January 2005

maryland Board of Pharmacy

DRUG THERAPY MANAGEMENT FINALLY A REALITY

Pharmacists, physicians and patients can finally enter into treatment agreements under the Drug Therapy Management Program (or Collaborative Practice as it is sometimes referred to). In general, the program will allow pharmacists and physicians to enter into time-limited agreements to treat specific disease states using approved protocols. Once the Maryland Board of Pharmacy (MBoP) and the Maryland Board of Physicians (MBP) approve a Physician-Pharmacist Agreement, the pharmacist and physician may establish single contracts with individual patients(Therapy Management Contracts).

The full text of the Drug Therapy Management statute and regulations are under HealthOccupations Article §§ 12-6A-01 – 12-6A-10, Annotated Code of MD and C.O.M.A.R. 10.24.29.01-.08, respectively. A summary of the program concepts is provided below.

PHYSICIAN-PHARMACIST AGREEMENT - an approved agreement between a licensed physician and a licensed pharmacist that is disease-state specific, stating the protocols that will be used. A physician-pharmacist agreement shall be valid for 2 years from the date of its final approval. A pharmacist is authorized to enter into a physician-pharmacist agreement if the pharmacist:

1. Is a licensed pharmacist;
2. Has Doctorate of Pharmacy Degree or equivalent training as established in regulations;
3. Is approved by the Board to enter into a physician-pharmacist agreement with a licensed physician; and
4. Meets the requirements that are established by regulations.

PHARMACIST INFORMATION FORM - provides information to the Board of Pharmacy so that the Board may determine if each pharmacist has the basic qualifications to perform under this Physician-Pharmacist Agreement. The Board of Pharmacy must approve each Pharmacist listed in the agreement.

PROTOCOLS - courses of treatment predetermined by the licensed physician and licensed pharmacist, according to generally accepted medical practice for the proper treatment of a particular therapeutic or diagnostic condition.

THERAPY MANAGEMENT CONTRACT - relates to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations for the purpose of improving patient outcomes. It means a voluntary, written arrangement that is disease-state specific signed by each party to the arrangement between:

1. One licensed pharmacist and the licensed pharmacist's designated alternate licensed pharmacists;
2. One licensed physician and alternate designated licensed physicians involved directly in patient care; and
3. One patient receiving care from a licensed physician and a licensed pharmacist pursuant to a physician-pharmacist agreement and protocol.

If interested in submitting an application to begin Drug Therapy Management visit the Board's web site at mdbop.org or contact Ms. Christina Harvin at the Maryland Board of Pharmacy (410 764-4794). ■

The mission of the Maryland Board of Pharmacy is to protect Maryland consumers and to promote quality health care in the field of pharmacy through licensing pharmacists and issuing permits to pharmacies and distributors; setting standards for the practice of pharmacy through regulations and legislation; receiving and resolving complaints and educating consumers. The Maryland Board of Pharmacy sets standards that ensure safety and quality health care for the citizens of Maryland.

Maryland Board of Pharmacy
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Baltimore MD 21215-2299
Tel: 410-764-4755
Fax: 410-358-6207
www.mdbop.org

From The Executive Director's Desk - OFFICIAL NOTIFICATION

Three Board Commissioners' Terms Expire in 2005

Maryland law requires Board notification of all licensed pharmacists and other interested parties of record in the State of anticipated pharmacist member Board vacancies, to solicit nominations to fill the vacancies and provide information for contacting representatives of the groups that submit nomination lists for new appointments to the Governor. This newsletter article serves as that notification.

The Board of Pharmacy is comprised of ten (10) pharmacist members and two (2) non-pharmacist consumer members. A Commissioner (as they are entitled) may serve a total of two consecutive four-year terms. The Commissioners' terms are staggered so that each year three (3) four-year terms expire. The full text of the statute is found in Health Occupations Section 12-202. Board seats that will be open for nominations in 2005 are: One (1) at-large seat, one (1) acute care hospital seat and one (1) independent pharmacy seat. The pharmacists currently filling these seats are serving second terms, and are therefore not eligible for reappointment.

Maryland law designates specific categories of representation for the 12 Board seats: Two (2) non-pharmacists, consumer members are appointed by the Governor to the Board with the advice of the Secretary and the consent of the Senate. Ten (10) pharmacist members are appointed by the Governor with the advice of the Secretary of the Department of Health and Mental Hygiene, from lists submitted by the appropriate Association as noted below:

ACUTE CARE HOSPITAL (Two seats): The Maryland Society of Health System Pharmacists submits three (3) pharmacists' names, who at the time of appointment practice primarily in an acute care hospital for each open seat;

INDEPENDENT (Two seats): The Maryland Pharmacists Association (MPhA) and the Maryland Pharmaceutical Society jointly submit three (3) pharmacists' names, who at the time of appointment, practice primarily in independent pharmacy for each open seat;

CHAIN STORE (Two seats): The Maryland Association of Chain Drug Stores submits three (3) pharmacists' names, who at the time of appointment, practice primarily in chain store pharmacy for each open seat;

HOME CARE INFUSION (One seat): The Maryland Society of Health-System Pharmacists submits three (3) pharmacists' names, who at the time of appointment, practice primarily in a pharmacy that specializes in the provision of home infusion/home care services for the open seat;

LONG TERM CARE (One seat): The Maryland Society of Consultant Pharmacists submits three (3) pharmacists' names, who practice primarily in a pharmacy that provides services to a long-term care facility, for the open seat, and

AT LARGE (Two seats): The Maryland Pharmacist Association (MPhA) submits a list of all interested pharmacists that have submitted their names to MPhA for each open seat.The requirements for appointment to the Board are as follows:

PHARMACIST APPOINTEES (10)
- Maryland Resident
- Licensed Maryland pharmacist
- In good standing with the Board
- Skilled and competent pharmacist
- Possesses at least five years of professional experience

CONSUMER APPOINTEES (2)
- Maryland Resident
- May not have been a pharmacist
- May not have a pharmacist in the household
- May not have participated in pharmacy field
- May not have had a substantial financial interest in a person regulated by the Board within two years prior to the appointment.

Eligible licensed pharmacists who wish to be considered for 2005 appointments should contact the appropriate association to obtain an application form and a description of Board member duties. Pharmacists should indicate the type of seat to which they wish to be appointed, and if an at-large seat is involved, whether they want to be considered for more than one type of seat (e.g., a clinical specialty seat as well as an at-large seat). To receive information on the duties of a Board Commissioner and for applications for the 2005 openings, write or call the following associations:

AT-LARGE SEAT:
Maryland Pharmacist Association
650 W Lombard St.
Baltimore MD 21201
(410) 727-0746

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From The Executive Director's Desk - OFFICIAL NOTIFICATION

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ACUTE CARE HOSPITAL SEAT:
Anna Leonardt
Maryland Society of Health System Pharmacists
8480M Baltimore National Pike, #252
Ellicott City, MD 21043
Phone: 410/465-9975
Fax: 410/465-7073
E-mail: ContactMSHP@aol.com

INDEPENDENT PHARMACY SEAT:
Maryland Pharmacist Association (see above);
and/or
Maryland Pharmaceutical Society
P.O. Box 1995
Baltimore, MD 21203-1995

Applications must be submitted to the appropriate organization by February 15, 2005. All appointments take place after April 30, 2005, as the terms of the incumbents expire and the Governor has made his decision. Commissioners' whose terms have expired serve until a replacement is sworn in. Happy New Year!!

LaVerne G. Naesea

BOARD ASSIGNS USP CHAPTER 797 TASK FORCE

The Maryland Board of Pharmacy assigned a Task Force, Chaired by member Donald Yee, to review the United States Pharmacopeia (USP) Chapter <797>, Pharmaceutical Compounding -- Sterile Preparations standards. The Task Force is assigned to review and recommend which aspects of USP Chapter <797> the Maryland Board of Pharmacy (MBOP) should enforce, as well as recommend resources needed by the Board in order to implement the recommendations. .

The USP Chapter <797> standards are intended to address problems that can occur during compounding of sterile preparations. It establishes criteria that all personnel who perform sterile preparation compounding must meet Chapter <797> standards that relate to maintaining clean facilities, personnel training and testing in aseptic technique, air quality evaluation and maintenance and knowledge of sterilization and solution stability principles.

Federal agencies have been able to require that the USP standards be met by all sterile-compounding pharmacies (hospital, home infusion and retail) since January 1, 2004. However, although the FDA may not survey pharmacies for compliance with the standards, it could fine or even jail responsible parties if it receives a complaint that products are being prepared inappropriately or if a contaminated product results in a patient death. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) implemented a timeframe for compliance with USP <797> by all hospital and home infusion pharmacies that they accredit starting in January 2005 through January 2008.

In addition to Task Force Chair Don Yee, members include, Cynthia Anderson, MD, RPh. of Medstar Health; Harry Stromberger, RPh, MBA, of Johns Hopkins Hospital, Central Services; Reid Zimmer, PD, of Clearview Associates, LLC; Patricia Holbrook, RPh. of St. Agnes Hospital, and Tilford Brackett, RPh. The MBOP Pharmacist Compliance Officer, Chandra Mouli, staffs the Task Force.

To learn more about USP <797> visit the JCAHO (www.jcaho.org) and ASHP websites (www.ashp.org). ■

EMERGENCY PREPAREDNESS UPDATE

The Board of Pharmacy is at the forefront in preparing volunteer practitioners to respond to state emergencies, such as biological or chemical terrorist attacks and natural disaster (e.g., hurricane, tornado, fire, flooding, etc.). Over 1000 pharmacists have volunteered to date and over half have undergone training. A number of pharmacist volunteers were selected as team leaders to act during exercises and real emergencies and/or as liaisons to work with local health department representatives on preparatory planning and exercises. Only trained volunteers are eligible for those assignments.

The Board has assigned one or more liaison pharmacists to each county to take part in planning, discuss in advance how pharmacists and technicians will be utilized and inform the local health department of what the Board of Pharmacy volunteers can do. When possible, the liaison also acts as the lead pharmacist in the event of an emergency. Since many pharmacists have volunteered for more than one county, and the possibility exists that pharmacists from one jurisdiction will have to be called on to help neighboring localities, it is essential that the liaison inform the Board, of actions being taken in a local jurisdiction in order to prevent overlapping of volunteer assignments.

The state provides trained volunteers with liability protection when performing assigned duties during an emergency. Some pharmacists have expressed a willingness to serve as volunteers, but they have not been able to attend training. Some have told the Board that they will work with their Local Health Department (LHD), which is possible since the LHD can determine that they can handle an emergency on their own without asking the State for resources. Pharmacists who respond to calls from their LHD should understand that the State does not offer them any liability protection.

In a widespread emergency, the Board would establish a command center and direct first the liaisons and team leaders that were available, then other volunteers, to locations identified by the counties. These areas may be staging areas away from the location of the incident from which the pharmacists are transported. On arrival, the liaison, or if not available, a team-leader, would get instructions from the LHD Officer in charge, and direct teams of pharmacists to treatment areas, matching skills of the pharmacists with needs.

Pharmacists and pharmacy technicians may be needed to dispense medication, offer counseling, help with triage functions, determine the need for medications and supplies, and sort medications at reception sites. Since each LHD has their own plan and resources and since each potential incident would call for different reactions, it is impossible to say exactly how pharmacists would be used in each incident. The liaison and/or team leaders will make determinations based on discussions with the LHD person in charge.

Liaisons and possibly team-leaders will also be involved in debriefing sessions both in exercises and actual events. Exercises in the next year will be both 'table top' (primarily to test communication systems and the availability of volunteers) and actual field exercises (volunteers called to locations for a drill).

To join the "Maryland Pharmacist Volunteer Corp" as a pharmacist or technician, please visit the Board's web site at www.mdbop.org and register. For more information, contact LaVerne Naesea at (410) 764-4794 or email: lnaesea@dhmh.state.md.us. ■

MSHP HOSTS FIRST ALL DAY CE SEMINAR

Submitted by: Terri F Clayman

The Maryland Society of Hospital Pharmacist (MSHP) will host its first all day continuing education seminar, March CE Madness, on Saturday March 12, 2005 at The Conference Center at Sheppard Pratt in Towson, Maryland. A total 6.25 hours of continuing education will be awarded with topics including HIV, non-small cell lung cancer, MRSA, diabetes, and palliative care. A trade show will occur during lunch and a reception will be held following the seminar in which participants can meet the new hospital pharmacy directors as well as view posters submitted by Maryland pharmacists. For more information Contact MSHP at 410-465-9975 or e-mail: ContactMSHP@aol.com. ■

A MESSAGE FROM FORMER NEWSLETTER EDITOR

Submitted by: Joan Lawrence, Volunteer Program Director, Department of Health and Mental Hygiene (DHMH), Office of Emergency Preparedness and Response (EP&R)

Some of you may know me by Board communications, or by the Board's bioterrorism trainings you participated in during my 3.8-year tenure with the Maryland Board of Pharmacy, as the Board's Public Information Officer and Bioterrorism Program Coordinator.

November 24, 2004 I accepted a position as the Volunteer Program Director, for the Department of Health and Mental Hygiene (DHMH), in the Office of Emergency Preparedness and Response (EP&R), Baltimore, Maryland. You have not heard the last of me. I will be working closely with all seven (7) health care professional boards (Pharmacy, Physicians, Nursing, Dental, Social Work, Professional Counselors and Psychology), providing leadership and support with program recruitment, implementation and coordination, as well as development of policies, protocols, training, exercises and deployment.

I will also develop partnerships with agencies such as the Governor's Homeland Security, and the Governor's Office on Service & Volunteerism, Maryland Emergency Management Agency (MEMA), Maryland Institute for Emergency Medical Systems Services (MIEMSS), Medical Reserve Corps (MRC), Human Resources and Services Administration (HRSA), Local Health Departments (LHD), and various states on systems, trainings, policies and protocols.

I have three (3) requests to make of you. First, if you have not signed up to become a volunteer, please do so, your skills and expertise are needed; complete your training through the Board of Pharmacy, and participate in state-sponsored drills with local health departments. It is critical that you have the best possible understanding of your role in an emergency. Also, please keep your 24-contact information current with the Board of Pharmacy so they may reach you quickly.

I look forward to working with you as you continue as a member or become a new member of the Maryland Pharmacist Volunteer Corps (MPVC). ■

PATIENT SAFETY

Dextromethorphan Concerns

Concerns about the illicit use of dextromethorphan (DXM) containing products are emphasized periodically when the 'recreational' use of the drug results in tragic events. The product is available in over 120 over-the counter cold medications. Most commonly abused are the Robitussin and Coricidin products including generic formulations containing DXM. It can also be obtained over the Internet in a powdered form and is used for 'robo-tripping' or 'skittling.' A recent correspondence to Governor Erhlich contained a plea from a mother whose son suffered a severe psychological addiction to Robitussin DM. The October 8, 2004 edition of the Washington Post carried a front page article titled: "Household Medicine Abused by the Young."

The Board of Pharmacy is alerting all pharmacies to watch the sales and 'shrinkage' off the shelves of DXM products closely and consider whether some or all should be kept behind the counter and sold only after counseling. Reviewing your placements is advisable from both a professional and business perspective. If it is not practical to put all products behind the pharmacy department counter, consider placing those that seem to 'move' the fastest, especially when it is not cold season, in safer places. At a minimum, perhaps rearrange shelving locations to locate DXM products where they are most visible to clerks, and train employees to call for the pharmacist on potentially suspicious sales. ■

Inspection Reports

The Division of Drug Control is legally mandated to perform annual inspections of all Maryland pharmacies on behalf of the Board of Pharmacy for review. While it is rare for an inspection report to require that immediate action be taken, some concerns show up much more often than others. The Board views the Drug Control visit to be as much of an educational process as it is a regulatory process. As such, permit holders may be allowed to implement corrective actions to practice sites when a noted concern is not an immediate danger to patients. However, when problems such as poor record-keeping are noted in consecutive inspections, the Board may require immediate remedial action by the permit holder, including requiring a corrective active plan to be prepared and submitted to the Board. The Board may also take more formal action if a satisfactory plan is not submitted. Problems that have been unusually noted during routine inspections involve the following:

- Maryland Criminal Law, Title 5-306, requires an inventory of controlled dangerous substances to be taken every 2 years and kept for 2 years. Problems in this area usually stem from the inability of the pharmacist on duty to find the inventory. This may be due to movement of pharmacists between stores during the year. Instances of the pharmacist forgetting to put the time that the inventory was taken (start of business, end of business day) have also been noted. Doing this may prevent the performance of accurate audits of controlled dangerous substances.
- DEA requires Form 222 (Schedule II ordering form) to be completed correctly when ordered items are received. The number of packages received and the date received are required. Although not legally required, inspections would be less disruptive if the invoice from the wholesale distributor is attached to the corresponding Form 222. In the event of an audit both items are required. Additionally, inspections would be expedited if the names of persons authorized to sign the forms are immediately available. The pharmacist should date and initial each distributor invoice containing information on the receipt of controlled drugs when received.
- Health Occupations 12.503. Unless otherwise directed by an authorized prescriber, a pharmacist may not dispense a drug presented more than 120 days after the prescription was written. This should NOT be interpreted to mean that a pharmacy can enter a prescription into the computer and the 120-day clock starts when the refills of an old order have run out. Pharmacists must confirm with the prescriber if the first use of the new order is over 120 days after having been written by the prescriber. Also, consider whether the prescriber who wrote a new prescription intended to void all remaining refills on the previous one. This is usually the case. The Board has received complaints from physicians when pharmacists allow patients to obtain medication past the time that the prescriber wanted the patient to return to them. Please note that PBM auditors may consider a prescription that was initially filled beyond 120 days to be an illegally filled prescription; not eligible for payment. Contracts normally require pharmacies to be in compliance with all applicable laws. Remember also that a prescription must be dated when written. The Board will accept a pharmacist filling in the date if it is documented that the date was confirmed with the prescriber.
- COMAR 10.7.01. A pharmacy shall have a refrigerator solely for the use of drugs requiring refrigeration. This was a major problem a number of years ago when a patient died from being given what was thought to be water, but turned out to be an acid, on request for fluid to take a first dose of medication. The placement of food/drink in medication refrigerators subsided quite a bit after that tragedy, but inspections have recently shown slippage in this critical area.
- COMAR 10.34.24 Record of Drug inventory acquisitions. A pharmacy permit holder must maintain records of all drug inventory acquisitions for 2 years. This includes not only wholesaler invoices, but records of drugs purchased from other pharmacies, out-of-state generic companies, secondary wholesalers and from chain warehouses.
- COMAR 10.07.01 Equipment. A pharmacy is required to have a Class A balance or one of equivalent or better sensitivity, a refrigerator for drugs, and additional equipment consistent with its scope of practice. This would include having appropriate equipment to compound or reconstitute medication. As an example, pharmacies should have a method of accurately measuring 9cc of diluent if that is called for in the dispensing directions, not use a 100cc graduate and guesstimate. There are also sections in Maryland law dealing with equipment and special requirements for hospital pharmacies. (COMAR 10.34.03) and for pharmacies preparing sterile products (COMAR 10.34.19).
- Health Occupations 12-505 related to expiration dating. Computers are often set to print an expiration date of one year from the date of entry into the computer, but pharmacists must verify that the date is correct. Instances have been found where a label was put on an original bottle that had a shorter shelf liferemaining than one year.

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Inspection Reports

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Additionally, reconstituted antibiotics need expiration parameters set to 7, 10, or 14 days as is appropriate for the specific agent.

- The Board has had several instances of patients receiving the wrong medication because of similarly spelled names (or even two people with the exact same name). A policy that requires more than one type of check in addition to the name (e.g., date of birth oradress check) would help remedy this problem. Of course, if the pharmacist counsels and reads directions, an error of this type is not likely to happen.
- Physician names. Physicians occasionally complain to the Board that they are identified in pharmacy computer records as having prescribed for persons who are not their patients. This usually results from pharmacy personnel inputting the physician name by choosing the first physician choice that appears (e.g. Dr. Smith) without confirming that it is the correct physician. This could lead to improper reviews by Maryland Medicaid or other insurers and to the pharmacist calling the wrong physicians on refill requests. Problems also may surface when the pharmacist cannot read the physician signature and the incorrect prescriber is selected from the names of group practitioners heading the prescription blank. ■

Scanned Records Acceptable

The Board has determined that a pharmacy that scans prescriptions into its computer records can consider the scanned information as the prescription records that must be saved for at least five years by Board of Pharmacy law. COMAR 10.34.20.03 requires that pharmacies maintain prescription records in a form that is readily and accurately retrievable that will not fade or deteriorate for five years from the date of dispensing. When original prescriptions, prescriptions received by facsimile device, and oral prescriptions that have been reduced to writing and meet all of the requirements of COMAR 10.34.20 are scanned into a computer, the originals do not have to be saved for Board of Pharmacy purposes. Prescriptions received directly into the computer by an electronic system that meets the requirements of COMAR 10.34.20.02 would logically not require to be maintained as hard copies.

However, there are exceptions and other considerations. As required by federal law, records of Controlled Dangerous Substances must be saved in hard copy form whether they have been written by the prescriber or reduced to writing by the pharmacist. Additionally, some contracts with Pharmacy Benefit Managers or insurers may call for records to be kept as long of 7 years. Permit holders should consider saving all records for at least that period of time and will have to make their own determination as to the need to maintain hard copies for PBM purposes. ■

DISCIPLINARY ACTIONS

Augustine R. Durso, Jr., P.D. License # 09953
License to practice pharmacy in Maryland was summarily suspended October 26,2004.

Frank Leung, PD. License # 15395
License to practice pharmacy in Maryland was summarily suspended November 8, 2004.

Hyacinth O. Uche, P.D. License # 11960
License to practice pharmacy in Maryland was suspended effective December 2, 2004.

The Maryland Pharmacy Coalition (MPC), comprised of MPhA, MSHP, Md-ASCP, MPhS and SGA (School of Pharmacy), is proud to sponsor the

FIFTH ANNUAL MARYLAND PHARMACY LEGISLATIVE DAY in Annapolis

Submitted by:
Howard Schiff, MPhA,
Executive Director

This is an opportunity to support your profession and MAKE A DIFFERENCE. Come learn about what is going on in the Maryland Legislature and how you can help educate your elected officials about pharmacy and our concerns. We cannot afford to sit by and let others make decisions that effect our profession. If you are not speaking to your legislator, they may be hearing another story. They need to hear from you.

We invite you to join us in Annapolis on February 17, 2005 to learn about this year's issues and to talk with your Delegates and Senators.

The day starts at 7:15 a.m. with a continental breakfast and includes appointments with legislators. Call 410-727-0746 for further information or to register. ■

Maryland Board of Pharmacy

LET US KNOW HOW WE ARE DOING...

Please email your questions, concerns or comments to the Board at the following emails. We value your feedback.
Licensing: Shirley Costley at: scostley@dhmh.state.md.us
Compliance: Chandra Mouli at: cmouli@dhmh.state.md.us
Personnel: Patricia Gaither at: pgaither@dhmh.state.md.us
Regulations: Christina Harvin at: cmharvin@dhmh.state.md.us
Website: Tamarra Banks at: tbanks@dhmh.state.md.us
General: LaVerne Naesea at: lnaesea@dhmh.state.md.us

ADDRESS OR EMPLOYMENT CHANGE?

To submit the Pharmacist Change of Information form on the Board's web site go to MDBORORG and click on Forms & Publications.

SPECIAL NOTICE

The Maryland Board of Pharmacy Newsletter is considered an official method of notification to pharmacists and pharmacies. These Newsletters may be used in administrative hearings as proof of notification. Please read them carefully and the Pharmacy Law Book for future reference.

Meetings

The public session of the Pharmacy Board meetings are open to the public 9:00 a.m. – 12:00 Noon at 4201 Patterson Avenue, Baltimore, MD 21215. The Board encourages all interested parties to attend.

BOARD PUBLIC
MEETING DATES:

(All meetings begin at 9:00 a.m.)

Wednesday, January 19, 2005

Wednesday, February 16, 2005

Wednesday, March 16, 2005

Wednesday, April 20, 2005

*Tuesday, May 17, 2005

Wednesday, June 15, 2005

Wednesday, July 20, 2005

December 21

* Regular meeting date changed
MBOP will participate in
the Annual Flower Mart
May 18, 2005

Maryland Board of Pharmacy

Maryland Board of Pharmacy
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