (3) based on its determination of the universal availability of electronic track and trace pedigree technology, make recommendations to the Board for a target date, no sooner than July 1, 2010, for implementation of electronic track and trace pedigree technology across the entire prescription pharmaceutical supply chain. The Board is also required to submit to EHE and HGO (1) on or before January 1, 2009, a report with the recommendations of the Workgroup; and (2) on or before July 1, 2009, the target date for implementation of electronic track and trace pedigree technology established by the Board.

Beginning at the September 10, 2007 Workgroup meeting, the Workgroup discussed how to approach the survey. Recognizing the need to educate the Workgroup participants concerning electronic track and trace technology, the Workgroup invited experts in the field to make presentations at the September, November and December 2007 meetings. The presentations will better enable the Workgroup to formulate valid survey questions.

At the September 10, 2007 Workgroup meeting John Howells, Director, Industry Relations at the Healthcare Distribution Management Association (HDMA), made a presentation introducing electronic product code (EPC) and radio frequency identification (RFID). RFID uses radio waves to identify items. An EPC system contains unique identifiers that allow identification of numerous items at the same time. A common example of this technology is the *Easy Pass* sensor system that is used to identify automobiles and bill automobile owners for highway tolls. Mr. Howells indicated that the industry is motivated to develop this technology so that it may improve patient safety, meet regulations, reduce costs and diversion, highlight short dated products and ensure more concise prescription dispensing.

There have been a number of industry initiatives to develop RFID technology. Mr. Howells listed in his presentation that GlaxoSmithKline, H.D. Smith, Pfizer, Purdue, Wal-mart CII, Department of Defense,

AmerisourceBergen, Cardinal, McKesson, CVS Caremark, Rite-Aid, Walgreens and others have conducted pilot programs. Pfizer is already using RFID technology for Viagra and Celebrex. There have also been a number of association white papers and cost/benefit studies. An RFID/Track & Trace Health Care Industry Adoption Summit has been scheduled for November 2007 in Washington, D.C. sponsored by NACDS and HDMA. A number of Workgroup participants, *Google Group* members, Board members and staff will attend this summit.

In his presentation Mr. Howells indicated that there are some major aspects that remain to be completed before industry wide adoption. They include:

- Uniform standards under development
- Uniform implementation of track and trace technology across states
- Data sharing, ownership
- Frequency, as in radio frequency
- Incorporating new technology
- Developing tag numbering schemes
- Insuring Privacy
- Agreed upon industry roll out plan

The Workgroup learned that tracking may occur at any level in the supply chain and is U.S. Federal Trade Commission (FTC) compliant. Antennas to read RFIDs may be hand-held readers or as large as four feet square. The sizes of the antennas are constantly changing as the technology develops. The cost for RFID tags ranges from a nickel to 10 to 20 cents per tag. The RFID tags could be placed on a pallet, case or bottle and eventually will be item driven. The RFID tags have the ability to record transaction times and dates, as well. The U.S. Food and Drug Administration (FDA) will publish a paper soon regarding the affects of RFID on proteins and biologicals. It has been suspected that radio frequencies may alter or interfere with the chemical make up of some proteins and biologicals. RFID technology can read up to 600 feet per minute in some cases, reading data and populating a database. The question remains as to what is shared from that database and with whom. It will be a challenge to only track products outside the normal distribution channel because different states require different tracking. Eventually the industry will need to track all products. HDMA is currently in the process of implementing standards which may be finalized by the end of the year. However, industry adoption of those standards by others in the industry will be a longer process.

Michael Rose from Johnson & Johnson and Ramesh Murthy from CVS Caremark, are scheduled to make presentations to the Workgroup at the November and December 2007 meetings, respectively. Each will present concerning their company's readiness, standards and approach to electronic pedigrees. A summary of those presentations will be included in the next Board report.

During early 2008 the Workgroup plans to formulate survey questions regarding the availability of electronic track and trace pedigree technology across the entire prescription pharmaceutical supply chain utilizing broad benchmark questions. The Workgroup will conduct the survey and then make recommendations to the Board for a target date that can be no sooner than July 1, 2010, for implementation of electronic track and trace pedigree technology across the entire prescription pharmaceutical supply chain.

CONCLUSION

During this first year that the Act has been in place the Board has convened the Workgroup, staffed the Workgroup and established the *Google Group* to efficiently disseminate information. The Board and the Workgroup have been proactive in revising COMAR 10.34.22 Licensing of Wholesale Prescription Drug or Device Distributors and publication of that regulatory proposal in the Maryland Register should occur in January 2008. During the fall of 2007, the Workgroup obtained information from industry experts and will be able to begin formulating and conducting the mandated survey in 2008. Full implementation of the Act is anticipated during 2008 and a recommended target implementation date for electronic track and trace technology will follow in 2009.

The Board, EHE, HGO and industry stakeholders have worked diligently over the past four years to bring this legislation to fruition. As concerns regarding the safety of U.S. prescription medications have grown, the Maryland Legislature was wise to address those concerns by placing stringent restrictions on those entities and individuals who distribute prescription medications in Maryland. The FDA has witnessed an increase in counterfeiting activities as well as a more sophisticated ability to introduce finished dosage form counterfeits into legitimate drug distribution channels over the years.²

Some in the industry were concerned that moving to electronic track and trace technology was neither practical nor possible due to developing technology and economic costs. The technology is available now and members of the industry have found it extremely useful for deterring diversion and counterfeiting of certain popular medications such as Oxycontin, Viagra and Celebrex. There will be increased costs as the wholesale prescription drug distributor industry, and also the prescription drug manufacturing industry (as in California), begins using RFID to track their products. The costs related to patients' safety, however, will be even greater if the industry does not take advantage of this available technology.

The Board would like to commend Senator Dyson and Delegates Morhaim and Montgomery for their leadership and perseverance during the many meetings and subcommittee hearings to negotiate legislation that was acceptable to all parties. Maryland joins California, Idaho, Wyoming, North Dakota, South Dakota, Kansas, Texas, Mississippi, Georgia, Connecticut, Arizona, New Mexico, Iowa, Florida and Virginia by passing legislation that further protects the prescription medication supply.

² FDA Counterfeit Drug Task Force Report: 2006 Update, http://www.fda.gov/oc/initiatives/counterfeit/report6_06.html

APPENDIX I

Wholesale Distributors SB 759 Workgroup

Board of Pharmacy Chairs

David Chason, Co-Chair
Donald W. Taylor, Co-Chair

Workgroup Participants

Stanton Ades
NACDS

Tracy L. Baroni Allmon
CVS Caremark

Lorenzo M. Bellamy
Rite Aid

Dan Bellingham
HDMA

Nancy A. Bukar
MedImmune

Pamela J. Burch
McKesson Pharmaceutical

Clem Cypra
PhRMA

Diane Darvey
NACDS

Nate Filler
Cardinal Health

Gil Genn
NACDS

Steve Hoag
University of Maryland

John Howells
HDMA

Deron Johnson

Amgen

Heather Morris
HDMA

Jennifer H. Palmer
Abbott

Julia Pitcher
J. William Pitcher
PhRMA

Nicole L. Palya
Stacey Poole
TAP Pharmaceuticals, Inc.

Hannah Powers
Rite-Aid

Gary L. Riddle
Schering-Plough Corporation

Martha Russell
Cardinal Health

Nicki Sandusky
Abbott

Howard Schiff, P.D.
Maryland Pharmacists Association

Linda Stahr
Department of Legislative Services

Thomas J. Warren
Johnson & Johnson

Michael Wolf
Pfizer

Board of Pharmacy Staff

LaVerne G. Naesea, Executive Director
Anna D. Jeffers, Legislation and Regulations Manager

APPENDIX II

List of Members invited/joined the Wholesale Distributor SB 759 Workgroup Google Group Site

Email address,nickname,group status,email status,email preference,posting permissions,join year,join month,join day,join hour,join minute,join second

ccypra@pharma.org, "", invited, non-verified, email, moderated, 2007, 6, 11, 13, 50, 16

cornstein@marylandlobbying.com, "", invited, nonverified, email, moderated, 2007, 6, 11, 13, 50, 16

hpowers@alexandrcleaver.com, "", invited, nonverified, email, moderated, 2007, 6, 11, 13, 50, 17

michael.wolfe@phizer.com, "", invited, non-verified, email, moderated, 2007, 6, 11, 13, 50, 17

shoag@rx.umaryland.edu, "", invited, non-verified, email, moderated, 2007, 6, 11, 13, 50, 17

DENTEN@gfrlaw.com, "", invited, non-verified, email, moderated, 2007, 6, 25, 07, 08, 33

Karen.Montgomery@house.state.md.us, "", invited, nonverified, email, moderated, 2007, 6, 25, 07, 08, 33

acorsig@pharma.org, "", invited, non-verified, email, moderated, 2007, 6, 25, 07, 08, 33

bpitcher@marylandlobbying.com, "", invited, nonverified, email, moderated, 2007, 6, 25, 07, 08, 33

dan.morhaim@house.state.md.us, "", invited, nonverified, email, moderated, 2007, 6, 25, 07, 08, 33

hpowers@alexandercleaver.com, "", invited, nonverified, email, moderated, 2007, 6, 25, 07, 08, 33

roy.dyson@senate.state.md.us, "", invited, nonverified, email, moderated, 2007, 6, 25, 07, 08, 33

tperry@gfrlaw.com, "", invited, non-verified, email, moderated, 2007, 6, 25, 07, 08, 33

ngomez@methapharm.com, "", invited, non-verified, email, moderated, 2007, 6, 26, 11, 49, 15

mdhandel@aol.com, "", invited, non-verified, email, moderated, 2007, 6, 28, 06, 25, 02

niznik@porziopharma.com, "", invited, non-verified, email, moderated, 2007, 6, 28, 07, 42, 13

gary.riddle@aspcap.com, "", invited, non-verified, email, moderated, 2007, 7, 9, 13, 19, 20

lbellamy@alexandercleaver.com, "", invited, nonverified, email, moderated, 2007, 7, 9, 13, 19, 20

Karensmont@aol.com, "", invited, non-verified, email, moderated, 2007, 7, 10, 14, 37, 41

Arnold.Clayman@omnicare.com, "", invited, nonverified, email, moderated, 2007, 7, 13, 13, 40, 33

KBattle@AlexanderClever.com, "", invited, nonverified, email, moderated, 2007, 8, 13, 12, 37, 31

fdieu001@umaryland.edu, "", invited, non-verified, email, moderated, 2007, 9, 6, 12, 45, 58
pam.burch@mckesson.com, "", invited, non-verified, email, moderated, 2007, 9, 10, 13, 42, 49
badwan@uic.edu, "", invited, non-verified, email, moderated, 2007, 9, 17, 07, 50, 12
eg@stateside.com, "", invited, non-verified, email, moderated, 2007, 9, 19, 09, 53, 44
gary.riddle@spcorp.com, "", invited, non-verified, email, moderated, 2007, 9, 25, 06, 50, 20
dbaron@pbnlaw.com, "", invited, non-verified, email, moderated, 2007, 9, 25, 08, 23, 06
MRose@CORUS.JNJ.com, "", invited, non-verified, email, moderated, 2007, 10, 1, 13, 50, 10
RMurthyl@cvs.com, "", invited, non-verified, email, moderated, 2007, 10, 4, 06, 02, 10
sdohi@coh.org, "", invited, non-verified, email, moderated, 2007, 10, 11, 12, 39, 04
jjb@smithrickert.com, "", invited, non-verified, email, moderated, 2007, 10, 26, 11, 42, 10
adjeffers@dhhm.state.md.us, "Anna Jeffers", **owner**, , no email, allowed, 2007, 6, 5, 09, 32, 07
regina.jones@medstar.net, "Gina", **member**, , no email, allowed, 2007, 7, 9, 08, 18, 13
mvanhook@engelnovitt.com, "", **member**, , no email, allowed, 2007, 6, 25, 07, 08, 33
mbolen@amerisourcebergen.com, "", **member**, , no email, allowed, 2007, 6, 29, 08, 02, 58
susan.trujillo@quarles.com, "Susan Trujillo", **member**, , no
email, allowed, 2007, 10, 30, 13, 49, 56
heatherlmorris@gmail.com, "Heather Morris", **member**, , email, allowed, 2007, 6, 20, 11, 25, 44
ccypa@phrma.org, "", invited, , email, moderated, 2007, 6, 25, 07, 08, 33
ggenn@gennandmurphy.com, "", invited, , email, moderated, 2007, 6, 25, 07, 08, 33
jpolli@rx.umaryland.edu, "", invited, , email, moderated, 2007, 6, 11, 13, 50, 17
ahhubbard@dhhm.state.md.us, "Anne
Hubbard", invited, , email, moderated, 2007, 6, 14, 08, 48, 29
annajeffers@yahoo.com, "", **member**, , email, allowed, 2007, 6, 5, 10, 14, 44
LNAESEA@dhhm.state.md.us, "", **member**, , email, allowed, 2007, 6, 8, 13, 20, 16
dave.chason@medstar.net, "", invited, , email, moderated, 2007, 6, 8, 13, 47, 06
malevi@comcast.net, "", **member**, , email, allowed, 2007, 6, 8, 13, 47, 06
EAnagnostiadis@nabp.net, "", invited, , email, moderated, 2007, 6, 11, 13, 50, 16
bukarn@medimmune.com, "", **member**, , email, allowed, 2007, 6, 11, 13, 50, 16
ddarvey@nacds.org, "", **member**, , email, allowed, 2007, 6, 11, 13, 50, 16
hmmorris@hdmanet.org, "", **member**, , email, allowed, 2007, 6, 11, 13, 50, 16
jennifer.palmer@abbott.com, "", **member**, , email, allowed, 2007, 6, 11, 13, 50, 17

linda.stahr@mlis.state.md.us, "", **member**, , email, allowed, 2007, 6, 11, 13, 50, 17
martha.russell@cardinal.com, "", **member**, , email, allowed, 2007, 6, 11, 13, 50, 17
stacey.poole@tap.com, "", **member**, , email, allowed, 2007, 6, 11, 13, 50, 17
tracy.baroniallmon@caremark.com, "", invited, , email, moderated, 2007, 9, 10, 13, 19, 17
Sara.Fidler@mlis.state.md.us, "", **member**, , email, allowed, 2007, 6, 12, 07, 09, 42
JBolin@nabp.net, "", **member**, , email, allowed, 2007, 6, 14, 07, 01, 28
deron@amgen.com, "", **member**, , email, allowed, 2007, 6, 14, 08, 34, 02
dbellingham@hdmanet.org, "", **member**, , email, allowed, 2007, 6, 15, 11, 56, 37
Jan.L.Burrus@gsk.com, "", **member**, , email, allowed, 2007, 6, 25, 07, 08, 33
furmanj@comcast.net, "", **member**, , email, allowed, 2007, 6, 25, 07, 08, 33
hschiff@marylandpharmacist.org, "", **member**, , email, allowed, 2007, 6, 25, 07, 08, 33
michael.wolf@pfizer.com, "", **member**, , email, allowed, 2007, 6, 25, 07, 08, 33
twarren@ompus.jnj.com, "TomW", **member**, , email, allowed, 2007, 6, 25, 09, 18, 41
thomasmercurio@gmail.com, "", **member**, , email, allowed, 2007, 6, 25, 10, 22, 05
jamespolli@yahoo.com, "JamesPolli", **member**, , email, allowed, 2007, 6, 26, 06, 05, 59
schiff@marylandpharmacist.org, "", **member**, , email, allowed, 2007, 6, 27, 09, 58, 46
nsandusky@fblaw.com, "", **member**, , email, allowed, 2007, 7, 9, 13, 19, 20
stanton.ades@omnicare.com, "", **member**, , email, allowed, 2007, 7, 9, 13, 19, 20
hansens@gene.com, "", **member**, , email, allowed, 2007, 7, 10, 09, 26, 46
David.Rudolph@house.state.md.us, "", **member**, , email, allowed, 2007, 7, 26, 08, 08, 03
dtaylor@intercom.net, "", **member**, , email, allowed, 2007, 8, 2, 07, 50, 01
nmilenkovich@mwe.com, "", **member**, , email, allowed, 2007, 8, 3, 08, 31, 47
RxExecutiveSecretary@dhmh.state.md.us, "", **member**, , email, allowed, 2007, 8, 6, 08, 32, 23
Nate.Filler@cardinalhealth.com, "", **member**, , email, allowed, 2007, 8, 7, 11, 06, 50
jeniznik@pbnlaw.com, "jeniznik", **member**, , email, allowed, 2007, 8, 14, 14, 04, 59
fdieu001@gmail.com, "Fay", **member**, , email, allowed, 2007, 9, 6, 14, 32, 18
alavin@venable.com, "Angel Lavin", **member**, , email, allowed, 2007, 9, 7, 13, 30, 32
Brian.Rosen@pharma.com, "Brian", **member**, , email, allowed, 2007, 9, 19, 08, 11, 09
nicole.palya@tap.com, "Nicole", **member**, , email, allowed, 2007, 10, 29, 07, 04, 45
Mike@epedigreesolutions.net, "ePedigree Solutions", **member**, , abridged
email, allowed, 2007, 10, 15, 08, 30, 01

APPENDIX III

NOT APPROVED BY THE BOARD OF PHARMACY
Recommended Final Draft Regulations by the Wholesale Distributor SB 759 Workgroup
August 13, 2007

Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 34 BOARD OF PHARMACY

Chapter 22 Licensing of Wholesale Prescription Drug or Device Distributors

Authority: Health Occupations Article, §§12-205, 12-601, and [12-602] 12-6C-01 – 12-6C-13, Annotated Code of Maryland

.01 Scope.

This chapter applies to any person engaged in the wholesale distribution of human prescription drugs or devices in Maryland.

.02 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) "Authenticate" means to affirmatively verify, before any wholesale distribution of a prescription drug occurs, that each transaction listed on the pedigree for the prescription drug has occurred.

(1-1) "Authorized Distributor of Record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug.

(1-2) "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(2) "Blood component" means that part of blood separated by physical or mechanical means.

(3) "Board" means the State Board of Pharmacy.

(4) "DEA" means the U. S. Drug Enforcement Administration.

(4-1) "Designated Representative" means an individual who:

(a) Is designated by the wholesale distributor;

(b) Serves as the primary contact of the wholesale distributor with the Board; and

(c) Is actively involved in and aware of the daily operation of the wholesale distributor.

(4-2) "Drop Shipment" means the sale of a prescription drug:

(a) To a wholesale distributor by:

(i) The manufacturer of the prescription drug; or

(ii) The manufacturer's co-licensed partner, third party logistics provider, or manufacturer's exclusive distributor; and

(b) Through which:

(i) The wholesale distributor or a pharmacy warehouse takes title to but not physical possession of the prescription drug;

(ii) The wholesale distributor invoices the pharmacy, pharmacy warehouse, or other person authorized by law to dispense or administer the prescription drug to a patient; and

(iii) The pharmacy, pharmacy warehouse, or other authorized person receives delivery of the prescription drug directly from:

1. The manufacturer; or

2. The manufacturer's co-licensed partner, third party logistics provider or the manufacturer's exclusive distributor.

(5) "Emergency medical reasons" includes transfers of prescription drugs or devices by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.

(6) "FDA" means the U. S. Food and Drug Administration.

(7) Health Care Entity.

(a) "Health care entity" means a person that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care.

(b) "Health care entity" does not include a community pharmacy or a wholesale distributor.

(c) "Health care entity" may not simultaneously be a health care entity and a community pharmacy or wholesale distributor.

(8) "Manufacturer" means a person licensed or approved by the U.S. Food and Drug Administration to engage in the manufacture of prescription drugs or prescription devices, consistent with the definition of "Manufacturer" under the U.S. Food and Drug Administration's regulations and guidelines implementing the Prescription Drug Marketing Act.

(8-1) "Manufacturer's exclusive distributor" means a person who:

(a) Contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer; and

(b) Takes title to the manufacturer's prescription drug, but does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug.

(8-2) "Normal Distribution Channel" means a chain of custody for a prescription drug that, directly or by drop shipment, goes:

(a) From:

(i) A manufacturer of the prescription drug; or

(ii) The manufacturer's co-licensed partner, third party logistics provider, or manufacturer's exclusive distributor; and

(b) To:

(i) A pharmacy or other designated person authorized by law to dispense or administer the prescription drug to a patient;

(ii) A wholesale distributor to a pharmacy or other designated person authorized by law to dispense or administer the prescription drug to a patient;

(iii) A wholesale distributor to a pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy or other designated person authorized by law to dispense or administer the prescription drug to a patient;

(iv) A pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy or other designated person authorized by law to dispense or administer the prescription drug to a patient; or

(v) An authorized distributor of record to another authorized distributor of record solely for distribution to an office-based health care practitioner authorized by law to dispense or administer the prescription drug to a patient.

(8-3) "Pedigree" means a document or electronic file containing information that records each wholesale distribution of a prescription drug.

(9) Prescription Drug.

(a) "Prescription Drug" means any drug required by federal law or regulation to be dispensed only by a prescription.

(b) "Prescription Drug" includes:

(i) A biological product; and

(ii) Finished dosage forms and bulk drug substances subject to § 503(b) of the Federal Food, Drug and Cosmetic Act.

(c) "Prescription Drug" does not include blood and blood components intended for transfusion or biological products that are also medical devices.

(9-1) "Prescription Device" means any device required by federal law or regulation to be dispensed only by a prescription.

(10) Repackage.

(a) "Repackage" means to repackage or otherwise change the container, wrapper, or labeling of a prescription drug to further the distribution of the prescription drug.

(b) "Repackage" does not include changes to a container, wrapper, or labeling of a prescription drug completed by the pharmacist responsible for dispensing the prescription drug to a patient.

(10-1) "Repackager" means a person who repackages prescription drugs.

(10-2) "Third Party Logistics Provider" means a person who:

(a) Contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer; but

(b) Does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition.

(11) Wholesale Distribution.

(a) "Wholesale Distribution" means the distribution of prescription drugs or prescription devices to persons other than a consumer or patient.

(b) "Wholesale distribution" does not include:

(i) Intra-company sales;

(ii) The sale, purchase, distribution, trade, or transfer of a prescription drug or an offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons;

(iii) The distribution of samples of a prescription drug by a manufacturer's representative;

(iv) Prescription drug returns conducted by a hospital, health care entity, or charitable institution in accordance with 21 CFR § 203.23;

(v) The sale of minimal quantities of prescription drugs by retail pharmacies to licensed health care practitioners for office use;

(vi) The sale, purchase, or trade of a prescription drug, an offer to sell, purchase, or trade a prescription drug, or the dispensing of a prescription drug in accordance with a prescription;

(vii) The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy to or with another pharmacy, whether accomplished as a purchase and sale of stock or business assets;

(viii) The sale, purchase, distribution, trade or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record if:

1. The manufacturer has stated in writing to the receiving authorized distributor of record that the manufacturer is unable to supply the prescription drug; and

2. The supplying authorized distributor of record states in writing that the prescription drug being supplied had until that time been exclusively in the normal distribution channel;

(ix) The delivery of, or offer to deliver, a prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs, if the common carrier does not store, warehouse, or take legal ownership of the prescription drug; or

(x) The sale or transfer from a retail pharmacy or pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to the original manufacturer or to a third party returns processor.

(12) Wholesale Distributors.

(a) "Wholesale distributor" means a person that is engaged in the wholesale distribution of prescription drugs or prescription devices.

(b) "Wholesale Distributor" includes:

(i) A manufacturer;

(ii) A repackager;

(iii) An own-label distributor;

(iv) A private-label distributor;

(v) A jobber;

(vi) A broker;

(vii) A warehouse, including a manufacturer's or distributor's warehouse;

(viii) A manufacturer's exclusive distributor or an authorized distributor of record;

(ix) A drug wholesaler or distributor;

(x) An independent wholesale drug trader;

(xi) A third party logistics provider;

(xii) A retail pharmacy that conducts wholesale distribution, if the wholesale distribution business accounts for more than 5 percent of the retail pharmacy's annual sales; and

(xiii) A pharmacy warehouse that conducts wholesale distribution.

.03 Minimum Application Requirements for Applicant.

A. The Board shall require the following minimum information from a wholesale distributor as part of an application for a permit and as part of a renewal of a permit:

(1) All trade or business names used by the permit holder which may not be identical to the name used by another unrelated applicant in the State;

(2) The full name or names of the owner and the operator of the wholesale distributor applying for or renewing a permit, including:

(a) For an individual:

(i) Full name of the individual;

(ii) Business address; and

(iii) Date of birth;

(b) For a partnership:

(i) Full name of each partner;

(ii) Address of each partner;

(iii) Date of birth of each partner;

(iv) Business address of the partnership; and

(v) Federal employer identification number of the partnership;

(c) For a publicly traded corporation, the:

(i) Full name and title of each corporate officer and director;

(ii) Business address of the corporation;

(iii) Federal employer identification number of the corporation;

(iv) Name of parent company or companies if applicable;

(v) Corporate names;

(vi) Name of the state of incorporation;

(c-1) For a non-publicly traded corporation, the:

(i) Full name and title of each corporate officer and director;

(ii) Business address of the corporation;

(iii) Federal employer identification number of the corporation;

(iv) Name of parent company or companies if applicable;

(v) Corporate names;

(vi) Shareholders of more than 10% of the corporation, including over-the-counter stock, unless the stock is traded on a major stock exchange, shall provide:

(aa) Full name; and

(bb) Business address; and

(vii) Name of the state of incorporation;

(d) For a sole proprietorship the:

(i) Full name of the sole proprietor;

(ii) Full name of the business entity;

(iii) Business address;

(iv) Date of birth of the sole proprietor; and

(v) Federal employer identification number of the partnership; or

(e) For a limited liability company:

(i) Full name of the limited liability company;

(ii) Full name of each member;

(iii) Full name of each manager;

(iv) Federal employer identification number of the limited liability

| company;

(v) Name of the state in which the limited liability company was

organized; and

(vi) Business address.

(3) A list of federal and state licenses, registrations, or permits, including the license, registration, or permit numbers issued to the wholesale distributor by federal authority or another state that authorizes the wholesale distributor to purchase, possess and distribute prescription drugs or devices;

(4) A list of disciplinary actions by federal or state agencies against the wholesale distributor as well as any such actions against principals, owners, directors or officers;

(5) A full description of the facility and warehouse including:

(a) Square footage;

(b) Security and alarm system descriptions;

(c) Terms of lease or ownership;

(d) Address; and

(e) Description of temperature and humidity controls;

(6) Written evidence that the wholesale distributor has obtained general and product liability insurance;

(7) A description of the wholesale distributor's import and export activities;

(8) Other relevant information that the Board may require.

B. As required by §A of this regulation, the wholesale distributor shall provide changes in information to the Board within 30 days of the effective date of the change.

.04 Personnel.

A. The permit holder shall affirm in the initial application and subsequent renewal applications that personnel employed in wholesale distribution have appropriate education and experience to assume responsibilities related to compliance with State licensing requirements.

B. Registered Agent.

(1) Each licensed wholesale distributor located outside of this State that wholesale distributes prescription drugs or devices in this State shall designate a registered agent in this State for service of process.

(2) Any licensed wholesale distributor that does not so designate a registered agent shall be deemed to have designated the Secretary of State to be its true and lawful attorney, upon who may be served all legal processes in any action or proceeding against such licensed wholesale distributor growing out of or arising from such wholesale distribution.

(3) A copy of any such service of process shall be mailed to such wholesale distributor by the Board by certified mail, return receipt requested, postage prepaid, at the address such licensed wholesale distributor has designated on its application for licensure in this State.

(4) If any wholesale distributor is not licensed in this State, service on the Secretary of State only shall be sufficient service.

C. Requirements and Responsibilities of the Designated Representative.

(1) The designated representative shall be aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the wholesale distributor including applicable State and federal laws.

(2) The designated representative shall complete:

(a) Training programs that address applicable State and federal laws and are provided by qualified in-house specialists, outside counsel, or consulting specialists with capabilities to help ensure compliance with all applicable State and federal laws and regulations; and

(b) The designated representative shall maintain current working knowledge of the requirements for wholesale distributor and assure on-going continue training for personnel to ensure compliance

(c) The designated representative shall be responsible for all record keeping requirements and make all records available for inspection.

.05 Violations and Penalties.

After a hearing held under Health Occupations Article, §12-601, Annotated Code of Maryland, the Board may deny, suspend, revoke, or place on probation a permit, reprimand a permit holder, or impose a fine if the permit holder:

A. Is convicted of, or pleads guilty or nolo contendere to violations of federal, State, or local drug or device laws or regulations;

B. Is convicted of, or pleads guilty or nolo contendere to a felony or to a crime involving moral turpitude, whether or not any appeal or other proceeding is pending to have the conviction or plea set aside;

C. Commits any of the following acts:

(1) Obtains or attempts to obtain a permit by:

(a) Providing false information to the Board; or

(b) Other fraudulent or deceptive means;

(2) Fails to:

(a) Establish or maintain inventories, records, or written policies and procedures as required by Regulation .07 of this chapter;

(b) Register with the Maryland Division of Drug Control and with the U.S. Drug Enforcement Agency as required by Regulation .07D of this chapter; or

(c) Permit the Board, the Maryland Division of Drug Control, the U.S. Drug Enforcement Agency, or other authorized federal, State, or local law enforcement officials showing proper

identification, to enter, inspect, copy records, or audit as required by Regulation .07D of this chapter;

(3) Willfully makes or maintains false inventories or records;

(4) Violates a provision of, or regulation promulgated under, Health Occupations Article, Title 12, Annotated Code of Maryland;

(5) Manufactures, repackages, sells, delivers, or holds or offers for sale any prescription drug or device that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or has otherwise been rendered unfit for distribution or wholesale distribution;

(6) Adulterates, misbrands, or counterfeits prescription drugs or devices;

(7) Receives prescription drugs or devices that are adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit, or delivers or proffers delivery of such prescription drug or device for pay or otherwise;

(8) Alters, mutilates, destructs, obliterates, or removes the whole or any part of the product labeling of a prescription drug or device or commits any other act with respect to a prescription drug or device that results in the prescription drug or device being misbranded;

(9) Forges, counterfeits, simulates, or falsely represents prescription drugs or devices without the authority of the manufacturer, or uses any mark, stamp, tag, label, or other identification device without the authorization of the manufacturer;

(10) Purchases or receives a prescription drug or device from a person that is not licensed to wholesale distribute prescription drugs or devices to that purchaser or recipient;

(11) Sells or transfers a prescription drug or device to a person who is not legally authorized to receive a prescription drug or device;

(12) Provides the Board, its representatives, or federal or State officials with false or fraudulent records or makes false or fraudulent statements regarding any matter within the provisions of these regulations;

(13) Wholesale distribution of prescription drugs or devices that were:

(1) Purchased by a public or private hospital or other health care entity;

(2) Donated or supplied at a reduced price to a charitable organization; or

(3) Stolen or obtained by fraud or deceit;

(14) Fails to obtain a license or operates without a valid license when a license is required;

(15) Obtains or attempts to obtain a prescription drug or device by fraud, deceit,

misrepresentation or engages in misrepresentation or fraud in the distribution or wholesale distribution of a prescription drug or device;

(16) Distributes a prescription drug or device to the patient without a prescription or prescription order from a practitioner licensed by law to use or prescribe the prescription drug or device;

(17) Fails to obtain, authenticate, or pass on a pedigree when required under these regulations;

(18) Receives a prescription drug pursuant to a wholesale distribution without first receiving a pedigree, when required, that was attested to as accurate and complete by the wholesale distributor;

(19) Distributes or wholesale distributes a prescription drug or device that was previously dispensed by a pharmacy or distributed by a practitioner;

(20) Fails to report prohibited acts as listed in these regulations;

(21) Fails to exercise due diligence as provided in Regulation .08 of this chapter;

(22) Otherwise conducts the wholesale distribution of prescription drugs or devices in a manner not in accordance with the law;

(23) Accepts payment or credit for the sale of prescription drugs in violation of 12-6C-09(D) of this Act; or

(24) If the requirements of 12-6C-09(A) are applicable and are not met, the purchasing or otherwise receiving a prescription drug from a pharmacy;

D. Is disciplined by a licensing or disciplinary authority of any state or country, or disciplined by a court of any state or country, for an act that would constitute a ground for Board action against a wholesale distributor permit holder under §A or B of this regulation.

E. The aforesaid “prohibited acts” do not include a prescription drug manufacturer, or agent of a prescription drug manufacturer, obtaining or attempting to obtain a prescription drug for the sole purpose of testing the prescription drug for authenticity.

.06 Minimum Requirements for the Storage and Handling of Prescription Drugs or Devices.

A. Facilities. Facilities at which prescription drugs or devices are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(1) Be of suitable size and construction to facilitate:

(a) Cleaning;

(b) Maintenance; and

(c) Proper operations;

(2) Have storage areas designed to provide adequate:

- (a) Equipment;
- (b) Humidity control;
- (c) Lighting;
- (d) Sanitation;
- (e) Security conditions;
- (f) Space;
- (g) Temperature; and
- (h) Ventilation;

(3) Have a quarantine area for storage of prescription drugs or devices that are:

- (a) Adulterated;
- (b) Damaged;
- (c) Deteriorated;
- (d) In immediate or sealed secondary containers that have been opened;
- (e) Misbranded; or
- (f) Outdated;

(4) Be maintained in a clean and orderly condition; and

(5) Be free from infestation by insects, rodents, birds, or vermin.

B. Security. A facility:

(1) Used for wholesale distribution shall be secure from unauthorized entry as follows:

(a) Access from outside the premises shall be:

(i) Kept to a minimum; and

(ii) Well controlled;

(b) The outside perimeter of the premises shall be well lit; and

(c) Entry into areas where prescription drugs or devices are held shall be limited to authorized personnel;

(2) Shall be equipped with:

(a) An alarm system to detect entry after hours;

(b) A security system that provides protection against theft and diversion;

(c) Appropriate software to facilitate the identification of evidence of tampering with computers or electronic records;

(d) An inventory management and control systems that protect against, detect, and document any instances of theft, diversion, or counterfeiting;

(e) A security system to protect the integrity and confidentiality of data and documents and make such data and documents readily available to the Board and federal and other state law enforcement officials;

(f) Video monitoring of all entrances and exits or alternate acceptable security; and

(g) A means to make the data and documentation required under this section available to the Board, an agent of the Board, or federal and other state law enforcement officials.

C. Storage.

(1) A wholesale distributor shall store a prescription drug or device at appropriate temperatures and under appropriate conditions in accordance with requirements:

(a) If any, of the labeling of the drug or device; or

(b) Set forth in current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF), under 21 CFR §205.50(c).

(2) If no storage requirements are established for a prescription drug or device, the drug or device may be held at a controlled room temperature, as defined in an official compendium as set forth in §C(1)(b) of this regulation to help assure that its identity, strength, quality, and purity are not adversely affected.

(3) A wholesale distributor shall use appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and logs to document proper storage of prescription drugs or devices.

(4) A wholesale distributor shall follow the record keeping requirements in Regulation .07 of this chapter for stored prescription drugs or devices.

D. Examination of Materials.

(1) Upon receipt, a wholesale distributor shall visually examine each outside shipping container for identity and to prevent the acceptance of:

- (a) Contaminated prescription drugs or devices; or
- (b) Prescription drugs or devices that are otherwise unfit for distribution.

(2) The examination required under §D(1) of this regulation shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(3) A wholesale distributor shall carefully inspect each outgoing shipment:

- (a) For identity of the prescription drug or device product; and
- (b) To ensure that there is no delivery of a prescription drug or device that has been damaged in storage or held under improper conditions.

(4) A wholesale distributor shall follow the record-keeping requirements in Regulation .07 of this chapter for incoming and outgoing prescription drugs or devices.

E. Returned, Damaged, and Outdated Prescription Drugs or Devices.

(1) A wholesale distributor shall quarantine and physically separate prescription drugs or devices that are outdated, damaged, deteriorated, misbranded, or adulterated from other prescription drugs or devices until the quarantined and separated drugs or devices are destroyed or returned to their supplier for proper disposal.

(2) The wholesale distributor shall identify, mark, quarantine, and physically separate from other prescription drugs or devices those prescription drugs or devices whose immediate or sealed outer or sealed secondary containers have been opened or used, until the drugs or devices are either destroyed or returned to their supplier for proper disposal.

(3) Prescription Drugs.

(a) If the conditions under which a prescription drug has been returned cast doubt on the prescription drug's safety, identity, strength, quality, or purity, then the wholesale distributor shall destroy or return the prescription drug to the supplier, unless examination, testing, or other investigation proves that the prescription drug meets appropriate standards of safety, identity, strength, quality, and purity.

(b) In determining whether the conditions under which a prescription drug has been returned cast doubt on the prescription drug's safety, identity, strength, quality, or purity, the wholesale distributor shall consider, among other things, the:

- (i) Conditions under which the prescription drug has been held, stored, or shipped before or during its return; and

(ii) Condition of the prescription drug and its container, carton, or labeling, as a result of storage or shipping.

(4) Prescription Devices.

(a) If the conditions under which a prescription device has been returned cast doubt on the prescription device's safety, identity, or quality, then the wholesale distributor shall destroy or return the prescription device to the supplier, unless examination, testing, or other investigation proves that the prescription device meets appropriate standards of safety, identity, strength, and quality.

(b) In determining whether the conditions under which a prescription device has been returned cast doubt on the prescription device's safety, identity, or quality, the wholesale distributor shall consider, among other things, the:

(i) Conditions under which the prescription device has been held, stored, or shipped before or during its return; and

(ii) Condition of the prescription device and its container, carton, or labeling, as a result of storage or shipping.

(5) A wholesale distributor shall follow the record keeping requirements in Regulation .07 of this chapter for outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs or devices.

.07 Minimum Requirements for Maintenance of Prescription Drug or Device Distribution Records.

A. Record Keeping.

(1) A wholesale distributor shall establish and maintain inventories and records of transactions regarding the receipt and distribution or other disposition of prescription drugs or devices.

(2) The records required under §A(1) of this regulation shall include the following information:

(a) The source of the prescription drugs or devices, including the:

(i) Name and principal address of the seller or transferor; and

(ii) Address of the location from which the prescription drugs or devices were shipped;

(b) The identity and quantity of the prescription drugs or devices received and distributed or disposed of;

(c) The dates of receipt and distribution or other disposition of the prescription drugs or devices; and

(d) The pedigrees, when required by Health Occupations Article, § 12-6C-10, Annotated Code of Maryland, for prescription drugs that are wholesale distributed outside the normal distribution channel.

(3) The wholesale distributor shall make available inventories and records for inspection and copying by authorized federal, State, or local law enforcement agency officials for a period of 3 years after their date of creation.

(4) The wholesale distributor shall keep the records described in this regulation readily available for inspection by authorized federal, State, or local law enforcement agency officials during the retention period, either:

(a) At the inspection site; or

(b) So as to be immediately retrievable by computer or other electronic means.

(5) Within 5 working days of a request by an authorized official of a federal, State, or local law enforcement agency, the wholesale distributor shall make available for inspection records kept at a central location apart from the inspection site and not electronically retrievable.

(6) Facilities shall establish and maintain procedures for reporting counterfeit and contraband or suspected counterfeit and contraband drugs or devices or counterfeiting and contraband or suspected counterfeiting and contraband activities to the Board and the FDA.

(7) Wholesale distributors shall maintain a system for the mandatory reporting of significant shortages or losses of prescription drugs and devices where it is known or suspected that diversion is occurring to the Board, the FDA, and, where applicable, to the DEA.

(8) Wholesale distributors may consider the following factors when determining if there has been a significant shortage:

(a) The schedule of the missing items;

(b) The abuse or misuse potential of the missing items;

(c) The abuse or misuse potential in the wholesale distributor's area of the missing substance;

(d) The quantity missing in relation to the total quantity purchased (one tablet vs. one bottle or container);

(e) Whether this is the first time a potentially significant shortage has occurred;

(f) Whether this loss was reported to local law enforcement authorities; and

(g) Whether there is a significant resale value of the missing items.

B. Written Policies and Procedures.

(1) A wholesale distributor shall establish, maintain, and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs or devices, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting errors and inaccuracies in inventories.

(2) A wholesale distributor shall include in the written policies and procedures the following:

(a) A procedure by which the oldest approved and unexpired stock of a prescription drug or device is distributed first;

(b) Procedures to be followed for adequate handling of a recall and withdrawal of a prescription drug or device due to:

(i) An action initiated at the request of the United States Food and Drug Administration or other federal, State, or local law enforcement or other government agency, including the Maryland Division of Drug Control;

(ii) A voluntary action by the manufacturer to remove a defective or potentially defective drug or device from the market; and

(iii) An action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design;

(c) A procedure to ensure that the wholesale distributor is prepared for, protected against, and is able to handle a crisis that affects security or operation of a facility if any of the following situations occurs:

(i) Strike;

(ii) Fire;

(iii) Flood;

(iv) Catastrophic health emergency as defined in Article 41, §2-201, Annotated Code of Maryland;

(v) Terrorist activities;

(vi) Other natural disaster; or

(vii) Other situations of local, State, or national emergency;

(d) A procedure to ensure that an outdated prescription drug or device is segregated from other drugs or devices and either returned to the manufacturer or destroyed.

(3) If deviation is appropriate, a wholesale distributor may temporarily deviate from the requirement in §B(2)(a) of this regulation that the oldest approved and unexpired stock be distributed first.

(4) The procedure required in §B(2)(d) of this regulation shall provide for written documentation of the disposition of an outdated prescription drug or device. This documentation shall be maintained for 2 years after disposition of the outdated prescription drug or device.

(5) A procedure for the disposing and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging cannot be used in counterfeiting activities, including all necessary documentation, maintained for a minimum of 3 years, and the appropriate witnessing of the destruction of any labels, packaging, immediate containers, or containers in accordance with applicable federal and State requirements.

(6) A procedure for identifying, investigating and reporting prescription drug inventory discrepancies involving counterfeit, suspect of being counterfeit, contraband, or suspect of being contraband, in the inventory and reporting of such discrepancies within 5 business days to the Board and appropriate federal or State agency upon discovery of such discrepancies.

C. Responsible Individuals. A wholesale distributor shall establish and maintain a list of officers, directors, managers, the designated representative and others in charge of wholesale distribution, storage, and handling, including:

(1) A description of their duties; and

(2) A summary of their qualifications.

D. Compliance with federal, State, and Local Law. A wholesale distributor shall:

(1) Operate in compliance with applicable federal, State, and local laws and regulations;

(2) Permit at reasonable times and in a reasonable manner, the Board, the State Division of Drug Control, and any other authorized federal, State, and local law enforcement officials showing proper identification to:

(a) Enter and inspect the distributor's premises and delivery vehicles; and

(b) Audit and copy the distributor's records and written operating procedures; and

(3) If dealing in controlled substances:

(a) Register with the Maryland Division of Drug Control and with the United States Drug Enforcement Administration; and

(b) Comply with all applicable federal, State, and local regulations.

E. Salvaging and Reprocessing.

(1) A wholesale distributor is subject to the provisions of applicable federal, State, or local laws or regulations that relate to prescription drug product salvaging or reprocessing, including 21 CFR Parts 207, 210, and 211.

(2) A wholesale distributor is subject to the provisions of any applicable federal, State, or local laws or regulations that relate to prescription device product salvaging or reprocessing.

.08 Due Diligence.

Wholesale distributors having transactions with persons not licensed by the Board or not certified by a third party recognized by the Board shall have in place policies and procedures to perform due diligence on transactions that take place that includes:

- A. Verification of alternate licensure;
- B. Verification of identity;
- C. Verification of recent inspections by a state or third party entity recognized by the Board;

APPENDIX IV

Approved by the Board of Pharmacy

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 34 BOARD OF PHARMACY

10.34.22 Licensing of Wholesale Prescription Drug or Device Distributors

Authority: **Health Occupations Article, §§12-205, 12-601, and [12-602] 12-6C-01 – 12-6C-13**
Annotated Code of Maryland

BEGIN ALL NEW

.01 Scope.

This chapter applies to any person engaged in the wholesale distribution of prescription drugs or devices in Maryland.

.02 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

- (1) "Authenticate" means to affirmatively verify, before any wholesale distribution of a prescription drug occurs, that each transaction listed on the pedigree for the prescription drug has occurred.
- (2) "Authorized Distributor of Record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug.
- (3) "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.
- (4) "Blood component" means that part of blood separated by physical or mechanical means.
- (5) "Board" means the State Board of Pharmacy.

(6) "Co-licensed Partner" means a person in a relationship in which two or more persons have the right to engage in the manufacturing or marketing of a prescription drug, consistent with the U.S. Food and Drug Administration's implementation of the Federal Prescription Drug Marketing Act.

(7) "DEA" means the U. S. Drug Enforcement Administration.

(8) "Designated Representative" means an individual who:

(a) Is designated by the wholesale distributor;

(b) Serves as the primary contact of the wholesale distributor with the Board; and

(c) Is actively involved in and aware of the daily operation of the wholesale distributor.

(9) "Drop Shipment" means the sale of a prescription drug:

(a) To a wholesale distributor by:

(i) The manufacturer of the prescription drug; or

(ii) The manufacturer's co-licensed partner, third party logistics provider, or manufacturer's exclusive distributor; and

(b) Through which:

(i) The wholesale distributor or a pharmacy warehouse takes title to but not physical possession of the prescription drug;

(ii) The wholesale distributor invoices the pharmacy, pharmacy warehouse, or other person authorized by law to dispense or administer the prescription drug to a patient; and

(iii) The pharmacy, pharmacy warehouse, or other authorized person receives delivery of the prescription drug directly from:

1. The manufacturer; or

2. The manufacturer's third party logistics provider or the manufacturer's exclusive distributor.

(10) "Emergency medical reasons" includes transfers of prescription drugs or devices by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.

(11) "FDA" means the U. S. Food and Drug Administration.

(12) Health Care Entity.

(a) "Health care entity" means a person that provides diagnostic, medical, surgical, or dental treatment, or chronic or rehabilitative care.

(b) "Health care entity" does not include a community pharmacy or a wholesale distributor.

(c) "Health care entity" may not simultaneously be a health care entity and a community pharmacy or wholesale distributor.

(13) "Manufacturer" means a person licensed or approved by the U.S. Food and Drug Administration to engage in the manufacture of prescription drugs or prescription devices, consistent with the definition of "Manufacturer" under the U.S. Food and Drug Administration's regulations and guidelines implementing the Prescription Drug Marketing Act.

(14) "Manufacturer's exclusive distributor" means a person who:

(a) Contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer; and

(b) Takes title to the manufacturer's prescription drug, but does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug.

(15) "Normal Distribution Channel" means a chain of custody for a prescription drug that, directly or by drop shipment, goes:

(a) From:

(i) A manufacturer of the prescription drug; or

(ii) The manufacturer's co-licensed partner, third party logistics provider, or manufacturer's exclusive distributor; and

(b) To:

(i) A pharmacy or other designated person authorized by law to dispense or administer the prescription drug to a patient;

(ii) A wholesale distributor to a pharmacy or other designated person authorized by law to dispense or administer the prescription drug to a patient;

(iii) A wholesale distributor to a pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy or other designated person authorized by law to dispense or administer the prescription drug to a patient;

(iv) A pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy or other designated person authorized by law to dispense or administer the prescription drug to a patient; or

(v) An authorized distributor of record to another authorized distributor of record solely for distribution to an office-based health care practitioner authorized by law to dispense or administer the prescription drug to a patient.

(16) "Pedigree" means a document or electronic file containing information that records each wholesale distribution of a prescription drug.

(17) Prescription Drug.

(a) "Prescription Drug" means any drug required by federal law or regulation to be dispensed only by a prescription.

(b) "Prescription Drug" includes:

(i) A biological product; and

(ii) Finished dosage forms and bulk drug substances subject to § 503(b) of the Federal Food, Drug and Cosmetic Act.

(c) "Prescription Drug" does not include blood and blood components intended for transfusion or biological products that are also medical devices.

(18) “Prescription Device” means any device required by federal law or regulation to be dispensed only by a prescription.

(19) Repackage.

(a) “Repackage” means to repackage or otherwise change the container, wrapper, or labeling of a prescription drug to further the distribution of the prescription drug.

(b) “Repackage” does not include changes to a container, wrapper, or labeling of a prescription drug completed by the pharmacist responsible for dispensing the prescription drug to a patient.

(20) “Repackager” means a person who repackages prescription drugs.

(21) “Third Party Logistics Provider” means a person who:

(a) Contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer; but

(b) Does not take title to the prescription drug or have general responsibility to direct the prescription drug’s sale or disposition.

(22) Wholesale Distribution.

(a) “Wholesale Distribution” means the distribution of prescription drugs or prescription devices to persons other than a consumer or patient.

(b) "Wholesale distribution" does not include:

(i) Intra-company sales;

(ii) The sale, purchase, distribution, trade, or transfer of a prescription drug or an offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons;

(iii) The distribution of samples of a prescription drug by a manufacturer’s representative;

(iv) Prescription drug returns conducted by a hospital, health care entity, or charitable institution in accordance with 21 CFR § 203.23;

(v) The sale of minimal quantities of prescription drugs by retail pharmacies to licensed health care practitioners for office use;

(vi) The sale, purchase, or trade of a prescription drug, an offer to sell, purchase, or trade a prescription drug, or the dispensing of a prescription drug in accordance with a prescription;

(vii) The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy to or with another pharmacy, whether accomplished as a purchase and sale of stock or business assets;

(viii) The sale, purchase, distribution, trade or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record if:

1. The manufacturer has stated in writing to the receiving authorized distributor of record that the manufacturer is unable to supply the prescription drug; and

2. The supplying authorized distributor of record states in writing that the prescription drug being supplied had until that time been exclusively in the normal distribution channel;

(ix) The delivery of, or offer to deliver, a prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs, if the common carrier does not store, warehouse, or take legal ownership of the prescription drug; or

(x) The sale or transfer from a retail pharmacy or pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to the original manufacturer or to a third party returns processor.

(23) Wholesale Distributors.

(a) "Wholesale distributor" means a person that is engaged in the wholesale distribution of prescription drugs or prescription devices.

(b) "Wholesale Distributor" includes:

(i) A manufacturer;

(ii) A repackager;

(iii) An own-label distributor;

- (iv) A private-label distributor;
- (v) A jobber;
- (vi) A broker;
- (vii) A warehouse, including a manufacturer's or distributor's warehouse;
- (viii) A manufacturer's exclusive distributor or an authorized distributor of record;
- (ix) A drug wholesaler or distributor;
- (x) An independent wholesale drug trader;
- (xi) A third party logistics provider;
- (xii) A retail pharmacy that conducts wholesale distribution, if the wholesale distribution business accounts for more than 5 percent of the retail pharmacy's annual sales; and
- (xiii) A pharmacy warehouse that conducts wholesale distribution.

.03 Minimum Application Requirements for Applicant.

A. The Board shall require the following minimum information from a wholesale distributor as part of an application for a permit and as part of a renewal of a permit:

- (1) The type of business form under which the applicant operates, such as partnership, corporation, or sole proprietorship;
- (2) The full name or names of the owner and the operator of the wholesale distributor applying for or renewing a permit, including:
 - (a) For an individual:
 - (i) Full name of the individual;
 - (ii) The telephone number of the individual;
 - (iii) Business address; and
 - (iv) Date of birth;
 - (b) For a partnership:

- (i) Full name of each partner;
- (ii) The telephone number of the partnership;
- (iii) Address of each partner;
- (iv) Date of birth of each partner;
- (v) Business address of the partnership; and
- (vi) Federal employer identification number of the partnership;
- (c) For a publicly traded corporation, the:
 - (i) Full name and title of each corporate officer and director;
 - (ii) The telephone number of the publicly traded corporation;
 - (iii) Business address of the corporation;
 - (iv) Federal employer identification number of the corporation;
 - (v) Name of parent company or companies if applicable;
 - (vi) Corporate names;
 - (vii) Name of the state of incorporation; and
 - (viii) Name and address of the resident agent of the corporation;
- (d) For a non-publicly traded corporation, the:
 - (i) Full name and title of each corporate officer and director;
 - (ii) The telephone number of the non-publicly traded corporation;
 - (iii) Business address of the corporation;
 - (iv) Federal employer identification number of the corporation;
 - (v) Name of parent company or companies if applicable;
 - (vi) Corporate names;
 - (vii) Shareholders of more than 10% of the corporation, including over-the-counter stock, unless the stock is traded on a major stock exchange, shall provide:

1. Full name; and
2. Business address;
- (viii) Name of the state of incorporation; and
- (ix) Name and address of the resident agent of the corporation
- (e) For a sole proprietorship the:
 - (i) Full name of the sole proprietor;
 - (ii) The telephone number of the sole proprietor;
 - (iii) Full name of the business entity;
 - (iv) Business address; and
 - (v) Date of birth of the sole proprietor;
- (f) For a limited liability company:
 - (i) Full name and business address of the limited liability company;
 - (ii) The telephone number of the limited liability company;
 - (iii) Full name of each member;
 - (iv) Full name of each manager;
 - (v) Federal employer identification number of the limited liability company;
 - (vi) Name of the state in which the limited liability company was organized; and
 - (vii) Name and address of the resident agent of the company;
- (3) Addresses, telephone numbers, and the names of contact persons for the facility used by the applicant for the storage, handling, and distribution of prescription drugs;
- (4) All trade or business names used by the permit holder which may not be identical to the name used by another unrelated applicant in the State;

- (5) A list of federal and state licenses, registrations, or permits, including the license, registration, or permit numbers issued to the wholesale distributor by federal authority or another state that authorizes the wholesale distributor to purchase, possess and distribute prescription drugs or devices;
- (6) A list of disciplinary actions by federal or state agencies against the wholesale distributor as well as any such actions against principals, owners, directors or officers;
- (7) For the designated representative and the immediate supervisor of the designated representative at the applicant's place of business the following information:
 - (a) Name;
 - (b) Places of residence for the past 7 years;
 - (c) Date and place of birth;
 - (d) The name and address of each business where the individual was employed during the past 7 years, and the individual's job title or office held at each business;
 - (e) A statement of whether, during the past 7 years, the individual has been the subject of any proceeding for the revocation of any professional or business license or any criminal violation and, if so, the nature and disposition of the proceeding;
 - (f) A statement of whether, during the past 7 years, the individual has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the possession, control, or distribution of prescription drugs, together with details concerning the event;
 - (g) A description of any involvement, including any investments other than the ownership of stock in a publicly traded company or mutual fund, by the individual during the past 7 years with any business that manufactures, administers, prescribes, distributes, or store prescription drugs, and any lawsuits in which the business was named as a party;
 - (h) Misdemeanor or Felony Offenses.

- (i) A description of any misdemeanor or felony offense of which the individual, as an adult, was found guilty, regardless of whether adjudication of the guilt was withheld or whether the individual pled guilty or nolo contendere;
 - (ii) If the individual indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal, within 15 days after the disposition of the appeal, a copy of the final written order of disposition; and
 - (iii) A photograph of the individual taken in the previous 180 days;
- (8) A full description of the facility and warehouse including:
- (a) Square footage;
 - (b) Security and alarm system descriptions;
 - (c) Terms of lease or ownership;
 - (d) Address; and
 - (e) Description of temperature and humidity controls;
- (9) Written evidence that the wholesale distributor has obtained general and product liability insurance;
- (10) A description of the wholesale distributor's import and export activities; and
- (11) Other relevant information that the Board may require.

B. The Board shall require the following information from the designated representative and the immediate supervisor of the designated representative at the applicant's place of business as part of the initial application for a permit:

- (1) Two complete sets of legible fingerprints taken on forms approved by the Director of the Central Repository and the Director of the Federal Bureau of Investigation;
- (2) The fee authorized under the Criminal Procedure Article, § 10-221(b)(7), Annotated Code of Maryland for access to State criminal history records; and

(3) The processing fee required by the Federal Bureau of Investigation for a national criminal history records check.

C. The information required under §A of this regulation shall be provided under oath.

D. The Board may not issue a an initial or renewal wholesale distributor permit to an applicant unless the Board or its designee:

(1) Conducts a physical inspection of the applicant's place of business, including any facility of the applicant;

(2) Finds that the place of business and facility, if any, meets the Board's requirements;

(3) Determines that the designated representative of the applicant meets the following qualifications:

(a) Is at least 21 years of age;

(b) Has been employed full time for at least 3 years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of, and recordkeeping relating to, prescription drugs;

(c) Is employed by the applicant full time in a managerial level position;

(d) Is actively involved in and aware of the daily operation of the wholesale distributor;

(e) Is physically present, except for an authorized absence such as sick leave or vacation leave, at the facility of the applicant during regular business hours;

(f) Is serving as a designated representative for only one applicant at a time, or for two or more wholesale distributors who are located in the same facility and are members of an affiliated group, as defined in § 1504 of the Internal Revenue Code;

(g) Does not have any convictions for a violation of any federal, State, or local laws relating to wholesale or retail prescription drug distribution or distribution of controlled substances; and

(h) Does not have any convictions for a felony under federal, State, or local laws; and

(4) Determines that the immediate supervisor of the designated representative of the applicant meets the following qualifications:

- (a) Is at least 21 years of age;
- (b) Has been employed full time for at least 3 years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of, and recordkeeping relating to, prescription drugs;
- (c) Is employed by the applicant full time in a managerial level position;
- (d) Is actively involved in and aware of the daily operation of the wholesale distributor;
- (e) Does not have any convictions for a violation of any federal, state, or local laws relating to wholesale or retail prescription drug distribution or distribution of controlled substances; and
- (f) Does not have any convictions for a felony under federal, state, or local laws.

E. An applicant for a wholesale distributor permit shall submit a surety bond of at least \$100,000, or other equivalent means of security acceptable to the State such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to an account established by the State under Health Occupations Article, 12-6C-05F(6), Annotated Code of Maryland.

- (a) A surety bond is not required for a pharmacy warehouse that is not engaged in wholesale distribution.
- (b) A single surety bond shall cover all facilities operated by the applicant in the State.

F. If a wholesale distributor distributes prescription drugs or prescription devices from more than one facility, the wholesale distributor shall obtain a permit for each facility.

G. The Board shall notify the applicant of the Board's acceptance or rejection of the application within 30 days after the date the Board receives a completed application, including the results of all required criminal history records checks.

H. The applicant shall pay to the Board an application fee set forth in COMAR 10.34.09.02.

I. The wholesale distributor shall provide changes in information provided pursuant to Regulation .03 of this chapter to the Board within 30 days of the effective date of the change.

.04 Personnel.

A. The permit holder shall affirm in the initial application and subsequent renewal applications that personnel employed in wholesale distribution have appropriate education and experience to assume responsibilities related to compliance with State licensing requirements.

B. Registered Agent.

(1) Each licensed wholesale distributor located outside of this State that wholesale distributes prescription drugs or devices in this State shall designate a registered agent in this State for service of process.

(2) Any licensed wholesale distributor that does not so designate a registered agent shall be deemed to have designated the Secretary of State to be its true and lawful attorney, upon who may be served all legal processes in any action or proceeding against such licensed wholesale distributor growing out of or arising from such wholesale distribution.

(3) If any wholesale distributor is not licensed in this State, service on the Secretary of State only shall be sufficient service.

C. Requirements and Responsibilities of the Designated Representative.

(1) The designated representative shall be aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the wholesale distributor including applicable State and federal laws;

(2) The designated representative shall have documented training sufficient to ensure that operations of the wholesale distributor are in compliance with applicable State and federal laws and are provided by qualified in-house specialists, outside counsel, or consulting specialists with capabilities to help ensure compliance with all applicable State and federal laws and regulations;

(3) The designated representative shall maintain current working knowledge of the requirements for wholesale distributor and assure on-going training for personnel to ensure compliance; and

(4) The designated representative shall be responsible for all record keeping requirements and make all records available for inspection.

.05 Violations and Penalties.

After a hearing held under Health Occupations Article, §12-601, Annotated Code of Maryland, the Board may deny, suspend, revoke, or place on probation a permit, reprimand a permit holder, or impose a fine if the permit holder:

A. Is convicted of, or pleads guilty or nolo contendere to violations of federal, State, or local drug or device laws or regulations;

B. Is convicted of, or pleads guilty or nolo contendere to a felony or to a crime involving moral turpitude, whether or not any appeal or other proceeding is pending to have the conviction or plea set aside;

C. Commits any of the following acts:

(1) Obtains or attempts to obtain a permit by:

(a) Providing false information to the Board; or

(b) Other fraudulent or deceptive means;

(2) Fails to:

(a) Establish or maintain inventories, records, or written policies and procedures as required by

Regulation .07 of this chapter;

(b) Register with the Maryland Division of Drug Control and with the U.S. Drug Enforcement Agency

as required by Regulation .07D of this chapter; or

(c) Permit the Board, the Maryland Division of Drug Control, the U.S. Drug Enforcement Agency, or other authorized federal, State, or local law enforcement officials showing proper identification, to enter, inspect, copy records, or audit as required by Regulation .07D of this chapter;

(3) Willfully makes or maintains false inventories or records;

- (4) Violates a provision of, or regulation promulgated under, Health Occupations Article, Title 12, Annotated Code of Maryland;
- (5) Manufactures, repackages, sells, delivers, or holds or offers for sale any prescription drug or device that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or has otherwise been rendered unfit for distribution or wholesale distribution;
- (6) Adulterates, misbrands, or counterfeits prescription drugs or devices;
- (7) Receives prescription drugs or devices that are adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit, or delivers or proffers delivery of such prescription drug or device for pay or otherwise;
- (8) Alters, mutilates, destructs, obliterates, or removes the whole or any part of the product labeling of a prescription drug or device or commits any other act with respect to a prescription drug or device that results in the prescription drug or device being misbranded;
- (9) Forges, counterfeits, simulates, or falsely represents prescription drugs or devices without the authority of the manufacturer, or uses any mark, stamp, tag, label, or other identification device without the authorization of the manufacturer;
- (10) Purchases or receives a prescription drug or device from a person who is not licensed to wholesale distribute prescription drugs or devices to that purchaser or recipient;
- (11) Sells or transfers a prescription drug or device to a person who is not legally authorized to receive a prescription drug or device;
- (12) Provides the Board, its representatives, or federal or State officials with false or fraudulent records or makes a false or fraudulent statements regarding any matter within the provisions of these regulations;
- (13) Wholesale distribution of prescription drugs or devices that were:
 - (a) Purchased by a public or private hospital or other health care entity;

- (b) Donated or supplied at a reduced price to a charitable organization;
 - (c) Stolen or obtained by fraud or deceit; or
 - (d) Donated to a drop-off site or repository under the Prescription Drug Repository Program set forth in Health-General Article, Title 15, Subtitle 6, Annotated Code of Maryland;
 - (14) Fails to obtain a license or operates without a valid license when a license is required;
 - (15) Obtains or attempts to obtain a prescription drug or device by fraud, deceit, misrepresentation or engages in misrepresentation or fraud in the distribution or wholesale distribution of a prescription drug or device;
 - (16) Distributes a prescription drug or device to the patient without a prescription or prescription order from a practitioner licensed by law to use or prescribe the prescription drug or device;
 - (17) Fails to obtain, authenticate, or pass on a pedigree when required under these regulations;
 - (18) Receives a prescription drug pursuant to a wholesale distribution without first receiving a pedigree, when required, that was attested to as accurate and complete by the wholesale distributor;
 - (19) Distributes or wholesale distributes a prescription drug or device that was previously dispensed by a pharmacy or distributed by a practitioner;
 - (20) Fails to report prohibited acts as listed in these regulations;
 - (21) Fails to exercise due diligence as provided in Regulation .08 of this chapter;
 - (22) Otherwise conducts the wholesale distribution of prescription drugs or devices in a manner not in accordance with the law;
 - (23) Accepts payment or credit for the sale of prescription drugs in violation of 12-6C-09(D) of this Act;
- or
- (24) If the requirements of 12-6C-09(A) are applicable and are not met, the purchasing or otherwise receiving a prescription drug from a pharmacy;

D. Is disciplined by a licensing or disciplinary authority of any state or country, or disciplined by a court of any state or country, for an act that would constitute a ground for Board action against a wholesale distributor permit holder under §A or B of this regulation; or

E. The aforesaid “prohibited acts” do not include a prescription drug manufacturer, or agent of a prescription drug manufacturer, obtaining or attempting to obtain a prescription drug for the sole purpose of testing the prescription drug for authenticity.

.06 Minimum Requirements for the Storage and Handling of Prescription Drugs or Devices.

A. Facilities. Facilities at which prescription drugs or devices are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(1) Be of suitable size and construction to facilitate:

(a) Cleaning;

(b) Maintenance; and

(c) Proper operations;

(2) Have storage areas designed to provide adequate:

(a) Equipment;

(b) Humidity control;

(c) Lighting;

(d) Sanitation;

(e) Security conditions;

(f) Space;

(g) Temperature; and

(h) Ventilation;

(3) Have a quarantine area for storage of prescription drugs or devices that are:

(a) Adulterated;

- (b) Damaged;
- (c) Deteriorated;
- (d) In immediate or sealed secondary containers that have been opened;
- (e) Misbranded; or
- (f) Outdated;
- (4) Be maintained in a clean and orderly condition; and
- (5) Be free from infestation by insects, rodents, birds, or vermin.

B. Security. A facility:

- (1) Used for wholesale distribution shall be secure from unauthorized entry as follows:
 - (a) Access from outside the premises shall be:
 - (i) Kept to a minimum; and
 - (ii) Well controlled;
 - (b) The outside perimeter of the premises shall be well lit; and
 - (c) Entry into areas where prescription drugs or devices are held shall be limited to authorized personnel;
- (2) Shall be equipped with:
 - (a) An alarm system to detect entry after hours;
 - (b) A security system that provides protection against theft and diversion;
 - (c) Appropriate software to facilitate the identification of evidence of tampering with computers or electronic records;
 - (d) An inventory management and control system that protects against, detect, and document any instances of theft, diversion, or counterfeiting;
 - (e) A security system to protect the integrity and confidentiality of data and documents and make such data and documents readily available to the Board and federal and other state law enforcement officials;
 - (f) Video monitoring of all entrances and exits or alternate acceptable security; and

(g) A means to make the data and documentation required under this section available to the Board, an agent of the Board, or federal and other state law enforcement officials.

C. Storage.

(1) A wholesale distributor shall store a prescription drug or device at appropriate temperatures and under appropriate conditions in accordance with requirements:

(a) If any, of the labeling of the drug or device; or

(b) Set forth in current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF), under 21 CFR §205.50(c).

(2) If no storage requirements are established for a prescription drug or device, the drug or device shall be held at a controlled room temperature, as defined in an official compendium as set forth in §C(1)(b) of this regulation to help assure that its identity, strength, quality, and purity are not adversely affected.

(3) A wholesale distributor shall use appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and logs to document proper storage of prescription drugs or devices.

(4) A wholesale distributor shall follow the record keeping requirements in Regulation .07 of this chapter for stored prescription drugs or devices.

D. Examination of Materials.

(1) Upon receipt, a wholesale distributor shall visually examine each outside shipping container for identity and to prevent the acceptance of:

(a) Contaminated prescription drugs or devices; or

(b) Prescription drugs or devices that are otherwise unfit for distribution.

(2) The examination required under §D(1) of this regulation shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(3) A wholesale distributor shall carefully inspect each outgoing shipment:

- (a) For identity of the prescription drug or device product; and
- (b) To ensure that there is no delivery of a prescription drug or device that has been damaged in storage or held under improper conditions.

(4) A wholesale distributor shall follow the record-keeping requirements in Regulation .07 of this chapter for incoming and outgoing prescription drugs or devices.

E. Returned, Damaged, and Outdated Prescription Drugs or Devices.

(1) A wholesale distributor shall quarantine and physically separate prescription drugs or devices that are outdated, damaged, deteriorated, misbranded, or adulterated from other prescription drugs or devices until the quarantined and separated drugs or devices are destroyed or returned to their supplier for proper disposal.

(2) The wholesale distributor shall identify, mark, quarantine, and physically separate from other prescription drugs or devices those prescription drugs or devices whose immediate or sealed outer or sealed secondary containers have been opened or used, until the drugs or devices are either destroyed or returned to their supplier for proper disposal.

(3) Prescription Drugs.

(a) If the conditions under which a prescription drug has been returned cast doubt on the prescription drug's safety, identity, strength, quality, or purity, then the wholesale distributor shall destroy or return the prescription drug to the supplier, unless examination, testing, or other investigation proves that the prescription drug meets appropriate standards of safety, identity, strength, quality, and purity.

(b) In determining whether the conditions under which a prescription drug has been returned cast doubt on the prescription drug's safety, identity, strength, quality, or purity, the wholesale distributor shall consider, among other things, the:

(i) Conditions under which the prescription drug has been held, stored, or shipped before or during its return; and

(ii) Condition of the prescription drug and its container, carton, or labeling, as a result of storage or shipping.

(4) Prescription Devices.

(a) If the conditions under which a prescription device has been returned cast doubt on the prescription device's safety, identity, or quality, then the wholesale distributor shall destroy or return the prescription device to the supplier, unless examination, testing, or other investigation proves that the prescription device meets appropriate standards of safety, identity, strength, and quality.

(b) In determining whether the conditions under which a prescription device has been returned cast doubt on the prescription device's safety, identity, or quality, the wholesale distributor shall consider, among other things, the:

(i) Conditions under which the prescription device has been held, stored, or shipped before or during its return; and

(ii) Condition of the prescription device and its container, carton, or labeling, as a result of storage or shipping.

(5) A wholesale distributor shall follow the record keeping requirements in Regulation .07 of this chapter for outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs or devices.

.07 Minimum Requirements for Maintenance of Prescription Drug or Device Distribution

Records.

A. Record Keeping.

(1) A wholesale distributor shall establish and maintain inventories and records of transactions regarding the receipt and distribution or other disposition of prescription drugs or devices.

(2) The records required under §A(1) of this regulation shall include the following information:

(a) The source of the prescription drugs or devices, including the:

(i) Name and principal address of the seller or transferor; and

- (ii) Address of the location from which the prescription drugs or devices were shipped;
 - (b) The identity and quantity of the prescription drugs or devices received and distributed or disposed of;
 - (c) The dates of receipt and distribution or other disposition of the prescription drugs or devices; and
 - (d) The pedigrees, when required by Health Occupations Article, § 12-6C-10, Annotated Code of Maryland, for prescription drugs that are wholesale distributed outside the normal distribution channel.
- (3) The wholesale distributor shall make available inventories and records for inspection and copying by authorized federal, State, or local law enforcement agency officials for a period of 3 years after their date of creation.
- (4) The wholesale distributor shall keep the records described in this regulation readily available for inspection by authorized federal, State, or local law enforcement agency officials during the retention period, either:
- (a) At the inspection site; or
 - (b) So as to be immediately retrievable by computer or other electronic means.
- (5) Within 5 working days of a request by an authorized official of a federal, State, or local law enforcement agency, the wholesale distributor shall make available for inspection records kept at a central location apart from the inspection site and not electronically retrievable.
- (6) Facilities shall establish and maintain procedures for reporting counterfeit and contraband or suspected counterfeit and contraband drugs or devices or counterfeiting and contraband or suspected counterfeiting and contraband activities to the Board and the FDA.
- (7) Wholesale distributors shall maintain a system for the mandatory reporting of significant inventory losses of prescription drugs and devices where it is known or suspected that diversion is occurring to the Board, the FDA, and, where applicable, to the DEA.
- (8) Wholesale distributors shall consider the following factors when determining if there has been a significant inventory loss:

- (a) The schedule of the missing items;
- (b) The abuse or misuse potential of the missing items;
- (c) The abuse or misuse potential in the wholesale distributor's area of the missing substance;
- (d) The quantity missing in relation to the total quantity purchased (one tablet vs. one bottle or container);
- (e) Whether this is the first time a potentially significant inventory loss has occurred;
- (f) Whether this loss was reported to local law enforcement authorities; and
- (g) Whether there is a significant resale value of the missing items.

B. Written Policies and Procedures.

(1) A wholesale distributor shall establish, maintain, and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs or devices, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting errors and inaccuracies in inventories.

(2) A wholesale distributor shall include in the written policies and procedures the following:

(a) A procedure by which the oldest approved and unexpired stock of a prescription drug or device is distributed first;

(b) Procedures to be followed for adequate handling of a recall and withdrawal of a prescription drug or device due to:

(i) An action initiated at the request of the United States Food and Drug Administration or other federal, State, or local law enforcement or other government agency, including the Maryland Division of Drug Control;

(ii) A voluntary action by the manufacturer to remove a defective or potentially defective drug or device from the market; and

(iii) An action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design;

(c) A procedure to ensure that the wholesale distributor is prepared for, protected against, and is able to handle a crisis that affects security or operation of a facility if any of the following situations occurs:

(i) Strike;

(ii) Fire;

(iii) Flood;

(iv) Catastrophic health emergency as defined in Article 41, §2-201, Annotated Code of Maryland;

(v) Terrorist activities;

(vi) Other natural disaster; or

(vii) Other situations of local, State, or national emergency;

(d) A procedure to ensure that an outdated prescription drug or device is segregated from other drugs or devices and either returned to the manufacturer or destroyed.

(3) If deviation is appropriate, a wholesale distributor may temporarily deviate from the requirement in §B(2)(a) of this regulation that the oldest approved and unexpired stock be distributed first.

(4) The wholesale distributor shall maintain documentation of the disposition of outdated prescription drugs or devices for 2 years after the disposition of the outdated prescription drugs or devices pursuant to procedures under §B(2)(d) of this regulation.

(5) A procedure for the disposing and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging cannot be used in counterfeiting activities, including all necessary documentation, maintained for a minimum of 3 years, and the appropriate witnessing of the destruction of any labels, packaging, immediate containers, or containers in accordance with applicable federal and State requirements.

(6) A procedure for identifying, segregating, investigating and reporting prescription drug inventory discrepancies involving counterfeit, suspect of being counterfeit, contraband, or suspect of being contraband, in the inventory and reporting of such discrepancies within 5 business days to the Board and appropriate federal or State agency upon discovery of such discrepancies.

C. Responsible Individuals. A wholesale distributor shall establish and maintain a list of officers, directors, managers, the designated representative and others in charge of wholesale distribution, storage, and handling, including:

- (1) A description of their duties; and
- (2) A summary of their qualifications.

D. Compliance with federal, State, and Local Law. A wholesale distributor shall:

- (1) Operate in compliance with applicable federal, State, and local laws and regulations;
- (2) Permit at reasonable times and in a reasonable manner, the Board, the State Division of Drug Control, and any other authorized federal, State, and local law enforcement officials showing proper identification to:

- (a) Enter and inspect the distributor's premises and delivery vehicles; and
- (b) Audit and copy the distributor's records and written operating procedures; and
- (3) If dealing in controlled substances:
 - (a) Register with the Maryland Division of Drug Control and with the United States Drug Enforcement Administration; and
 - (b) Comply with all applicable federal, State, and local regulations.

E. Salvaging and Reprocessing.

- (1) A wholesale distributor is subject to the provisions of applicable federal, State, or local laws or regulations that relate to prescription drug product salvaging or reprocessing, including 21 CFR Parts 207, 210, and 211.

(2) A wholesale distributor is subject to the provisions of any applicable federal, State, or local laws or regulations that relate to prescription device product salvaging or reprocessing.

.08 Due Diligence.

Wholesale distributors having transactions with persons not licensed by the Board or not certified by a third party recognized by the Board shall have in place policies and procedures to perform due diligence on transactions that take place that includes:

- A. Verification of alternate licensure;
- B. Verification of identity; and
- C. Verification of recent inspections by a state or third party entity recognized by the Board.

END ALL NEW

JOHN M. COLMERS
Secretary of Health and Mental Hygiene