



STATE OF MARYLAND

DHMH

Department of Health and Mental Hygiene

Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor –

Joshua M. Sharfstein, M.D., Secretary

MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue • Baltimore, Maryland 21215-2299

Michael Souranis, Board President - LaVerne G. Naesea, Executive Director

December 1, 2012

The Honorable Joan Carter Conway, Chairman
Senate Education, Health and Environmental Affairs Committee
Miller Senate Office Building, 2 West Wing
11 Bladen Street
Annapolis, MD 21401 - 1991

The Honorable Peter A. Hammen, Chairman
House Health and Government Operations Committee
House Office Building, Room 241
6 Bladen Street
Annapolis, MD 21401

Re: HB 283 (Chapter 658, 2012) Report on the implementation and use of sanctioning guidelines required by Chapters 533 and 534 of the Acts of the General Assembly of 2010

Dear Chair Carter Conway and Chair Hammen:

The Maryland Board of Pharmacy (the "Board") respectfully submits the following report on the implementation and use of sanctioning guidelines as required by Chapters 533 and 534 of the Act of the General Assembly of 2010.

Implementation

The Board's Disciplinary Committee convened a Sanctioning Guidelines Subcommittee (the "Subcommittee") that met monthly for a year from April 2011 until April 2012 to research in detail and draft sanctioning guidelines regulations for pharmacies, wholesale distributors, pharmacists and pharmacy technicians. The Subcommittee reviewed the current COMAR 10.34.11 Monetary Penalties, past and current disciplinary cases, fines, and sanctions imposed by the Board. The Subcommittee determined that the best place for the sanctioning guidelines was in the existing chapter COMAR 10.34.11 Monetary Penalties, instead of promulgating a new chapter. The Subcommittee also considered other Health Occupation board's sanctioning guidelines regulations that were published during this time for format and consistency.

The Board approved the revised COMAR 10.34.11, which has been renamed "Disciplinary Sanctions, Monetary Penalties and Civil Fines," at a public board meeting on June 20, 2012. The

410-764-4755 • Fax 410-358-9512 • Toll Free 800-542-4964
DHMH 1-877-463-3464 • Maryland Relay Service 1-800-735-2258
Web Site: <http://dhmh.maryland.gov/pharmacy/SitePages/Home.aspx>

The Honorable Joan Carter Conway
The Honorable Peter A. Hammen
Page Two
December 1, 2012

proposal was published in the Maryland Register on August 24, 2012 and 2 comments have been received. Those comments were considered and responded to in writing by the Board as described below.

The comment received by the Maryland Pharmacists Association (the "MPhA") expressed concern that some pharmacists may not feel that they are judged by their peers when subject to the Board's disciplinary proceedings. The Board explained in its response that the composition of the Board is set in statute and provides for Board members from a variety of practice settings including chain store pharmacies, independent pharmacies, acute-care hospital pharmacies, long-term care facility pharmacies, home infusion/home care service pharmacies, pharmacists at-large; and consumer members. The individuals who serve on the Board use their knowledge and experience from these practice settings to further the mission of the Board and to ensure fairness in deliberations concerning practice and disciplinary matters. Although not all the Board members have experience in all the practice areas, the Board does consist of members who share the concerns of pharmacists in general and also share the concerns of the Board members' respective practice areas.

Additionally the MPhA questioned whether nonresident mail order pharmacies are subject to the same disciplinary process as any permit holder and how would the Board know if an infraction has occurred. The Board's jurisdiction over the nonresident pharmacies was expanded in the 2012 Legislation Session to give the Board greater power to discipline nonresident pharmacies if they violate certain required standards in the Maryland Pharmacy Act. That legislation is available for your review at the following link:

http://mlis.state.md.us/2012rs/chapters_noln/Ch_182_sb0132T.pdf The response further explained that the Board's disciplinary process is complaint driven and the Board investigates every complaint received. With the new law, more complaints concerning nonresident mail order pharmacies will fall within the Board's jurisdiction and may be investigated and pursued by the Board.

A comment was also received from the Maryland Association of Chain Drug Stores ("MACDS") which expressed concern with the potential severity of the penalties set forth in the proposed regulations. The Board's response explained that the sanctioning guidelines included in this proposal are for public sanctions for pharmacists, pharmacies, wholesale distributors and pharmacy technicians. The penalties in the sanction guidelines offer various ranges of sanctions that the Board will be required to stay within depending on the circumstances and the facts of the case. The MACDS had specifically requested that "reprimands" be imposed when infractions have not been severe. It was indicated that reprimands are within the sanctioning guidelines for pharmacists, pharmacy technicians, and wholesale distributors, but the Maryland Pharmacy Act does not allow for reprimands of a permit holder.

The Honorable Joan Carter Conway
The Honorable Peter A. Hammen
Page Three
December 1, 2012

The Board further explained that many times the Board resolves disciplinary matters through preliminary non-public actions. Those resolutions are not public and the sanctions imposed for non-public actions have not been included in the proposal published in the Maryland Register.

The Board has the ability, depending on the circumstances, to issue a non-public Letter of Education or Letter of Admonishment. Oftentimes these letters will educate a licensee, who may not have been fully familiar with the law, and perhaps require a licensee to complete continuing education courses to prevent a similar violation from occurring in the future. It is not the Board's intention, nor the intent of the legislature who mandated these regulations, to impose the most severe penalties available. The intent of these regulations is to provide the public, licensees, permit holders, and registrants with a range of sanctions that may be imposed.

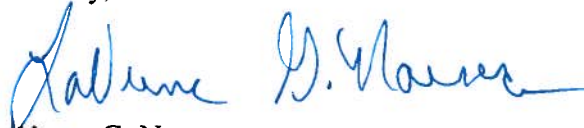
The above responses were approved at the October 17, 2012 Board Meeting and the Board voted to adopt the regulations as proposed. A Notice of Final Action is anticipated to be published December 14, 2012 with an effective date of December 24, 2012.

Use of Sanctioning Guidelines

Since the regulations are not in effect at this time, the Board is not able to report on the actual use of the sanctioning guidelines. The Board anticipates, however; that these guidelines will simplify the sanctioning process and provide licensees with a range of sanctions that may be imposed. These guidelines will also formalize the Board's existing consistent disciplinary decision making process.

I hope this information is helpful to you. Should you have questions or additional concerns, please feel free to contact Anna D. Jeffers, Legislation and Regulations Manager at (410) 764-4794.

Sincerely,



LaVerne G. Naesea
Executive Director

cc: Sarah Albert, Department of Legislative Services, MSAR #9285
Marie Grant, Director, Office of Governmental Affairs, DHMH
Anna D. Jeffers, Legislation and Regulations Manager, Board of Pharmacy
Christi Megna, Assistant Director, Office of Governmental Affairs, DHMH
Mike Souranis, President, Board of Pharmacy