



MARYLAND Department of Health

Larry Hogan, Governor · Boyd Rutherford, Lt. Governor · Dennis Schrader, Secretary

MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue, Baltimore, Maryland 21215-2299

Mitra Gavvani, Board President • Deena Speights-Napata, Executive Director

December 29, 2017

The Honorable Larry Hogan
Office of the Governor
State House
Annapolis, Maryland 21401-1925

The Honorable Thomas V. Mike Miller, Jr.
President of Senate
State House, H-107
Annapolis, MD 21401 – 1991

The Honorable Michael Erin Busch
Speaker of House of Delegates
State House, H-101
Annapolis, MD 21401- 1991

RE: Annual Report on the Implementation of the Wholesale Distributor Permitting and Prescription Drug Integrity Act

Dear Governor Hogan, President Miller and Speaker Busch:

In accordance with Health Occupations Article, §12-6C-13, Annotated Code of Maryland, the Maryland Board of Pharmacy (the "Board") respectfully submits this report on implementation of the Wholesale Distributor Permitting and Prescription Drug Integrity Act (the "Act").

This is the 11th annual report on the implementation of the Act. The Act defines requirements for persons applying to be licensed to distribute prescription drugs or devices into, out of, or within Maryland. The Act further requires a pedigree, or history of the distribution chain, for prescription drugs that are distributed in Maryland.

Legislation has been enacted reducing the surety bond requirement to \$50,000 for wholesale distributors that distribute less than \$10,000,000 of their gross receipts from sales of prescription drugs and devices in Maryland (Chapter 170, 2009). Other legislation passed which waived the requirement for inspecting out of state wholesale distributors. This legislation also altered the criminal background check requirement for an in-state applicant for a wholesale distributor permit by requiring that the designated representative and the supervisor of the designated representative submit fingerprints directly to the Criminal Justice Information System Central Repository of the Department of Public Safety and Correctional Services (Chapter 462 and 463, 2012).

There still exist the challenge for the Board regarding the implementation of the U.S. Drug Supply Chain Security Act (DSCSA) which was signed into law by President Obama on November 27, 2013. This federal legislation outlines the critical steps needed to create an electronic, interconnected system to identify and track certain prescription drugs. This legislation will require

manufacturers and repackagers to place an identifier on all prescription drugs and also requires trading partners pass, receive, and maintain certain distribution information. This legislation also provides national uniformity regarding pedigrees, the national implementation timeline for electronic track and trace of pedigrees, and the licensure of third party logistics providers. As noted in the last Annual Report, States are no longer allowed to establish or follow laws or regulations for tracing products through the distribution system which are inconsistent with, more stringent than, or in addition to, any requirements applicable under DSCSA. No State shall regulate third-party logistics providers as wholesale distributors. As a result, Maryland no longer licenses third-party logistic providers.

Maryland and many other states are still awaiting implementation of the Federal regulations in order to re-structure their laws and regulations to comply with the current federal standards. Federal regulations are expected in the near future that will determine the revisions the Board will make to the Wholesale Distributor Permitting and Prescription Drug Integrity Act to comply with DSCSA. The National Association of Board of Pharmacy (NABP) has yet to take a position on these standards and therefore has not provided guidance to states concerning the implementation of these standards.

Should you have questions or additional concerns, please feel free to contact Brian Logan, Legislation and Regulations Liaison, at (410)764-5057.

Respectfully,



Deena Speights-Napata
Executive Director
Maryland Board of Pharmacy