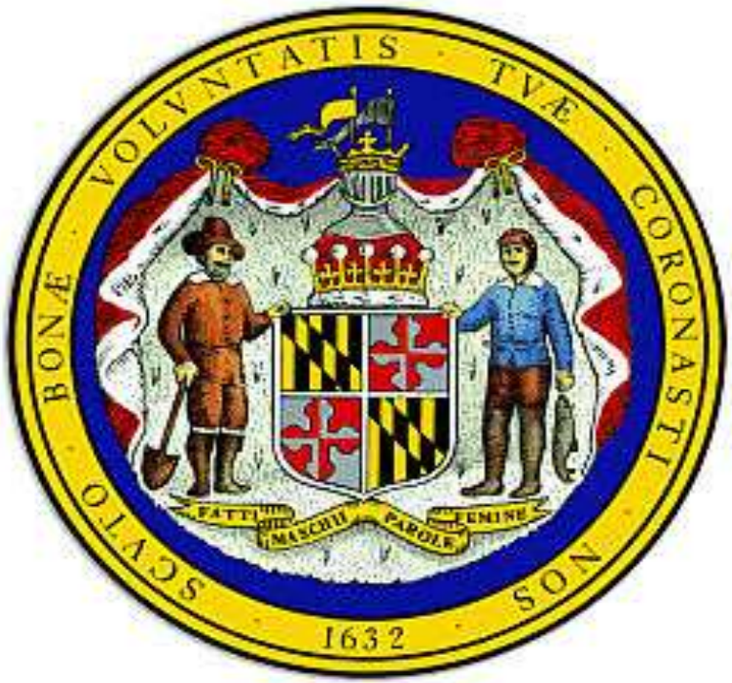
University of Maryland Eastern Shore School of Pharmacy

2014

STATE LAWS - MARYLAND



Main Sections of Maryland Laws and Regulations Pertaining to Pharmacy

Health Occupations (HO)

Health General (HG)

Title 15 – Health Insurance (IN)

Criminal Law (CR)

Public Safety (PS)

Title 10 - Department of Health and Mental Hygiene

Related DHMH Regulations

COMAR 10.34 Board of Pharmacy ***

MARYLAND LAW – HEALTH OCCUPATIONS (HO)

HO State Definitions

Compounding means:

The preparation, mixing, assembling, packaging, or labeling of a drug or device:

(i) As the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice; or

(ii) For the purpose of, or incident to, research, teaching, or chemical analysis and not for the sale or dispensing of the drug or device.

HO State Definitions (cont)

Delegated pharmacy act:

(1) Means an activity that constitutes the practice of pharmacy delegated by a licensed pharmacist.

(2) Delegated pharmacy act does not include:

(i) An act within the parameters of a therapy management contract;

(ii) The administration of an influenza vaccination;

(iii) The delegation of a pharmacy act by a registered pharmacy technician, pharmacy student, or pharmacy technician trainee;

(iv) A pharmacy activity performed by a pharmacy student;

(v) A pharmacy activity performed by an applicant for a license to practice pharmacy; or

(vi) The performance of other functions prohibited in regulations adopted by the Board.

HO State Definitions (cont)

Dispense

Means the procedure which results in the receipt of a prescription or nonprescription drug or device by a patient or the patient's agent and which entails the:

(1) Interpretation of an authorized prescriber's prescription for a drug or device;

(2) Selection and labeling of the drug or device prescribed pursuant to that prescription; and

(3) Measuring and packaging of the prescribed drug or device in accordance with State and federal laws.

Distribute

Means the process resulting in the provision of a prescription or nonprescription drug or device to a separate, intervening individual, licensed and practicing under this article, -- prior to administration of the provided drug or device to the patient pursuant to a prescription issued by an authorized prescriber.

HO State Definitions (cont)

Non-prescription drug

Means a drug which may be sold without a prescription and which is labeled for use by the consumer

Non-resident pharmacy

Means a pharmacy located outside this State that, in the normal course of business, ships, mails, or delivers drugs or devices to a person in this State pursuant to a prescription.

HO State Definitions (cont)

Pharmaceutical care

Means the utilization of a patient's drug regimen for the purpose of achieving definite outcomes related to the:

Cure or prevention of a disease,

Elimination or reduction of a patient's symptoms, or

Arresting or slowing of a disease process by identifying, resolving, or preventing actual or potential drug therapy problems and

Which may include patient counseling and providing information to licensed and certified health care providers.

HO State Definitions (cont)

Practice pharmacy - means to engage in any of the following activities:

(i) Providing pharmaceutical care;

(ii) Compounding, dispensing, or distributing prescription drugs or devices;

(iii) Compounding or dispensing nonprescription drugs or devices;

(iv) Monitoring prescriptions;

(v) Providing information, explanation, or recommendations to patients and health care practitioners about the safe and effective use of prescription or nonprescription drugs or devices;

(vi) Identifying and appraising problems concerning the use of, or monitoring of therapy, with drugs or devices;

(vii) Administering a vaccination;

(viii) Delegating a pharmacy act to a registered pharmacy technician, pharmacy student, or an individual engaged in a Board approved pharmacy technician training program;

(ix) Supervising a delegated pharmacy act performed by a registered pharmacy technician, pharmacy student, or an individual engaged in a Board approved pharmacy technician training program;

(x) Providing drug therapy management

MARYLAND BOARD OF PHARMACY

Maryland State Board of Pharmacy

Maryland Board of Pharmacy contact information:

Maryland Board of Pharmacy

4201 Patterson Avenue

Baltimore, Md. 21215

410-764-4755

http://dhmh.maryland.gov/pharmacy

Maryland Commissioners 2010

Maryland State Board of Pharmacy

The Board is comprised of:

12 Commissioners who represent different areas of pharmacy practice:

- Chain (2)
- Independent (2)
- Acute Care (2)
- At Large (2)
- Long Term Care (1)
- Home infusion (1)
- Consumer Members (2) **

** May not have any relatives in the pharmacy arena within the last 2 years

Maryland State Board of Pharmacy (cont)

Potential members are nominated by the designated pharmacy groups representing the different arenas of pharmacy practice

i.e. MPhA, MSHP, MACDS (2- 3 nominations each required)

Appointed by and serve at the discretion of the Governor to a 4 year term – may be reappointed for a 2nd 4 year term.

The Board appoints a President, Secretary and Treasurer from the sitting Commissioners.

Commissioners may be removed from the Board by the Governor for incompetence, misconduct or for failure to attend 2 consecutive Board meetings without being excused.

Board must notify public when a vacancy exists on Board (usually via newsletter)

Maryland State Board of Pharmacy (cont)

The Board is self-funded (depends on fees charged to Board registrants for all operational monies)

Hires an Executive Director who manages the daily activities at the Board's office and oversees the Board's staff.

The staff is tasked with implementing and carrying-out the decisions of the Board.

Main units of the Board:

- Licensing
- Disciplinary
  - Inspectors
- Legislative
- MIS

Maryland State Board of Pharmacy (cont)

Mission of Board of Pharmacy –

Protect Maryland consumers and to promote quality healthcare in the field of pharmacy through licensing pharmacists and registering technicians, issuing permits to pharmacies and distributors, setting pharmacy practice standards, and through developing and enforcing regulations and legislation, resolving complaints and educating the public.

Maryland State Board of Pharmacy (cont)

Duties of the Board

- Enforce State laws and regulations
- Develop regulations and legislation
- License pharmacies, pharmacists, distributors
- Register technicians
- Inspect pharmacies and distributors
- Conduct investigations for possible violations of laws and/or regulations
- Levy necessary disciplinary actions
- Approve CEs
- Provide consumer education
- Initiate programs and projects as necessary to protect the public

Maryland State Board of Pharmacy (cont)

Agenda items and issues are first assigned to a Committee (composed of 1 – 2 staff members and 5- 6 Commissioners) for initial discussion.

The Committee then makes a recommendation to the full Board. The Board is not bound by the recommendation and may either accept, reject or change the committee's decision.

The full Board meets monthly and must have a quorum (7) present to conduct business.

- Public Session
- Closed Public Session
- Administrative Session

The full Board votes on each item, with the President of the Board only voting to break a tie. Motions must carry by a majority of the Commissioners present. The Executive Director and members of the staff do not vote.

DUTY TO REPORT

Pharmacist Rehabilitation Program (cont)

Disturbing facts:

40% of pharmacists have reported that they had used a prescription drug without a prescriber's authorization.

20% reported that they had done so 5 or more times.

It is estimated that 15 – 18 percent of pharmacists in the U.S. have been impaired at some point in their pharmacy careers.

Pharmacist Rehabilitation Program

"Duty to report"

A. Except when the conduct in question includes drug or alcohol abuse or dependency, a pharmacist or a pharmacy technician shall report to the Board:

(1) Conduct which violates a statute or regulation pertaining to the practice of pharmacy;

(2) Conduct by a pharmacy technician or a pharmacist that deceives, defrauds, or harms the public; and

(3) The unauthorized practice of pharmacy.

B. A pharmacist or pharmacy technician shall report to the pharmacist rehabilitation committee conduct by a pharmacy technician or a pharmacist that involves drug or alcohol abuse or dependency.

Pharmacist Rehabilitation Program (cont)

C. The pharmacist rehabilitation committee may evaluate and provide assistance to any pharmacist or registered pharmacy technician in need of treatment and rehabilitation for alcoholism, drug abuse, chemical dependency, or other physical, emotional, or mental condition.

D. The proceedings, records, and files of a pharmacist rehabilitation committee are not discoverable and are not admissible in evidence in any civil action.

Pharmacist Rehabilitation Program (cont)

Currently, the only approved pharmacist, pharmacy technician, pharmacy student rehabilitation committee in Maryland is:

PEAC - The Pharmacists' Education and Advocacy Council of Maryland

PEAC contact information:

5212 Onion Road, Pylesville, MD 21132
410-983-0302
410-808-0748
http://peacmaryland.org/

Email: info@PEACMaryland.org
Tony Tommasello, President and Executive Director

Pharmacist Rehabilitation Program (Cont)

PEAC's Mission

Our mission is to preserve professional health through advocacy and education. PEAC services benefit:

Individual pharmacists, by offering a confidential avenue for addressing a variety of problems that might contribute to impaired practice and loss of license. Our records are confidential.

Pharmacy technicians

Pharmacy students, by offering a confidential avenue for addressing a variety of problems that might contribute to poor academic performance and academic dismissal.

Employers, by providing a process through which pharmacists' problems can be addressed and mended. Because of ongoing monitoring, employers can be confident in the performance of pharmacists who are engaged in PEAC programs.

Private citizens, by reducing the problem of impaired pharmacists thereby improving the safety of the pharmacy workforce.

Pharmacist Rehabilitation Program (Cont)

Three Paths to PEAC Assistance

1. Self-Referral

   Pharmacists can self-refer. This is the best way to obtain PEAC help. The pharmacist can often avoid job termination and punitive action.

2. Referral by pharmacists or others **

   Once satisfied that outside reports are legitimate, PEAC contacts the allegedly impaired pharmacist to arrange a meeting and discuss the allegations.

   **Identities of the concerned colleagues making the report are not disclosed.

3. Referrals by Maryland Board of Pharmacy

Pharmacist Rehabilitation Program (Cont)

Referrals by Maryland Board of Pharmacy

The BOP investigates reports from a variety of sources. An administrative process determines guilt and acts to protect the public by restricting a pharmacist's practice.

Pharmacists, under Board orders, will be monitored by the Board's internal rehabilitation committee.

Pharmacists are not required by consent order to participate in the PEAC program. However, PEAC's services are available to Board-referred pharmacists for a fee.

Pharmacists are under scrutiny by the Board throughout the treatment process.

The pharmacist's name is published in the BOP newsletter and reported to HIPDB as required.

Pharmacist Rehabilitation Program (Cont)

**ANY violation of the PEAC contract by a self-referred pharmacist, technician or student of the 3 - 5 year PEAC contract will result in immediate notification of the individual to the Maryland Board of Pharmacy.

The affected pharmacist, technician or student will then be under the same public terms as described on the last screen.

HIPAA Case

Former drug addicts are protected by the Americans with Disabilities Act (ADA).

In the case of *Robert Reilly v. Lehigh Valley Hospital*, a hospital security guard completed a six-page employee health information form . On that form, he denied being diagnosed with or treated for alcoholism or drug addiction.

After one of his shifts, the security guard went to the emergency room of the hospital where he worked for an eye injury that he believed he had sustained on the job. While being treated, he revealed to the treating physician that he had a history of narcotics use and was a recovering drug addict. The treating physician noted this history on the Emergency Department Physician Clinical Report.

This report was sent to the hospital's health services department, which manages workers' compensation injuries. Shortly thereafter, the department notified Human Resources that the employee was a recovering addict and had not been truthful on his employment form. As a result, the hospital terminated his employment for failure to disclose that he was a recovering addict.

The security guard sued the hospital claiming he was terminated because he was a recovering drug addict. Although the ADA specifically protects former drug addicts who are no longer using illegal drugs, the hospital terminated the security guard for his dishonesty, which is permissible.

ADA

Apparently under the ADA, even HIV-positive individuals are now covered. Refusal to dispense certain medications may lead to law suits.

Issue of not providing pain medications for patients suffering from chronic pain becoming more of a hot topic.
True chronic pain patients may also be covered under the ADA.

Law suits are becoming more common and pharmacists are on the hot seat. Physicians are stating that they are writing legitimate prescriptions. DEA has stated: *"We are not doctors. We're regulators and enforcers of the law. If a drug is prescribed for a legitimate medical purpose, we're certainly not going to get in the way."*

PERMIT HOLDER REQUIREMENTS

Pharmacy Permits

A two (2) year pharmacy permit expires on May 31st (currently on even numbered years) after its effective date, unless the pharmacy permit is renewed for another 2-year term.

A pharmacy permit shall be displayed conspicuously in the pharmacy for which it is issued.

Pharmacy Permits (cont)

A pharmacy

(1) Shall be operated in compliance with the law and with the rules and regulations of the Board;

(2) Shall be located and equipped so that the pharmacy may be operated without endangering the public health or safety;

(3) Shall ensure that a licensed pharmacist be immediately available on the premises to provide pharmacy services at all times the pharmacy is in operation;

(4) Shall be supervised by a licensed pharmacist who is responsible for the operations of the pharmacy at all times the pharmacy is in operation;

(5) Shall provide complete pharmaceutical service by preparing and dispensing all prescriptions that reasonably may be expected of a pharmacist;

(6) Shall provide services to the general public and may not restrict or limit its services to any group of individuals unless granted a waiver from this requirement by the Board;

(7) May not offer pharmaceutical services under any term or condition that tends to interfere with or impair the free and complete exercise of professional pharmaceutical judgment or skill;

(8) May not make any agreement that denies a patient a free choice of pharmacist or pharmacy services;

(cont)

Pharmacy Permits (cont)

(9) Shall maintain at all times a current reference library that is appropriate to meet the needs of:

(i). The practice specialty of that pharmacy; and

(ii). The consumers the pharmacy serves

(10) Shall maintain at all times the minimum professional and technical equipment and sanitary appliances that are necessary in a pharmacy:

(i). To prepare and dispense prescriptions properly; and

(ii). To otherwise operate a pharmacy; and

(iii). Be kept in a clean and orderly manner;

(11) Shall store all prescription or nonprescription drugs or devices properly and safely subject to the rules and regulations adopted by the Board;

(12) Shall make and keep on file for at least 5 years a record of each prescription prepared or dispensed in the pharmacy;

(13) Shall provide such personnel, automation, and technology as are necessary to allow the licensed pharmacist employee sufficient time to utilize the pharmacist's knowledge and training and to perform competently the functions of a licensed pharmacist as required by law;

(cont)

Pharmacy Permits (cont)

(14) With regard to a prescription drug that is delivered in this State by the United States mail, a common carrier, or a delivery service and is not personally hand delivered directly to a patient or to the agent of the patient at the residence of the patient or at another location designated by the patient, shall:

(i) Provide a general written notice in each shipment of a prescription drug that alerts a consumer that, under certain circumstances, a medication's effectiveness may be affected by exposure to extremes of heat, cold, or humidity; and

(ii) Provide a specific written notice in each shipment of a prescription drug that provides a consumer with a toll-free or local consumer access telephone number accessible during regular hours of operation, which is designed to respond to consumer questions pertaining to medications;

(cont)

Pharmacy Permits (cont)

(15) (i) May maintain a record log of any prescription that is requested to be filled or refilled by a patient;

(ii) If the prescription record of a patient includes the patient's Social Security number, shall keep the Social Security number confidential;

(iii) May not list in the record log the type of illness, disability, or condition that is the basis of any dispensing or distribution of a drug by a pharmacist; and

(16) Shall provide information regarding the process for resolving incorrectly filled prescriptions in accordance with existing regulations by:

(i) Posting a sign** that is conspicuously positioned and readable by consumers at the point where prescription drugs are dispensed to consumers; or

(ii) Including written information regarding the process with each prescription dispensed.

Pharmacy Permits (cont)

What should a permit holder have before requesting an opening inspection for a new pharmacy?

Location

- Study of proposed area/competition
- Lease
- Diagram of proposed pharmacy floor plan
- Permits (local and state)

Business Plan

- Type of pharmacy (full service or waiver)
- Computer, printers, etc
- Wholesaler agreement(s)
- Agree to and sign 3rd party agreements

Pharmacy Permits (cont)

What must a permit holder have before the opening inspection for a new pharmacy according to Maryland regulations?

A Class A prescription balance and weights, or a prescription balance with equivalent or superior sensitivity.

A refrigerator(s), solely for the storage of drugs requiring refrigeration, with a thermometer or a temperature monitoring device.

Additional equipment to enable it to prepare and dispense prescriptions properly consistent with its scope of practice.

Hot and cold running water.

A library of current reference sources consistent with its scope of practice that is accessible to all appropriate personnel.

A copy of the current edition of *The Maryland Pharmacy Laws and Regulations*.

The pharmacy must be designed to prevent unauthorized entry when the prescription area is closed during any period that the rest of the establishment is open.

A security system.

Pharmacy Permits (cont)

A pharmacy may not be located in a residence

A permit holder has 60 days, following issuance of a pharmacy permit, to have and maintain an operational pharmacy.

If not, the pharmacy permit will be rescinded, and the permit holder must return the issued permit to the Board of Pharmacy within 10 days of notification.

Pharmacy Permits (cont)

After a pharmacy has passed the Board of Pharmacy's opening inspection, the permit holder will receive a Board permit number and may:

- Apply to DDC for a Maryland CDS permit
- Apply to DEA for a federal CDS permit
- Order and stock medications

Pharmacy Permits (cont)

A pharmacy is permitted to be closed for:

- Federal holidays
- State or federal emergencies
- Religious holidays

Must post signs conspicuously informing patients of intended closings and hours of operation.

PHARMACIST REFUSAL TO FILL A PRESCRIPTION ??

PHARMACEUTICAL INFORMATION

Pharmaceutical Information

Only a licensed pharmacist ,or an individual engaging in a professional experience program and acting under the direct supervision of a licensed pharmacist, may provide information to the public, or another health care practitioner concerning prescription or nonprescription drugs or devices including information as to their therapeutic values, potential side effects, and use in the treatment and prevention of diseases.

GENERIC SUBSTITUTION

Generic Substitution

Unless a prescriber affirmatively indicates that a prescription is to be dispensed as written, the pharmacist may substitute a lower priced generic equivalent for the name brand drug actually prescribed.

DAW Codes

Code	Description
0	No Product Selected
1	Substitution not allowed Prescriber
2	Substitution not allowed Patient
3	Substitution allowed-Pharmacist selects
4	Generic not in stock
5	Brand dispensed as generic
6	Override (Maryland Medicaid – where the branded medication is State preferred)
7	Brand Name mandated by State law
8	Generic not available in marketplace

Generic Substitution (cont)

It is specifically provided by Maryland statute that a pharmacist who substitutes a generic equivalent drug or device and follows the proper notification of the substitution to the patient incurs no greater liability in filling the prescription than if the brand name had been dispensed.

Generic Substitution (cont)

Documentation has proven that patients are much less likely to fill a prescription when prescribers specify that generic substitution may not occur.

Various studies have shown a 4% (when patients requested the brand named medication) to 16% (when prescribers indicated brand only) drop in filled prescriptions being picked up by the patient.

UNAUTHORIZED REFILLS

Guidelines for Unauthorized Refills

(1)The pharmacist may refill a prescription for a drug or device for which the refill has not been authorized if the pharmacist:

(i) Attempts to obtain an authorization from the authorized prescriber; and

(ii) Is not able readily to obtain the authorization; and

(2) The refill of the prescription is not for a controlled dangerous substance; and

(3) The drug or device is essential to the maintenance of life; and

(4) (i) The drug or device is essential to the continuation of therapy in chronic conditions; and

(ii) In the pharmacist's professional judgment, the interruption of the therapy reasonably might produce an undesirable health consequence, be detrimental to the patient's welfare, or cause physical or mental discomfort .

Guidelines for Unauthorized Refills (cont)

The pharmacist must:

1. Document

(i) Enter on the back of the prescription or on another appropriate uniformly maintained, readily retrievable record, such as a medication record, the date and the quantity of the drug or device dispensed; and

(ii) Signs or initials the record; and

(2) The pharmacist notifies the authorized prescriber of the refill of the prescription within 72 hours of dispensing the drug or device.

(b) *Limitations.*- If a pharmacist refills a prescription under this section, the pharmacist may provide only 1 refill of the prescription and the refill quantity dispensed shall be in conformity with the prescriber's directions for use and may not exceed a 14-day supply or unit of use.

REFILLS DURING A DECLARED STATE OF EMERGENCY

Guidelines for Unauthorized Refills (cont)

Declared State of Emergency:

If the federal or State government declares a state of emergency, a pharmacist working in the area declared an emergency area may refill a prescription for a drug for which the refill has not been authorized if:

(1) As a result of the emergency, the pharmacist is unable to obtain an authorization from the authorized prescriber;

(2) The refill of the prescription is not for a controlled dangerous substance;

(3) The quantity dispensed does not exceed a 14-day supply or unit of use; and

(4) The pharmacist notifies the authorized prescriber of the refill of the prescription within 7 days of dispensing the drug.

MARYLAND LAW – HEALTH GENERAL (HG)

Confidentiality of Medical Records

A health care provider shall:

(1) Keep the medical record of a patient or recipient confidential; and

(2) Disclose the medical record only:

(i) Upon authorization of the patient or recipient; or

(ii) As otherwise provided by law (following slides).

Confidentiality of Medical Records (cont)

Permitted disclosure.- A health care provider may disclose a medical record without the authorization of a person:

1. (i) To the provider's authorized employees, agents, medical staff, medical students, or consultants for the sole purpose of offering, providing, evaluating, or seeking payment for health care to patients or recipients by the provider;

   (ii) To the provider's legal counsel;

2. If the person given access to the medical record signs an acknowledgment not to re-disclose any patient identifying information, to a person for:
   (i) Educational or research purposes
   (ii) Evaluation and management of health care delivery systems;
   (iii) Accreditation of a facility by professional standard setting entities;
3. To a government agency performing its lawful duties ;
4. To another healthcare provider for the sole purpose of treating the patient or recipient on whom the medical record is kept;

(cont)

Confidentiality of Medical Records (cont)

5. If a claim has been, or may be, filed by, covered insureds, covered beneficiaries, or enrolled recipients only, to third party payors and their agents, or any other person obligated by contract or law to pay for the health care rendered for the sole purposes of:
   (i) Submitting a bill to the third party payor;
   (ii) Reasonable prospective, concurrent, or retrospective utilization review or predetermination of benefit coverage;
   (iii) Review, audit, and investigation of a specific claim for payment of benefits; or
   (iv) Coordinating benefit payments under more than one medical insurance policy;
6. If a health care provider makes a professional determination that an immediate disclosure is necessary, to provide for the emergency health care needs of a patient or recipient;
7. Except if the patient has instructed the health care provider not to make the disclosure, or if the record has been developed primarily in connection with the provision of mental health services, to immediate family members of the patient or any other individual with whom the patient is known to have a close personal relationship;
8. To an appropriate organ, tissue, or eye recovery agency for a patient whose organs and tissues may be donated for the purpose of evaluating the patient for possible organ and tissue donation;

Mental Health Records

Permitted disclosures generally:

When a medical record developed in connection with the provision of mental health services is disclosed without the authorization of a person in interest,

***only the information in the record relevant to the purpose for which disclosure is sought may be released – mental health records have an extra layer of restrictions.

Time Frame for Maintaining Health Records

Except for a minor patient, unless a patient is notified, a health care provider may not destroy a medical record about a patient for 5 years after the record or report is made. (another reason for keeping patient profiles for at least 5 years)

In the case of a minor patient, a medical record may not be destroyed until the patient attains the age of majority plus 3 years or for 5 years after the record or report is made, whichever is later.

Time Frame for Maintaining Health Records (cont)

After the death, retirement, surrender of the license, or discontinuance of the practice or business of a health care provider, the health care provider, shall:

Publish a notice in a daily newspaper that is circulated locally for 2 consecutive weeks:

(i) Stating the date that the medical records will be destroyed or transferred; and

(ii) Designating a location, date, and time where the medical records may be retrieved, if wanted.

Destruction of Health Records

A health care provider shall maintain, store and cause the destruction of medical records to:

1. Ensure confidentiality;
2. Provide limited access to the medical records until the records are destroyed; and
3. Ensure that the method of destruction renders the medical records unreadable.

PRESCRIPTION REQUIREMENTS

Prescription Requirements

A prescription may be written or oral.

However, a pharmacist may not dispense a drug on an oral prescription unless the pharmacist promptly writes out and files the prescription.

A prescription for a controlled dangerous substance may not be written on a preprinted prescription form that states the name, quantity, or strength of the controlled dangerous substance.

When a prescription is written, a separate prescription form is required for each controlled dangerous substance***.

Prescription Requirements (cont)

A prescription shall be legible**

A stock bottle for a legend medication, at all times prior to dispensing, must bear one of the following statements:

"Caution: Federal Law Prohibits Dispensing Without Prescription"

"Caution: State Law Prohibits Dispensing Without Prescription

"Rx Only"

A dispensed prescription must be in compliance with all labeling requirements of federal and state law.

Prescription Requirements (cont)

Prescription refills.- A pharmacist may not refill and dispense a prescription unless the refill is authorized by:

(1) The health practitioner's specification in the original prescription as to how many times it may be refilled; or

(2) Pursuant to an oral order of the health practitioner that is promptly written out and filed by the pharmacist.

Label Requirements for Prescription Drugs

A drug that is dispensed under a prescription shall bear a label that states:

1. The date the prescription is filled
2. The date the prescription was written
3. The name and address of the dispenser
4. The serial number of the prescription
5. The name of the prescriber
6. The name of the drug or device, including both the brand name and the generic equivalent name

(cont)

Label Requirements for Prescription Drugs (cont)

7. The manufacturer of the drug if a substitution is made by the pharmacist
8. The strength of the drug
9. The name of the patient
10. Directions for use
11. Expiration date, which shall be the lesser of 1 year from the date of dispensing or the actual expiration date of the drug (or for a shorter time period if determined appropriate by the pharmacist)
12. Any appropriate special handling instructions as to cautionary statements, proper storage, etc.

INSPECTIONS

Agencies' Powers to Inspect

General inspections.-

(1) After presentation of appropriate credentials to the owner, operator, or agent in charge, the Secretary or a representative of the Secretary may enter and inspect at any reasonable time:

(i) Any factory, warehouse, or other establishment in which any food, drug, device, or cosmetic is manufactured, processed, packed, or held for a commercial purpose; and

(ii) Any vehicle used to transport or hold any food, drug, device, or cosmetic for a commercial purpose.

(2) An inspection carried out under this section may include an inspection of the establishment or vehicle itself and of any pertinent equipment, labeling, and finished and unfinished products.

(3) An inspection shall be completed with reasonable promptness.

Inspections (cont)

Agents of the Board of Pharmacy have the right to enter the premises of a permit holder during regular business hours of operation to perform inspections for compliance with federal and State laws and regulations.

A failure to allow this inspection means that the permit issued for the operation is subject to revocation !!!

If a warrant is issued for the premises, agents of the Board may accompany law enforcement officials during any search and investigation.

Inspections (cont)

What is the best way to deal with a government investigation?

When law-enforcement officers visit, while your inclination is to cooperate fully, be aware that everything you say can and will be used in favor of , or against, you by authorities.

There are no protections. Things you say that you believe are innocuous may not have the same meaning to law enforcement. In fact, your statements/actions may be one more link in the chain of evidence that authorities believe establishes your guilt.

Further, bear in mind that law-enforcement officers are entitled to use ruses to further their investigations and interview techniques.

Everything they may tell you during an interview, including the focus of their investigation and other facts, may or may not be true, and this is generally permissible.

Inspections (cont)

Sometimes law enforcement arrives simply wishing to speak and/or ask questions.

Other times, they arrive requesting you to sign a form consenting to a search of your records, or they arrive with a formal search warrant in hand.

If they have a warrant, that is, a formal authorization by a court to conduct a search or inspection of records, you are obliged to stay out of their way and allow them to conduct the search.

They, in turn, must leave you with an inventory of any confiscated records or assets.

DIVISION OF DRUG CONTROL

Division of Drug Control

Created by the Maryland Department of Health and Mental Hygiene to:

- Register any person who manufacturers, distributes or dispenses CDS in Maryland
- Perform inspections of entities listed above to ensure compliance with all federal and State laws and regulations related to CDS
- May impound drugs and devices following issuance of a subpoena

**DDC has been appointed as the Board's agent to perform pharmacy closing inspections - (involving CDS inventory).

Division of Drug Control (Cont)

DDC inspectors do carry badges.

DDC inspectors may utilize “enforcement warrants” – a warrant that authorizes an inspection at any time for the purpose of enforcement of Maryland CDS laws and regulations.

Therefore --- “Be prepared, because you know not the day or the hour” --- of any inspection.

Division of Drug Control (Cont)

Contact Information:

Phone: 410-764-2890

Fax: 410-358-1793

Hours of Operation:

Monday - Friday

8:30 AM to 5:00 PM

Email: http://dhmh.maryland.gov/laboratories/drugcont/

Division Chief:

Audrey P. Clark, MPA

audrey.clark@maryland.gov

Deputy Division Chief:

Chandra Mouli, RPh

chandra.mouli@maryland.gov

IMPOUNDMENT OF DRUGS

Impoundment of Drugs

If drugs pose an imminent threat to the public health, safety, or welfare, or if the confidentiality of prescription records is in imminent danger of being compromised, the Department (DHMH) may:

(i) Issue an impoundment order; and

(ii) Immediately impound drugs or prescription records without prior notice to the permit holder or authorized prescriber.

Impoundment of Drugs (cont)

The Department may issue an impoundment order if:

1. A permit holder's permit or authorized prescriber's license has expired or has been revoked or suspended;

2. A board has requested that the Department impound the drugs;

3. The drugs pose an imminent threat to the public health, safety, or welfare;

4. The Department may issue an impoundment order based on an on-site observation by a law enforcement official, the Department.

Process for Impoundment of Drugs

Before execution of an impoundment order, the Department shall:

(1) Attempt to serve written notice of the impoundment on the permit holder or authorized prescriber by certified mail at the last known address in the board's licensing files; and

(2) Provide the permit holder or authorized prescriber with an opportunity to:

(a) Avoid impoundment by allowing the permit holder or authorized prescriber to dispose of the drugs or prescription records in a manner acceptable to the Department;

(b) Review the nature, type, and amount of information upon which the Department issued the impoundment order; and

(c) Avoid impoundment by providing the Department with information upon which the Department could reasonably conclude that the impoundment is not warranted.

Disposition of Impounded Drugs

If the Department executes an impoundment order against a permit holder or authorized prescriber, the Department shall:

(1) Arrange for the drugs or prescription records to be kept in a secure location;

(2) Ensure that any location which stores impounded drugs provides the necessary temperature controls and equipment to properly maintain the drugs; and

(3)Provide the permit holder or authorized prescriber with a list of all drugs and prescription records impounded.

Final Disposition of Impounded Drugs

If the permit holder or authorized prescriber has not petitioned the Department within 30 days, the Department may destroy or transfer the impounded drugs or prescription records.

The Department shall destroy or transfer:

(a) Impounded drugs in accordance with all relevant State and federal laws

(b) The permit holder or authorized prescriber shall reimburse the Department for the reasonable expenses relating to the collection, storage, and disposition of impounded drugs or prescription records.

PHYSICIAN PRESCRIBING

Who May Prescribe in Maryland ? (cont)

Certified nurse practitioner
Dentist*
Mid-Wives****
Ophthalmologist*
Optometrist***
Physician
Physician assistant**
Podiatrist*
Veterinarian*

*Prescribing must be within scope of practice
** Prescribing must follow provisions of contract and delegated authority
*** Prescribing must follow established formularies and delegated authority
****Must be certified and must be within limited scope of practice

Who May Dispense in Maryland ? (cont)

To obtain a license allowing a prescriber to dispense medications:

(1) The licensee shall complete an application on a form approved by the appropriate licensing Board and pay a fee (must be sufficient to provide funding allowing DDC to perform inspections) for:

(a) Physicians;

(b) Podiatrists; or

(c) Dentists.

(2) The applicant:

(a) Shall comply with the dispensing requirements set forth in regulations.

(b) Must be thoroughly familiar with the statutes and regulations which govern dispensing of prescription drugs.

Each permit issued to a licensee expires 5 years after its date of issuance and is renewable upon timely submission of a renewal application.

Healthcare Professional

A “healthcare professional” is a qualified person who delivers proper health care in a systemic way professionally to any individual in need of health care services.

MARYLAND'S HEALTH INSURANCE ARTICLE TITLE 15

Notice to Pharmacies of Change in Pharmaceutical Benefits

Any insurer that wants to provide a policy in Maryland must comply with all provisions of the Maryland Insurance Article administered by the Maryland Insurance Administration.

*Important Note: The Board of Pharmacy has no jurisdiction over insurance questions or complaints.

At least 30 days before the change is effective, an entity that provides pharmaceutical benefits shall notify in writing all pharmacies under contract with the entity of any of the following changes in the pharmaceutical benefit program rules or requirements:

(1) exclusion of coverage for classes of drugs as specified by the contract;
(2) changes in prior or preauthorization procedures; or
(3) selection of new prescription claims processors.

Choice of Pharmacy

Maryland's insurance regulations state that:

> A nonprofit health service plan that provides pharmaceutical services shall allow a subscriber, member, or beneficiary to fill prescriptions at the pharmacy of the subscriber's, member's, or beneficiary's choice.

Coverage for Off-Label Use of Drugs

A policy or contract that provides coverage for drugs may NOT exclude coverage of a drug for an off-label use of the drug if the drug is recognized for treatment in any of the standard reference compendia or in the medical literature.

Coverage of a drug required by this subsection also includes medically necessary services associated with the administration of the drug.

*Specifically excluded from the definition of off-label use are drugs determined by the FDA as ineffective or experimental.

Coverage for Off-Label Use of Drugs (cont)

Recognized references (for verified uses):

USP

AMA Drug Evaluations

American Hospital Formulary Service Drug Information

Peer-reviewed national professional medical journals

Coverage for Maintenance Drugs

"Maintenance drug" means a drug anticipated to be required for 6 months or more to treat a chronic condition.

An entity shall allow an insured or enrollee, if authorized by an authorized prescriber, to receive up to a 90-day supply of a maintenance drug in a single dispensing of the prescription.

These provisions do not apply to the first prescription or for any change in a prescription for a maintenance drug that the authorized prescriber prescribes.

Coverage for Contraceptive Drugs

Insurers and nonprofit health service plans that provide coverage for prescription drugs under health insurance policies or contracts shall provide coverage for any contraceptive drug or device that is approved by the FDA for use as a contraceptive and that is obtained under a prescription written by an authorized prescriber (unless specifically excluded in the contract).

May not impose a different copayment or coinsurance for a contraceptive drug or device than is imposed for any other prescription.

Reimbursement for Pharmaceutical Products

A policy or contract may NOT impose a copayment, deductible, or other condition on an insured or certificate holder who uses the services of a community pharmacy that is not imposed when the insured or certificate holder uses the services of a mail order pharmacy, if the benefits are provided under the same program, policy, or contract.

Does NOT specify that the copayment or deductible must be the same!

Formulary Drugs

"Formulary" means a list of prescription drugs or devices that are covered, or not covered, by an entity.

Coverage for a prescription drug or device that is not in the formulary must be provided if, in the judgment of the prescriber:

(1) there is no equivalent prescription drug or device in the entity's formulary; or

(2) an equivalent prescription drug or device in the entity's formulary:

(i) has been ineffective in treating the disease or condition of the member; or

(ii) has caused or is likely to cause an adverse reaction or other harm to the member

MARYLAND PHARMACY CRIMINAL LAW (CR)

Criminal Law Definitions (cont)

Controlled dangerous substance

(i) a drug or substance listed in Schedule I through Schedule V; or

(ii) an immediate precursor to a drug or substance listed in Schedule I through Schedule V.

Controlled dangerous substance does not include distilled spirits, wine, malt beverages, or tobacco.

Criminal Law Definitions (cont)

Controlled paraphernalia:

(1) a hypodermic syringe, needle, or any other object or combination of objects adapted to administer a controlled dangerous substance by hypodermic injection;

(2) a gelatin capsule, glassine envelope, or other container suitable for packaging individual quantities of a controlled dangerous substance; or

(3) lactose, quinine, mannite, mannitol, dextrose, sucrose, procaine hydrochloride, or any other substance suitable as a diluent or adulterant.

Criminal Law Definitions (cont)

Drug dependent person means a person who:

(1) Is using a controlled dangerous substance; and

(2) Is in a state of psychological or physical dependence, or both, that:

(i) arises from administration of that controlled dangerous substance on a continuous basis; and

(ii) is characterized by behavioral and other responses that include a strong compulsion to take the substance on a continuous basis in order to experience its psychological effects or to avoid the discomfort of its absence.

Criminal Law Definitions (cont)

Drug-induced conduct

(a) In this section, "drug" does not include alcohol.

(b) Prohibited - A person may not administer a controlled dangerous substance or other drug to another without that person's knowledge, and commit against that other person:

(1) a crime of violence; or

(2) a sexual offense in the third degree.

(c) Penalty - A person who violates this section is guilty of a misdemeanor and on conviction is subject to imprisonment not exceeding 1 year or a fine not exceeding $2,500 or both.

(d) Sentencing - A sentence imposed under this section may be separate from and consecutive to or concurrent with sentence for any crime based on the act or acts establishing the violation of this section.

Criminal Law Definitions (cont)

False prescription:

A person may not pass, issue, make, or possess a false, counterfeit, or altered prescription for a controlled dangerous substance with intent to distribute a controlled dangerous substance.

Information not privileged:

Information that is communicated to an authorized prescriber in an effort to illegally obtain a controlled dangerous substance is not a privileged communication.

Criminal Law Definitions (cont)

Ultimate user means:

A person who lawfully possesses a controlled dangerous substance for the person's own use, for the use of a member of the person's household, or for administration to an animal owned by the person or by a member of the person's household.

Possession is defined as a person that:

Must know of the presence of the substance;

Must have some knowledge of the character or illicit nature of the substance; and

Must have some control of the substance

Possessing or Administering a CDS -Violations

A person may not:

(1) possess or administer to a controlled dangerous substance, unless obtained directly or by prescription or order from an authorized provider acting in the course of professional practice; or

(2) obtain or attempt to obtain a controlled dangerous substance, or procure or attempt to procure the administration of a controlled dangerous substance by:

(i) fraud, deceit, misrepresentation, or subterfuge;
(ii) the counterfeiting or alteration of a prescription or a written order;
(iii) the concealment of a material fact;
(iv) the use of a false name or address;
(v) falsely assuming the title of or representing to be a manufacturer, distributor, or authorized provider; or
(vi) making, issuing, or presenting a false or counterfeit prescription or written order.

PUBLIC SAFETY (PS)
TITLE 15

Public Safety (cont)

Governor's Declaration of a Catastrophic Health Emergency :

- Must identify the nature of the emergency
- Must identify the area(s) affected
- Lasts for 30 days (or less if the Governor determines that the emergency no longer exists)
- May be renewed for successive periods (each period not to exceed 30 days)

Public Safety (cont)

Once an Emergency Order is issued, the Governor may pick actions to be included from a long list of options:

- Seize anything or location needed to respond to the emergency
- Rationing
- Creating or distributing stockpiles
- Setting prices
- Require individuals to undergo medical testing
- Require quarantine(s)
- Order health care practitioners to participate in surveillance, treatment and suppression efforts
- Evacuation, closing or decontamination of any facility

Public Safety (cont)

Liability

A health care provider is generally immune from civil or criminal liability if the health care provider:

- Acts in good faith
- Acts under a catastrophic emergency proclamation
- Acts within the context of his/her training

MARYLAND REGULATIONS COMAR 10:34 PHARMACY

Requirements for Pharmacist Licensure

What requirements must an individual meet to apply for a pharmacist's license in Maryland?

The individual must:

- Be of good moral character
- Be at least 18 years of age
- Be a graduate of an approved pharmacy school (Accreditation Council for Pharmacy Education - ACPE)
- Have completed a professional experience program (PEP)
- Pass an examination (National Association of Boards of Pharmacy License Examination - NAPLEX)
- Pass the Multistate Pharmacy Jurisprudence Exam (MPJE)
- Demonstrate oral competence in the English language

Requirements for Pharmacist Licensure (cont)

Licensure examinations means the Board-approved examinations required of applicants for licensure which include the following:

(a) Exam:

(i) Part I: NAPLEX, (75) and

Must list Maryland as the primary state of licensure.

(ii) Part II: Pharmacy Law Test-MPJE (75);

Federal and State (where exam is taken) laws

(b) Exam:

(i) Prescreening Test of Oral English Competency (Skype),

or

(ii) Test of Oral English Competency (TOEFL)

(c) Exam:

(i) Foreign Pharmacy Graduate Equivalency Exam (FPGEE)

Requirements for Pharmacist Licensure (cont)

Submit New Pharmacist Application + $150 fee

Register to take the FPGEE Exam (if required) and the NAPLEX and MPJE Exams online at the (NABP) website at www.nabp.net by clicking on Examination Programs.

Receive an Authorization To Test (**ATT**) Number from the NABP through your e-mail and schedule appointments to take exams through Pearson VUE's website at www.pearsonvue.com/NABP or call 1-888-709-2679.

Pass all exams with a 75 or better.

Receive a Candidate Number from the Board (sent automatically upon receipt of a completed application). This number will allow you to track your exam scores online at the Board's website www.dhmh.maryland.gov/pharmacy by clicking on *Examination Score Results*.

Requirements for Pharmacist Licensure (cont)

TEST OF ORAL ENGLISH COMPETENCY (TOEFL)

All applicants must pass an examination of Oral English competency.

This examination is designed to demonstrate that an applicant speaks proficient English that can be easily understood by the average pharmacy customer.

In order to meet the English competency requirements, an applicant may first take a pre-screening English competency examination (SKYPE now available).

If the applicant passes the pre-screening examination, the English competency requirements are met without further testing. If the applicant fails the pre-screening examination, the applicant must take and pass a more comprehensive test of Oral English competency.

The passing score for the Oral English competency portion of the examination is determined by the Board approved vendor.

Requirements for Pharmacist Licensure (cont)

FOREIGN PHARMACY GRADUATES EQUIVALENCE EXAM (FPGEE)

(FPGEE) Foreign pharmacy graduates shall pass the Foreign Pharmacy Graduate Equivalence Examination (FPGEE), which is administered by the National Association of Boards of Pharmacy (NABP), before submitting an application for licensure. The FPGEE is offered twice each year, and it is administered at Pearson VUE test sites throughout the continental United States.

A copy of the FPGEE certificate or the original FPGEE, TOEFL and TSE scores must be submitted with the application for licensure.

All practical experience must be earned in the United States under the supervision of a licensed pharmacist.

Each individual must contact the pharmacy where he/she desires to gain this experience and arrange employment or volunteer work. Volunteer and/or work experience must total 1,560 hours. These hours are to be recorded on the Pharmacy Experience Affidavit and submitted to the Board with the pharmacist's application. Contact NABP @ (847) 391-4406 for details regarding the FPGEE.

Requirements for Pharmacist Licensure (cont)

Pre-NAPLEX

Effective March 1, 2014, the Pre-NAPLEX will be expanded to further assist candidates preparing to take NAPLEX.

To provide NAPLEX candidates with additional practice, the number of test questions included in the Pre-NAPLEX has been increased from 50 to 100.

The Pre-NAPLEX is still be available in two forms, so that candidates opting to take the practice exam twice will receive two different sets of practice examination questions.

Also beginning on March 1, 2014, the fees for the Pre-NAPLEX will increase from $50 to $65.

Requirements for Pharmacist Licensure (cont)

FAILING AN EXAM

To retake the NAPLEX or MPJE examinations, you must register on line at www.nabp.net.

The National Association of Boards of Pharmacy (NABP) will issue you a confirmation number that will allow you to re-take the NAPLEX or MJPE examinations.

If you receive a grade of less than 75 on any part of the examination, you will be required to retake only the part of the examination that you fail.

The Maryland Board of Pharmacy recommends that candidates who take the examination three (3) times without passing should obtain additional education in their weaker subjects prior to taking the examination again.

Requirements for Pharmacist Licensure (cont)

Internship Program or Training Required

An applicant shall complete one of the following as a prerequisite to Board licensure:

A. 1,000 hours of a school-supervised professional experience program conducted by a school of pharmacy accredited by the American Council of Pharmaceutical Education; or

B. 1,560 hours of full-time training, under the direct supervision of licensed pharmacists (applies to foreign graduates)

If an approved school or college of pharmacy offers a partial fulfillment of internship requirements as a part of its curriculum, time spent in a program by an applicant may be accepted by the Board to replace a portion of the required 1,560-hour internship training under this regulation.

ACPE requires:

Introductory Pharmacy Practice Experiences (IPPEs) = 300 hours
Advanced Pharmacy Practice Experiences (APPEs) = 1440 hours

Requirements for Pharmacist Licensure (cont)

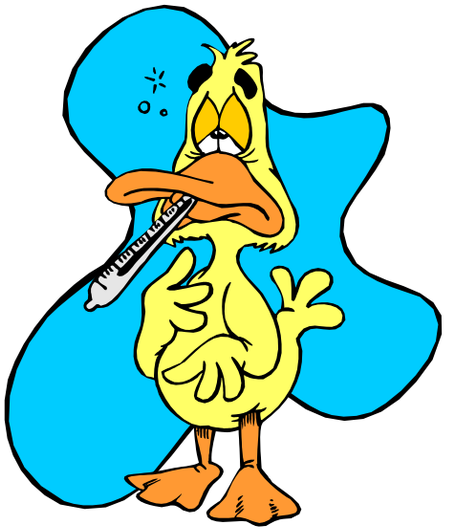
Reciprocity:

A pharmacist licensed in another state may apply for reciprocity in Maryland if he:

- Is of good moral character
- Pays the required application fees
- Meets the qualification required by Maryland law
- Passes the MPJE
- Passes the English proficiency exam

A Maryland licensed pharmacist may contact another state pharmacy board to request reciprocity in that state.

BOARD DISCIPLINARY ACTIONS



Board of Pharmacy Disciplinary Actions

Close Case
Cease and Desist
Letter of Education
Letter of Admonishment
Informal Hearing
Case Resolution Conference
Show Cause Hearing
Evidentiary Hearing
Probation
Suspension of License/Registration
Revocation of License/Registration
Denial of Licensure/Registration

All actions are administrative – no criminal actions may be initiated by the Board – however, the Board may refer cases for further investigations and possible criminal actions.

Board of Pharmacy Disciplinary Actions (cont)

Close case/investigation

- Every complaint is given a case number
- There is a statutory provision providing qualified immunity to any individual who gives information to the Board or makes a complaint (must be given in "good faith")
- Every complaint is investigated
  - Phone call to each party
  - Data collection form sent to each party
  - All collected information presented to Disciplinary Committee for consideration and discussion
- If available evidence is insufficient to proceed, or is found to be unsubstantiated, then the Disciplinary Committee may make a recommendation to the full Board to close the case.

After the Disciplinary Committee makes its recommendation, then the case is presented to the full Board for more discussion and a final decision.

Board of Pharmacy Disciplinary Actions (cont)

Cease and Desist Letter

Means a public letter issued by the Board ordering:

(a) A registrant or licensee to cease doing a specified activity; or

(b) An unlicensed person to cease the unauthorized practice of pharmacy or the unauthorized operation of a pharmacy.

**Public actions are public and must be posted on the Board's website.

Board of Pharmacy Disciplinary Actions (cont)

Letter of Education-

Means an informal action consisting of a nonpublic letter:

(i) Issued by the Board, closing the case if the Board does not believe that the registrant's or licensee's conduct rose to the level of a violation of the Maryland Pharmacy Act; and

(ii) In which the Board educates the registrant or licensee regarding the laws and standards of the practice of pharmacy or operating a pharmacy.

A Letter of Education may include a Letter of Agreement in which a registrant or licensee agrees to certain conditions to have the matter resolved.

Board of Pharmacy Disciplinary Actions (cont)

Letter of Admonishment-

Means an informal action taken by the Board consisting of a nonpublic letter closing the case if the Board believes a registrant or licensee engaged in conduct that violated the Maryland Pharmacy Act (but that violation did not create a significant danger to the health of the public)

May include a Letter of Agreement in which a registrant or licensee agrees to certain conditions instead of the Board issuing formal charges.

Board of Pharmacy Disciplinary Actions (cont)

Informal hearing-

May be held if the Board desires to make a "strong" statement of concern to the person(s) involved in an incident and means that the Board will essentially close the case, without formal disciplinary action or issuing a final order, by sending a:

(a) Letter of Education;

(b) Letter of Admonishment; or

(c) Letter of Agreement.

Non-public (no prosecutor present)

Board of Pharmacy Disciplinary Actions (cont)

Case Resolution Conference (CRC)-

Means a voluntary, informal, and confidential meeting between the parties to a contested case and the Board's Case Resolution Conference Committee to discuss possible settlement of a disciplinary matter pending before the Board.

CRCs will always result in a projected settlement offer being presented to the person involved.

The offer may, or may not, be accepted by that person's signing a Letter of Consent.

The proposed settlement will also be presented to the full Board for consideration, and the Board has the opportunity to accept the proposal or decide to require more conditions or even to "throw out" the proposal (even if already accepted by the person involved) and refer the case for formal charges.

Board of Pharmacy Disciplinary Actions (cont)

Show cause hearing (Pre-deprivation hearing)

Means a non-evidentiary formal hearing in which the registrant or licensee may demonstrate to the Board why the Board should not issue a proposed order or continue to take an action that the Board has indicated that it is proposing.

State prosecutor is present.

Evidence is not presented – Oral arguments only

No witnesses

Outcome may lead to formal disciplinary actions

Board of Pharmacy Disciplinary Actions (cont)

Evidentiary hearing-

Means an formal evidentiary hearing in which the registrant or licensee may demonstrate to the Board why the Board should not issue a proposed order or continue to take an action that the Board may take.

State prosecutor is present.

Evidence is presented.

Case is tried like a regular trial in a court. May have witnesses.

Outcome may lead to formal disciplinary actions.

Board of Pharmacy Disciplinary Actions (cont)

Summary Suspension-

Means the immediate, indefinite suspension of a registration or license issued if the Board believes emergency action is necessary to protect the public health, safety, or welfare.

Post-deprivation hearing-

Means a show cause or an evidentiary hearing scheduled by the Board after the Board has issued an order for summary suspension in which the registrant or licensee may challenge the Board's basis for issuing, or continuing, the order of summary suspension.

Ex Parte Hearing

If after due notice, the individual against whom the action is contemplated fails or refuses to appear before the Board, nevertheless the Board may hear and determine the matter.

Board of Pharmacy Disciplinary Actions (cont)

Actions that the Board take against a license, registration or permit may be either:

Informal

Formal

Board of Pharmacy Disciplinary Actions (cont)

Informal actions:

Means that the Board closes a case, without formal disciplinary action or issuing a final order, by sending a:

(a) Letter of Education;

(b) Letter of Agreement (may include conditions);

(c) Letter of Admonishment (may include conditions);

(d) Informal Hearing (may include conditions); or

(e) Case Resolution Conference (CRC) (will usually include some conditions)

Board of Pharmacy Disciplinary Actions (cont)

Formal actions (State prosecutor present):

Means a public record issued by the Board resolving a formal disciplinary action by consent or after an adjudication, which:

(a) Denies a registration or license;

(b) Sanctions by:

(i) Probation;

(ii) Fine; or

(iii) Suspension or revocation of a registration or license;

(c) Summarily suspends a registration or license;

(d) Results in the surrender of a registration or license;

(e) Resolves the contested case by consent of the parties; or

(f) Takes any other action that the Board may take by law.

Authority to Order Practitioners' Health Investigations

Consent order-

Means a final order issued by the Board that has been negotiated and agreed to by both the registrant or licensee and the Board to resolve a formal disciplinary action.

Maryland law allows the Board to direct a pharmacist licensee or a pharmacy technician registrant to submit to an examination (usually psychological) by a healthcare practitioner if the Board has "reason to believe" that the licensee or registrant may cause harm to any person affected by the licensee or registrant.

Board of Pharmacy Disciplinary Actions (cont)

Final orders – MUST be posted on Board's website and MUST be reported to the national Healthcare Integrity and Protection Data Bank (HIPDB).

Means a public order has been issued by the Board resolving a formal disciplinary action by consent or after a hearing.

Healthcare Integrity and Protection Data Bank (HIPDB)

Created by HIPAA to combat fraud and abuse in healthcare

A registrant may not employ in any position which allows access to CDS any person who has been convicted of a felony relating to CDS, or who, at any time has had an DEA application denied, revoked or surrendered for cause.

Flagging system to alert users of a practitioner's, provider's or supplier's past actions.

Listing is mandatory for any adverse actions taken by any healthcare disciplinary entity. In 2012, twenty-three (23) Maryland pharmacists were reported to HIPDB.

All reported pharmacists lost their Maryland license, or were placed on a probationary status (at least temporarily).

Healthcare Integrity and Protection Data Bank (HIPDB)

Once on the list, only the disciplined individual (or a registrant desiring to employ that individual) may apply for removal from the HIPDB listing.

Getting off list is "difficult" and totally at the discretion of the Office of Inspector General (OIG).

Some individuals may remain on list indefinitely!!

***April 2013, the Health Resources and Services Administration (HRSA) issued a final rule that will essentially eliminate reporting to HIPDB and require all reports be submitted to the National Practitioner Data Bank (NPDB).

- All data currently in HIPDB must be transferred into the NPDB and must be reconciled to close gaps and eliminate duplication between reporting requirements.

Board of Pharmacy Disciplinary Actions (cont)

Letter of Surrender-

Means a public record accepted by the Board in which:

(i) The licensee agrees to surrender the licensee's license or permit; or

(ii) The registrant agrees to surrender the registrant's registration.

"Letter of surrender" may include conditions for the Board's acceptance of the surrender.

The Board must AGREE prior to the voluntary surrender of a license or registration.

Board of Pharmacy Disciplinary Actions (cont)

Allowing a license or registration to lapse does not allow the licensee or registrant to escape disciplinary action while under investigation or while charges are pending.

2014 Virginia Statute – effective July 1 – State may not issue or renew a license, or registration, for any professional whose license has been revoked or suspended in any other jurisdiction.

Applicant must show by clear and convincing evidence that he is safe and competent to practice.

Board of Pharmacy Disciplinary Actions (cont)

Important Notes:

Any action(s) taken by the Board does not preclude, and in fact is separate from, prosecution by other authorities.

Any civil action for damages initiated by a citizen against a licensee or registrant is a proceeding that is separate from any administrative action by the Board.

Board of Pharmacy Disciplinary Actions (cont)

Probation

A. The Board may impose conditions of probation that the Board considers appropriate, including:

(1) Re-education or completion of approved courses;

(2) Payment of a fine (max of $10,000 per incident);

(3) Practicing pharmacy or operating a pharmacy under supervision;

(4) Monitoring by the Board or by an individual or entity approved by the Board with periodic reporting to the Board;

(5) Periodic review of a licensee's practice or operations;

(6) Periodic audits of a licensee's billing practice;

(7) An examination by a physician or other appropriate health care provider;

(8) Limitation of the licensee's practice or operations;

(9) Limitation of the pharmacy technician's scope of duties;

(10) Drug screenings;

(11) Individual or group counseling or therapy;

(12) Obtaining a passing score on an appropriate examination; or

(13) Any other condition the Board considers appropriate for the rehabilitation or retraining of a registrant or a licensee.

Board of Pharmacy Disciplinary Actions (cont)

B. A term of probation may be defined by a specific period of time or the successful completion of certain conditions or acts by the registrant or licensee.

C. A registrant or licensee seeking release from probation shall do so by petitioning the Board to terminate the probation when the:

(1) Specific period of time has passed; or

(2) Registrant or licensee has successfully completed the conditions or acts required for release.

D. If, at any time, the Board has reason to believe that the registrant or licensee is not in compliance with the conditions of probation, the Board shall:

(1) Charge the registrant or licensee with a violation of probation;

(2) Take an action provided for in the final order in the event of a violation of probation, including suspension of the registration, license, or permit;

(3) Consider a summary suspension of the registration, license, or permit; or

(4) Take any other action the Board considers appropriate and which the Board may take by law.

PHARMACIST CODE OF CONDUCT

Pharmacist Code of Conduct

A pharmacist shall:

(1) Abide by all federal and State laws relating to the practice of pharmacy and the dispensing, distribution, storage, and labeling of drugs and devices

(2) Verify the accuracy of the prescription before dispensing the drug or device if the pharmacist has reason to believe that the prescription contains an error; and

(3) Maintain proper sanitation, hygiene, biohazard precautions, and infection control when performing tasks in the prescription process.

Pharmacist Code of Conduct (cont)

A pharmacist may not:

(1) Engage in conduct which departs from the standard of care ordinarily exercised by a pharmacist;

(2) Practice pharmacy under circumstances or conditions which prevent the proper exercise of professional judgment; or

(3) Engage in unprofessional conduct.

(4) A pharmacist may not perform a therapeutic interchange without the prior approval of the authorized prescriber.

(5) A pharmacist may not fraudulently seek or accept compensation for a pharmacy product or service not provided.

COMPETENCE

A pharmacy technician or a pharmacist shall:

A. Maintain knowledge of the current pharmacy and drug laws and health and sanitation laws relevant to the practice of pharmacy; and

B. Provide a pharmaceutical service only within the scope of the pharmacy technician's or pharmacist's training and education.

Discrimination, Harassment, and Sexual Misconduct

A. In the practice of pharmacy, a pharmacy technician or a pharmacist may not:

(1) Discriminate based on age, gender, race, ethnicity, national origin, religion, sexual orientation, disability, socioeconomic status, or other basis as proscribed by law; or

(2) Sexually harass a patient, coworker, employee, or supervisee, which includes but is not limited to an unwanted, deliberate, or repeated comment, gesture, or physical contact of a sexual nature.

B. Sexual Misconduct. A pharmacy technician or a pharmacist may not:

(1) Dispense or offer to dispense a prescription drug or device in exchange for:

(a) A sexual act, or

(b) Sexual contact such as the intentional touching of an intimate part of an individual's body, whether clothed or unclothed; or

(2) Engage in sexual behavior including, but not limited to, a sexual act or sexual contact with a client or patient in the context of a professional evaluation, treatment, procedure, or other service to the client or patient.

Prescription Errors

"To Err Is Human"

Alexander Pope

Errors (cont)

Error Myths

If we try really hard, we will not make errors

If we punish people when they make errors, they will not make more errors

Error Facts

All of us make errors every day (not necessarily medical mistakes)

No one makes an error on purpose

Errors ARE made for reasons

Errors (cont)

Medical errors are now the #1 cause of death and injury in the U.S. (2009)

- 784,000 deaths due to medical mistakes
  - Heart – only 700,000
  - Cancer – only 560,000
  - Accidents – only 125,000
- 2.2 million ADRs per year
  - 450,000 occur in hospitals
  - 530,000 affect Medicare outpatients
  - 800,000 occur in comprehensive care facilities
- 51.5 million medical errors occur during the filling of 3 billion prescription annually
  - 4 errors per 250 Rxs per pharmacy per day
  - Estimated – in hospitals, there is one error per patient per day

Errors (cont)

If admitted to a hospital worldwide, your chances of dying due to a medical error would be approximately 1 in 10 -- (1 in 300 in U.S.)

The U.S. has a much worse record for hospital deaths than Europe (approximately 3 times worse).

U.S. Intensive Care Units – most expensive and best staffed hospital component

Fortunately, the majority of reported error events resulted in temporary or reversible patient harm, but there was, on average, 1 potentially fatal event per day

Errors (cont)

High Alert Drugs

ISMP list at:

www.ismp.org/Tools/highalertmedications.pdf

Sample Potential Problem Categories:

- Chemotherapy
- Electrolytes
- Narcotics
- Anticoagulants
- Insulin
- Sound-Alike/Look-Alike

Errors (cont)

Sources of pharmacist medication errors:

- Wrong drug dispensed
- Wrong strength dispensed
- Calculation error
- Abbreviation or symbol misinterpreted
- Illegible handwriting (no verification)
- Disruption in workflow
- Sound-alike, look-alike drug names
- Failure to verify verbal orders
- Ambiguous orders
- Lack of drug knowledge

Errors (cont)

We all know Murphy's Law:

"Anything that can go wrong WILL go wrong"

Perhaps, we aren't as familiar with the newly modified Murphy's Law:

"Anything that can go wrong PROBABLY won't go wrong"

Unfortunately, that often becomes our actual way of thinking.

Errors (Cont.)

Big Question??

How should we address the question of errors and where is the main area of responsibility?

- Individual ?
- System ?

INDIVIDUAL MAY BE - OR IS RESPONSIBLE

Errors (cont.)

Types of errors:

1. Skill-based - attributed to:
   - Slips
   - Lapses
2. Mistakes – attributed to:
   - Knowledge-based
   - Rule-based
3. Violations
   - No harm intended
   - Bad intentioned

Errors (cont.)

Skill-based

- A. Slips
  - Tend to occur with automatic, skill-based activities
  - You see what you expect to see or hear what you expect to hear
  - Usually occur following a change of a well-rehearsed routine (distractions)
  - Mental Fatigue
    - Forget what I was doing/talking about
- B. Lapses
  - Tend to occur with rule-based activities
  - Memory failure
    - Know what to do, but forgets a step
    - Went to shelf – forgot what I went to get
- C. Distractions
  - External (working environment)
    - Noise(s)
    - Temperature
    - Commotion
  - Internal (mental)
    - Preoccupation with outside issues (home)
    - Fatigue

ERRORS (CONT)

Slips & Lapses ---"Semi-cures"

- Make your double check a "real" double check
  - 2 pairs of eyes better than one
  - Second checker actually detects 90% errors****
- Make double checks independent of others by removing confirmation bias:
  - "What is this drug?" Versus "Is this Rx for Hydroxyzine?"
- REALLY read the label every time !!
  - Circle NDC number on Rx label stub
- Avoid fatigue
- Avoid distractions - if interrupted, start over at step one
- Scan all stock bottles (many look alike bottles/vials)

Errors (cont.)

Mistakes

A. Knowledge-based activities

Inadequate or incomplete training

Didn't ask for help or verify (jumped to a conclusion)

Cost vs benefit (requires time to ask questions)

Too busy

Too hard

Fear of intimidation

B. Rule-based activities

Verbal orders (didn't take time to repeat/understand)

Illegible orders (didn't take time to make the call –thought that you could read (understand) the Rx – "guessed")

Failure to utilize good rules already in place (use of work-arounds)

Errors (cont)

C. Violations

No Harm Intended – "work-arounds"

Not following a policy or regulation because it:

- Gets in the way of taking care of patients such as borrowing medication from another patient (and not getting a new order to save time/effort)
- Because you think that it is unnecessary or inefficient

Bad Intentioned

Criminal

Intentional falsification of records

Intending to cause harm (may rationalize by thinking that you are saving the patient pain/suffering)

Errors (cont)

We are all "good" guessers. We are almost never wrong.

When checking a prescription, remember the "FIVE RIGHTS":

- Right patient
- Right drug
- Right dose
- Right time
- Right route

SYSTEM MAY BE/OR IS RESPONSIBLE

Root Cause Analysis

Problem solving method aimed at identifying the root cause of problems or incidents.

By directing corrective measures at identified root causes, it is hoped that the likelihood of the problem reoccurring will be minimized.

Aimed at changing the "system" to prevent errors rather than punishing an individual or individuals that made the error.

Find the reason(s) the pharmacist used a "work-around".

Why did the pharmacist think that a "work-around" was necessary?

How could the system be changed so that the "work-around" would not be necessary?

Errors (cont)

Hydralazine	Hydroxyzine
Cerebyx	Celebrex
Vinblastine	Vincristine
Chlorpropamide	Chlorpromazine
Glipizide	Glyburide
Daunorubicin	Doxorubicin

Prevention of Errors

A prescription error is defined as any Rx that reaches the patient

that has ANYTHING incorrect!!

Learn when and how to get your brain out of "automatic mode"

- Identify your personal critical steps in your prescription routine
- Jog your brain – use "circling, underlining or other techniques to stay alert

Minimize distractions:

- Maintain a "mental space" around your work area
- Don't distract fellow workers during critical steps
- Don't allow conversations around you to become a focus
- If distracted, start over at step one

Prevention of Errors
Best Practices

Hear (REALLY HEAR) the concerns of others (patients):

- Stop whatever you are currently doing
- Actually listen to the entire issue being said
  - Medication is a different color or shape
  - Don't automatically say generic
  - Actually check & verify
- Thank the person for asking (addressing) the issue
  - Fully explain to patient or caregiver the reason behind the issue and any corrective action(s) taken
- Correct the reason for the issue
  - Written note of issue and needed corrective action(s)
  - Follow up with other RPhs and staff
- Restart your previously interrupted process from the beginning

Prevention of Errors
Best Practices

It doesn't matter if you make work in:

- Community
- Hospital
- Institutional
- Other

Take the responsibility to make your "corner of the world" a safer place

Error Communications

You are the pharmacist!!!

Assume that a prescription error has occurred, the patient did receive an incorrect medication, the patient did take the wrong drug and the patient did suffer an adverse drug reaction (ADR).

The patient, or patient's caregiver has called you regarding the consequences of the ADR. They are asking for your help at this point.

What advice would you give the patient now?

Error Communications (cont)

Apology Laws:

Most states' apology laws protect only the expression of regret, not any accompanying information related to fault -- this is the case in Maryland

Therefore, the best option may be to offer a partial apology (careful wording):

I am sorry for your pain (or other adverse drug reaction)

vs

I am sorry for misfilling your prescription and for the pain you are experiencing.

We all know that health care providers have a legal obligation under state and federal law to keep patients and their families fully informed about all aspects of their care.

Many times providers want to express sympathy for health status, failure to thrive or an unintended event. Why not do it more often? It's the fear of being sued and having that "I'm sorry" used against you later in court as an admission of fault.

Error Communications (cont)

There's a big difference between expressing sympathy for a patient's or family's situation and admitting the facility or organization caused that situation by negligent care.

"I'm sorry for the situation" is not the same as saying "I'm sorry we made an error", and that's a very important distinction.

A heartfelt, sincere apology may mitigate potential liability and may also:

- Act as a healing agent for the pharmacist who has made an error
- Demonstrate moral courage and integrity
- Help to restore the relationship with the patient

Liability Insurance

Should you have an individual pharmacist liability insurance policy ??????????

Keep in mind that almost every liability policy includes language similar to:

"…policy does not pay for damages arising out of a willful violation of a regulation or statute relating to pharmacy services, or any violation of a criminal or penal statute or criminal act"

or

"…policy does not pay for damages or injuries arising out of the insured rendering or failure to render professional health care services"

Pharmacist's Liability Insurance

Liability companies will usually recommend that you do NOT admit any error or make any apology.

It is recommended that each pharmacist obtain and maintain their own liability insurance.

Do not rely on your employer's liability insurance covering you.

- They are more intent on protecting the company than you
- You may be sued individually
- The amount of any decision may exceed the limit on the employer's contract
- You would not be covered if working off-site (i.e. - filling in at another pharmacy)

Errors (cont)

Take Home Points!!

If you have ANY question or concern –verify with prescriber !!!!

Document! -- Document! -- Document!!

Board of Pharmacy Disciplinary Actions (cont)

Administrative & Judicial Review:

The Maryland Administrative Procedures Act sets forth provisions allowing for judicial review of an action taken by the Board.

Board actions are termed "quasi-judicial" actions.

Actions taken by the Board may be appealed directly to a circuit court.

Judicial Review (cont)

Judicial review of the final decision of any administrative agency is limited to review of the record produced by the agency and generally fits into 3 categories:

Fact finding by the agency (resolution of any conflicting evidence)

The agency interpretation of the law (did the agency apply the correct principles of law governing the case in question)

Whether the agency decision was arbitrary or capricious

Judicial Review (cont)

Notes:

An administrative judge may NOT substitute his credibility determinations for those made by the Board.

Sanctions imposed by the Board may NOT be overturned except for the most extreme of all circumstances.

Deference MUST be given to the Board's determination of what sanction(s) furthers the purposes of:

- Protection of the public, and
- Maintains the quality of the profession of pharmacy

Errors (cont)

If an error does occur, it may result in:

ERRORS & OBRA-90

OBRA-90 changed pharmacists' responsibilities regarding patient counseling and the associated potential for errors.

Pharmacists must now "offer to discuss" with each patient or caregiver matters that in the pharmacist's judgment are significant, such as:

- Name and description of the medication
- Dosage form
- Route of administration
- Duration of therapy

The requirement of counseling patients significantly increases pharmacists' liability. Many potential errors would be caught during discussion with the patient.

Patient counseling not required for:

- Inpatients in a hospital
- Residents of a comprehensive care facility

Error Reporting

Incident reports

Anytime an error REACHES the patient, it must be reported.

Failure to report an incident in a timely manner may result in a denial of coverage if a claim is filed

Reasons for companies requiring incident reports:

Pharmacy manager – in order to evaluate operations and to analyze working procedures in the pharmacy (improve systems)

Home office – must be informed of all negative, potentially serious ramifications

Pharmacy's insurance company (risk management department) – must analyze each error to determine which may result in a claim

Incident Reports

Incident reports are not protected from discovery!!!!!

What does that mean to you?

They are confidential and HIPAA applies, but are subject to subpoena and may be used against the pharmacy or pharmacist in court.

Incident Reports (cont)

What should be included?

Names, addresses, phone numbers of all persons involved

Drug name(s), strengths, dosage(s) involved

Pertinent facts surrounding the error

Other pertinent facts

Witnesses (if any, to actual incident)

QUALITY ASSURANCE

Quality Assurance

Patient Safety:

Every Maryland pharmacy must establish methods to provide patients with information regarding the patient's role and responsibility in preventing medication errors; i.e.:

The patient's rights when receiving a prescription

The patient's role and responsibility in preventing a medication error

The procedures to follow when reporting a suspected medication error to:

A permit holder, provider, or facility, or

The Board

This information must be provided to the patient before or at the time the medication is given to the patient.

Quality Assurance Programs

Every Maryland pharmacy is required to have a quality assurance program!
Education on the pharmacy's quality assurance program is required for the entire pharmacy staff.

Each pharmacy permit holder shall conduct an analysis of its medication delivery system at least every 6 months to determine which medications in the prescription area of the pharmacy are high-alert medications, as part of the pharmacy's ongoing quality assurance program.

Documentation of Periodic Review. The records, proceedings, files, and any other documents of the ongoing quality assurance program shall include for each:

(1) Periodic review required
(2) Analysis of a pharmacy's medication delivery system to identify high-alert medications required

Unless otherwise specified in law, the permit holder shall maintain the on-going quality assurance program records for 2 years.

Quality Assurance Programs

On-going Quality Assurance Program.

(a) "On-going quality assurance program" means a program that systematically and routinely reviews the medication delivery system of a pharmacy for the purpose of minimizing the occurrence of medication errors.

(b) "Ongoing quality assurance program" includes:

(i) The systematic and routine collection of information regarding the performance of the medication delivery system as it becomes available;

(ii) The investigation of medication errors at the time the error is reported or discovered, or within a reasonable amount of time after the medication error is reported or discovered

Quality Assurance Programs (Cont)

The on-going quality assurance program shall include the records, proceedings, files, and any other documents of the ongoing quality assurance program, including for each medication error:

(1) The date of the error;

(2) A brief description of the error;

(3) The results of the evaluation by the ongoing quality assurance program's investigation; and

(4) Remedial action taken or recommendations.

PHARMACIST LICENSE RENEWALS

License Renewals

How long is an active Maryland pharmacist's license valid?

A pharmacist's license is valid for 2 years

During which calendar month must a pharmacist renew their license?

Due last day of birth month following 1st renewal - (should actually be renewed at least 14 days prior to last day of birth month)

License Renewals

What must a pharmacist complete prior to having their pharmacist license renewed?

Renewal requires:

- Payment of a renewal fee
- Submission of a renewal application
- Statement of completion of required CEs (audits are conducted on a % of applications)

Continuing Education Requirements

A. A pharmacist licensed to practice in Maryland applying for licensure renewal shall earn 30 hours of approved continuing pharmaceutical education within the 2-year period immediately preceding the licensee's renewal application.

B. A pharmacist shall attest to the fact that the pharmacist has completed the continuing pharmaceutical education requirement on a verified form. The licensee shall retain supporting documents for inspection by the Board for 4 years after the date of renewal for which the continuing education credits were used.

C. Maryland Special CE Requirements for Renewal:

2 hours must be live CE

1 hour must be in medication errors

If vaccination certified:

4 hours in programs related to vaccinations

Continuing Education Requirements (cont)

CPE Monitor is a national, collaborative effort by NABP and the Accreditation Council for Pharmacy Education (ACPE) to provide an electronic system for pharmacists and pharmacy technicians to track their completed continuing pharmacy education (CPE) credits.

Pharmacists and pharmacy technicians will receive a unique ID after setting up their e-Profile with NABP. Pharmacists and pharmacy technicians will need to provide their NABP e-Profile ID and date of birth to the provider when they register for CPE or submit a request for credit.

It will also offer state boards of pharmacy the opportunity to electronically authenticate the CPE units completed by their licensees, rather than requiring pharmacists and technicians to submit their proof of completion statements upon request or for random audits.

Display of License

A pharmacist must conspicuously display his license in his main practice site.

Failure to 'display' the license may result in a fine of $1000.

A pharmacist must carry his wallet card at all times while working.

PHARMACIST LICENSE REINSTATEMENT

Board of Pharmacy Disciplinary Actions (cont)

Reinstatement of License:

A registrant or licensee must petition the Board for a lifting of the suspension of a registration, license, or permit or a reinstatement following revocation or surrender of a registration, license, or permit.

Pharmacists applying for reinstatement of licenses between 2 & 5 years after expiration are required to retake & pass the MPJE.

Pharmacists applying for reinstatement of licenses between 5 & 10 years after expiration are required to take & pass the MPJE as well as submitting evidence of having completed 1000 hours of pharmacy work experience.

Pharmacists applying for reinstatement of licenses more than 10 years after expiration are required to take & pass the MPJE, submit evidence of having completed 1000 hours of pharmacy work experience and must pass the North American Pharmacist Licensure examination.

PHARMACY SECURITY

PERMIT HOLDER RESPONSIBILITIES

Pharmacy Security

The pharmacy permit holder shall:

(1) Ensure that the prescription area:

(a) Maintains temperature and ventilation at levels that do not affect the prescription drugs or devices stored in the area,and

(b) Permits reasonable communication between the pharmacist and the public when the pharmacy is open;

(2) Pharmacy must be secure and well-controlled with only authorized personnel having access to areas with prescription drugs and records;

(3) Prevent an individual from being in the prescription area unless a pharmacist is immediately available*** on the premises to provide pharmacy services;

(4) Monitor unauthorized or emergency entry after the prescription area has been secured by the pharmacist;

(cont)

Pharmacy Security (cont)

(5) Prevent unauthorized entry when the prescription area is closed during a period that the rest of the establishment is open;

(6) Must have a security system that can detect theft and diversion, and computer software that detects any tampering, a system to protect integrity of data and a way for the Board to easily access records;

(7) Designate personnel with authorized access to computerized patient records; and

(8) Maintain current computerized records in a manner which permits reconstruction within 48 hours.

Pharmacy Security (cont)

A pharmacy permit holder may store patient records away from the prescription area in a manner that prevents unauthorized disclosure or loss.

If the prescription area is not open the same hours as the establishment, the pharmacy permit holder shall prominently display signs indicating the business hours of the prescription area.

If the prescription area is not open the same hours as the establishment, the pharmacy permit holder shall secure the pharmacy area to prevent access when pharmacy is not open.

Licensees must report stolen CDS to the Board, the local police, the Maryland Division of Drug Control and the U.S. DEA.

Pharmacy Security (cont)

Potential Issues – Employee vs Employer

Employers have the right to monitor everything you do while using their resources (i.e. computer, telephone, etc).

Personal cell phones, if used in the work environment, may be seized and used as evidence.

PHARMACY SECURITY

PHARMACIST RESPONSIBILITIES

Pharmacy Security (cont)

The pharmacist shall:

(1) Secure the prescription area and its contents in order that the pharmacy permit holder or the pharmacy permit holder's agent may:

(a) Monitor unauthorized or emergency entry after the prescription area has been secured by the pharmacist, and

(b) Prevent unauthorized entry when the prescription area is closed during a period that the rest of the establishment is open;

(2) Have sole possession of a means of access to the pharmacy, except in emergencies; and

(3) Establish a means of access for use in an emergency when the pharmacist is not available to access the prescription area.

Pharmacy Security (cont)

A pharmacist shall be immediately available on the premises to provide pharmacy services at all times the pharmacy is in operation.

NOTIFICATIONS REQUIRED BY BOARD

Required Notifications

A licensed pharmacist shall report to the Board the pharmacist's current mailing address on the pharmacist's biennial license renewal form. The mailing address may be the pharmacist's residence address.

Within 30 days of the date a pharmacist changes the pharmacist's name or mailing address, the pharmacist shall notify the Board in writing.

Within 30 days of a change in the pharmacist's primary employment location, the pharmacist shall notify the Board in writing (unless owned by the same corporation, partnership or owner – must still be updated on renewal application).

The same requirement has now been requested for changes in pharmacists' contact:

- Phone numbers
- E-mail addresses

PHARMACY INSPECTIONS

Types of Pharmacy Inspections

Who is authorized to inspect a pharmacy in Maryland?

Board of Pharmacy conducts:

- Opening inspections
  - No inventory present
- Annual inspections
  - Required by Statute

DDC conducts:

- CDS inspections
- Closing inspections

DEA

FDA

PHARMACY EQUIPMENT

New Pharmacy Opening Inspection

Requirements (prior to requesting an opening inspection):

- Class A prescription balance or equivalent
- Refrigerator(s) with thermometer(s)
- Equipment sufficient for scope of practice
- Hot and cold running water
- Library of current reference materials sufficient for scope of practice
- Current edition of Maryland Pharmacy Law Book
- Security system in accordance with COMAR 10.34.05.02
- Means of securing pharmacy area if hours are different from rest of establishment
- Name of main pharmacist assigned to pharmacy (a pharmacist must be present if any prescription drugs are on premises)
- Pharmacy must be operational within 60 days or permit will be voided and must be returned to Board.

Pharmaceutical Area Temperatures

The regulations specify 3 difference temperature ranges for pharmacies:

Room temperature

Refrigerator temperature

Freezer temperature

Required Pharmacy References

Reference Libraries.

A. A pharmacy permit holder shall maintain an adequate reference library to enable it to prepare and dispense prescriptions properly, consistent with its scope of practice.

B. A pharmacy permit holder shall maintain a library of reference sources appropriate to the type of pharmacy practice at that particular location.

A pharmacy permit holder shall include in the pharmacy's library current material regarding the technical, clinical, and professional aspects of practice with emphasis in the area in which the pharmacy specializes.

Required Pharmacy References (cont)

C. A pharmacy permit holder shall maintain a library containing reference sources that:

(1) Enable the pharmacist to compound medications in a safe and effective manner;

(2) List the possible drug interactions and possible adverse effects of medications dispensed by the pharmacy;

(3) List the therapeutic usage and dosages of medications dispensed by the pharmacy;

(4) List the therapeutic equivalents for medications; and

(5) Provide guidelines for the counseling of patients.

D. A pharmacy permit holder that specializes in nuclear or parenteral prescriptions may limit the library it maintains pursuant to B of this regulation to the pharmacy permit holder's area of specialization.

E. A pharmacy may utilize web sites as supplemental reference materials.

FACSIMILE PRESCRIPTIONS

Facsimile Prescriptions

If my software accepts e-prescriptions how do I know that the prescriptions are legitimate?

Answer: You must ascertain that the pharmacy software version you are using verifies that the provider is listed as an approved intermediary by the Maryland Health Care Commission (MHCC). This documentation must be renewed every two years based on information provided to the MHCC by the intermediary.

What are the names of some of the approved intermediaries?

Answer: MHCC maintains a list of approved vendors in Maryland including Rx Hub and SureScripts. Go to this link to obtain the names of MHCC approved electronic health networks: http://mhcc.maryland.gov/edi/ehn/index.html

May I receive electronic prescriptions through my fax machine?

Answer: Yes you can, if the prescription is not for a controlled substance. Faxed prescriptions for controlled substances CIII – CV must be validated orally.

May I accept prescriptions sent to my fax machine by a prescriber that does not carry a “pen to paper” signature but reads ”electronically signed” or a similar message?

Answer: No, you cannot. These prescriptions may not have been transferred directly to you by an approved intermediary and therefore are not legitimate prescriptions.

Facsimile Prescriptions (cont)

May I accept e-prescriptions brought into the pharmacy by the patient or his agent that do not carry a “pen to paper” signature but read” electronically signed” or a similar message?

Answer: No, you cannot. These prescriptions would not have been transferred directly to you by an approved intermediary and therefore are not legitimate prescriptions.

The prescription may have been produced by software that the prescriber is using but the transmission has not been received directly from the approved intermediary and therefore the validity checks may have not been performed.

These prescriptions may not be accepted for reimbursement by third party payers. Use professional discretion and contact the physician to validate the prescription.

PRESCRIPTION & PROFILE INFORMATION

Information Required on Prescriptions and Profiles

In addition to the information required by law on every prescription, patient drug profile, or computerized patient drug record, the following information shall be legibly entered on all patient drug profiles or computerized patient drug records:

A. The date of filling or refilling;

B. The initials of, or other identifying symbol for:

(1) The pharmacist responsible for filling or refilling the prescription; and

(2) The data-entry pharmacy technician involved in the dispensing process.

EXPIRED MEDICATIONS

Expired Medications

The pharmacist is responsible for removal of all expired medications prior to the actual dispensing.

The pharmacist must check the expiration date of the medication as part of the final check of the prescription filling process.

Expired Medications (cont)

Best Practice:

Pharmacy personnel should check all stock at least every 3 months (monthly better) and pull all medications that are expired, or will be expiring prior to next scheduled check.

Pharmacy may do its own checks or hire a returns company to perform the checks and prepare the actual returns.

Expired medications should be returned to:

- Manufacturer
- Distributor/Wholesaler
- Reverse distributor

Records of any returns involving CDS must be maintained by the pharmacy for 3 years.

Expired Medications (cont)

Expired medications should not be flushed down the drain.

Please use a reverse distributor!!

"Hmphh. Happy as clams, indeed
They're just all on Prozac."

PRESCRIPTION TRANSFERS

Transfers – Primary Pharmacy

A pharmacist from a primary pharmacy may permanently transfer a prescription order to a secondary pharmacy to be dispensed to a specific patient if:

A. The prescription is lawfully refillable;

B. The prescription is not for a Schedule II CDS;

C. The pharmacist transferring the prescription from the primary pharmacy indicates on the prescription or within the prescription computer database:

(1) That the prescription has been permanently transferred;

(2) The name of the secondary pharmacy;

(3) The name of the pharmacist who transferred the prescription to the secondary pharmacy;

(4) The name of the pharmacist at the secondary pharmacy to whom the prescription was transferred if the transfer occurred in an oral manner; and

(5) The date on which the prescription was transferred to the secondary pharmacy.

Secondary Pharmacy Receiving a Prescription Transfer

The pharmacist at the secondary pharmacy who receives a permanently transferred prescription document is responsible for maintaining documentation in a readily retrievable and identifiable manner which includes:

A. That the prescription was transferred from another pharmacy;
B. The name and information identifying the specific location of the primary pharmacy;
C. The name of the pharmacist who transferred the prescription to the secondary pharmacy;
D. The name of the pharmacist at the secondary pharmacy who accepted the transferred prescription;
E. The date of issuance of the original prescription order;
F. The date on which the prescription order was first filled;
G. The date of the last refill;
H. The number of remaining refills;
I. The original prescription number; and
J. The date on which the prescription was transferred to the secondary pharmacy.

Refilling of Transferred Prescriptions

A pharmacist at the primary pharmacy may not refill a prescription that has been transferred to a secondary pharmacy.

The use of unified prescription records by more than one pharmacy through a common computerized prescription database does not constitute a permanent transfer of a prescription order.

What does that actually mean?

It essentially means that a pharmacist in one chain pharmacy may transfer the prescription to another pharmacist in the same pharmacy chain and still retain the right to refill that prescription in the future.

The prescription is actually not considered to be a transferred prescription as it is still in the same pharmacy computer system and all refill information is still attached to the specific prescription.

PATIENT PRESCRIPTION RETURNS

Question ?

May a pharmacist take back patients' medications that have been dispensed and left the pharmacy?

1. Yes
2. No

A pharmacist may accept the return of a properly labeled and properly sealed manufacturer's package or an individual unit dose of a drug or a device that the pharmacist determines to have been handled in a manner which preserves the strength, quality, purity, and identity of the drug or device during an interim period between the sale of the drug or device and its return to the pharmacy.

A pharmacist may not: Return to the pharmacy's stock or offer for sale a prescribed drug or device that has been previously sold and has left the pharmacy's possession except as provided above.

A pharmacy technician may not accept the return of prescription drugs or devices from a patient.

PERMANENT PHARMACY CLOSURES

Requirements for Closure of a Pharmacy

Prior to Closure:

A. At least 14 days before a location's anticipated date of ceasing to operate as a licensed pharmacy, the pharmacy permit holder shall notify the Board in writing, by certified mail, return receipt requested, or hand delivered to the Board's office of the day on which the licensed pharmacy will cease to operate as a pharmacy and request a closing date.

B. Upon above notification, the Board shall notify the Board's agent to schedule the closing inspection. This may be done by the Board, in conjunction with the Board's agent.

C. The Board, or the Board's agent (currently DDC), shall perform the closing inspection within 72 hours of the pharmacy ceasing to operate.

D. At the closing inspection of a licensed pharmacy, the pharmacy permit holder shall provide to the Board, or the Board's agent, all information and documentation required.

(cont)

Requirements for Closure of a Pharmacy (cont)

E. The pharmacy permit holder shall remove or completely cover all indications that the premises was a pharmacy within 30 days after the date the licensed pharmacy ceases to operate as a pharmacy.

F. The pharmacy permit holder shall notify all prescription drug suppliers to the pharmacy, before ceasing to operate as a pharmacy, of the date that the location will cease to operate as a pharmacy.

G. The pharmacy permit holder shall notify the public of the date that the pharmacy will cease to operate as a pharmacy by that date.

H. The pharmacy permit holder shall notify the public of the location to which the patients' records have been transferred, by the date the pharmacy ceases to operate.

I. If patient records are not transferred, the pharmacy permit holder shall notify the public of the:

(1) Location of the patient records;

(2) Method by which the patient records shall be maintained; and

(3) Procedure by which patients and other authorized individuals or entities may access the patient records.

Requirements for Closure of a Pharmacy (cont)

Information and Documentation Due at the Closing Inspection.

The notification required by the Board after a licensed pharmacy ceases to operate as a pharmacy shall include:

A. The exact date on which the pharmacy ceased to operate as a pharmacy;

B. A copy of the inventory required by the DEA;

C. Any unused or voided DEA Form 222s;

D. The pharmacy permit;

E. State DHMH controlled dangerous substance registration for cancellation;

F. The names, addresses, telephone numbers, and DEA registration numbers of the persons or business entities to whom any prescription drugs in stock were returned or transferred and for any prescription files or patient records transferred;

(cont)

Requirements for Closure of a Pharmacy (cont)

G. If prescription drugs are destroyed, the pharmacy permit holder shall provide the Board with a letter, signed under oath by the pharmacy permit holder, stating the required information (date, place and manner of destruction, etc).

H. If any patient records or other documents containing patient information are destroyed, the pharmacy permit holder shall provide the Board with a letter, signed under oath by the pharmacy permit holder, stating the required information.

I. If any patient records or other documents containing patient information are transferred, the pharmacy permit holder shall provide the Board with a letter, signed under oath by the pharmacy permit holder, stating the required information.

Requirements for Closure of a Pharmacy (cont)

Disposition of Prescription Drugs Other than Controlled Dangerous Substances.

With the exception of controlled dangerous substances, all prescription drugs in stock shall be disposed of by one or more of the following means:

A. Returning them to a distributor or manufacturer; or

B. Transferring them to another licensed pharmacy, authorized prescriber, or other person or entity approved by the Board or the DDC.

Disposition of Controlled Dangerous Substances:

The pharmacy permit holder shall comply with the federal procedures governing the disposal of controlled dangerous substances.

WAIVER PHARMACY

Waiver Pharmacy vs Regular Pharmacy

The application for a waiver permit shall be evaluated in accordance with the following criteria:

(1) The pharmacy restricts or limits its service to a group or groups of individuals requiring such specialty services;

(2) The pharmacy is in or makes use of a specialized setting by virtue of certain equipment, systems, location, or physical structure;

(3) At least one pharmacist at the applicant's proposed facility has received education or training in the specialized area in addition to that required for other licensees under this subtitle;

(4) The applicant demonstrates a need for the specialized type of pharmacy in the community or population proposed to be served.

REGISTERED PHARMACY TECHNICIANS

Pharmacy Technicians

Persons must be registered by the Board to perform delegated pharmacy acts in Maryland.

Currently there are only 2 routes to become a registered pharmacy technician:

1. Be, or become, nationally certified by:
    A. Pharmacy Technician Certification Board (PTCB)
    B. Institute for Certification of Pharmacy Technicians (ExCPT)
2. Submit a technician application and pass Maryland requirements

Pharmacy Technicians (cont)

Nationally certified applicants must:

(1) Submit a signed completed application on a form provided by the Board;

(2) Submit evidence of current certification*** by a national pharmacy certification program;

(3) Pay the Board's registration fee; and

(4) Submit a request for a State Criminal History Records check (Criminal Justice Information Services-CJIS).

Requires 2 sets of fingerprints be taken by a law enforcement agency.

Pharmacy Technicians (cont)

Other (non-nationally certified) applicants must:

(1) Submit to the Board a signed completed application

(2) Be 17 years old or older (technically 16 yrs and 6 months);

(3) Meet the following educational requirements:

(a) Be a high school graduate or have attained a high school equivalency diploma, or

(b) Be enrolled and in good standing at a high school

(4) Provide satisfactory proof to the Board of the applicant's successful completion of a pharmacy technician training program approved by the Board that:

(a) Is no longer than 6 months duration; and

(b) Includes at least 160 hours of work experience;

(5) Pass an examination approved by the Board;

(6) Pay the Board's registration fee; and

(7) Submit a request for a State Criminal History Records check.

Pharmacy Technicians (cont)

Pharmacy students who are practicing in a pharmacy as part of a school of pharmacy sanctioned experiential learning rotation are not subject to these regulations (as long as they are only working in their rotations- must have documentation).

Pharmacy students performing pharmacy technician functions and who are working as a technician and are NOT in a school of pharmacy sanctioned experiential learning program shall:

(1) Submit a signed completed application for exemption from the registration requirements; and

(2) Comply with the following conditions:

(a) Provide verification of enrollment and good standing at an accredited school of pharmacy yearly;

(b) Pay an exemption fee; and

(c) Submit a request for a State Criminal History Records check.

Pharmacy Technicians (cont)

A pharmacy technician's registration:

(1) Expires on the date set by the Board (month of birth – same as RPh requirement) unless it is renewed for an additional term; and

(2) May not be renewed for a term longer than 2 years.

The registrant may renew the registration for an additional term of 2 years if the registrant:

(1) Pays to the Board a renewal fee; and

(2) Submits to the Board:

(a) A renewal application on the form that the Board requires; and

(b) Satisfactory evidence of compliance with the continuing education requirements.

Pharmacy Technicians (cont)

Technician Continuing Education Requirements:

(1) A pharmacy technician registered to practice in Maryland shall earn 20 hours of approved continuing pharmaceutical education within the 2-year period immediately preceding the registrant's renewal application.

(2) A pharmacy technician shall:

(a) Attest to the fact that the pharmacy technician has completed the continuing pharmacy technician education requirement;

(b) Retain supporting documents for inspection by the Board for 4 years after the date of renewal for which the continuing education credits were used.

Pharmacy Technicians (cont)

The Maryland Board of Pharmacy reports:

- Overwhelming number of pharmacy technicians being reported for stealing CDS resulting in:
  - Investigations
  - Suspensions
  - Fines (includes pharmacies)

UNLICENSED PERSONNEL

Unlicensed Personnel

Unlicensed personnel does not include technicians who are registered with the Board of Pharmacy as Registered Technicians.

Unlicensed Personnel (cont)

Duties of the Pharmacist.

A. The pharmacist shall provide supervision to unlicensed personnel.

B. The pharmacist may not delegate any pharmacy acts to unlicensed personnel.

Duties of Unlicensed Personnel.

A. Unlicensed personnel under the supervision of a pharmacist may perform operational support which the unlicensed personnel have been trained to adequately perform in the prescription area.

B. Unlicensed personnel who perform duties in the prescription area shall maintain the confidentiality of patient specific data.

PHARMACIST INTERNS

Pharmacist Interns

2014 Maryland Statute

A person must apply for, and be approved by the Board, before being allowed to practice pharmacy under the direct supervision of a licensed pharmacist.

Applicant must:

Be currently enrolled in, and have completed one year,
of pharmacy education in a doctor of pharmacy
program accredited by the ACPE.

or

Have graduated from a doctor of pharmacy program accredited by the ACPE.

or

Be a graduate of a foreign school of pharmacy who has established educational equivalency and has passed an oral English exam

Pharmacist Interns

Once registered, the registration is valid for 2 years from the date of issue.

The registration may be renewed one time.

The registration expires:

On the 2 year anniversary of the date of issue

Upon the date that the registered pharmacy intern becomes a licensed pharmacist

Pharmacist Interns

The registered pharmacy intern must display the pharmacist intern registration prominently in the primary work location.

The registered pharmacy intern must have the wallet registration card on the registered pharmacy intern's person at all times while working.

The registered pharmacy intern must wear identification that conspicuously identifies that person as a registered pharmacy intern.

PHARMACIST EXTERNS

Pharmacist Externs

Maryland does not recognize the term extern – In other states the term pharmacist-extern means a person that has graduated from a college of pharmacy, but has not yet been licensed to practice as a pharmacist.

Most pharmacist-externs are foreign graduates due to the increased work experience requirements.

PRESCRIPTION DELIVERY

Delivery of Prescriptions

A. A prescription medication may be delivered to the patient for whom the prescription is prescribed, wherever the patient is located; or

B. Instead of delivering medication directly to the patient under A of this regulation, medication may be delivered to:

(1) An agent authorized by the patient; or

(2) The residence of the patient, regardless of whether the patient is present at the residence at the time of delivery.

Delivery of Prescriptions (cont)

Authorization by a patient for delivery may be made either in person, in writing or orally.

The pharmacist is required to document the authorization and manner of authorization:

On the prescription;

In the patient's profile; or

In another record established and maintained by the pharmacy for the purpose of recording delivery authorizations

Key provisions for delivery:

A pharmacist must be in a position to readily consult with the patient upon receipt of the medication (may be provision of a toll-free phone number)

Medication must be delivered to the person, or agent, for whom it is intended

Must be labeled in a manner that does not indicate that the package contains drugs

Must be no evidence of tampering with delivered medication

Delivery of Prescriptions (cont)

Prescription medications delivered to individuals shall be:

A. Enclosed in a container that reveals to the patient any tampering of the container that may have occurred during delivery or storage;

B. Packaged in a manner which does not indicate that the contents are medications;

C. Packaged in a manner that indicates:

(1) The name and address of the patient or authorized agent; and

(2) Any special storage conditions or requirements; and

D. Packaged to contain:

(1) Written information regarding the prescription drug or device which is considered significant in the professional judgment of the pharmacist; and

(2) A local or toll free telephone number for the pharmacy.

PERMIT HOLDER NAME CHANGE

Permit Holder Name/Hour Change

The name of an individual or entity required to possess a pharmacy or distribution permit may be changed on a permit if:

The permit holder submits to the Board within 30 days before or after the name change, notification on a form that the Board requires.

Hours of pharmacy operation

The permit holder shall notify the Board within 30 days before or after the change in hours of operation.

DISPENSING OR DISTRIBUTING AT A SETTING THAT DOES NOT POSSESS A PHARMACY PERMIT

Dispensing or Distributing at a Setting That Does Not Possess a Pharmacy Permit

The setting must be:

(a) Operated or funded by a public health authority of the State;

(b) A medical facility or clinic that is operated on a nonprofit basis and is not otherwise required to possess a pharmacy permit; or

(c) A health center that operates on a campus of an institution of higher education.

(d) If a pharmacy for which a permit is issued is destroyed or otherwise rendered inoperable, a pharmacist may dispense or distribute from a temporary site (for up to 60 days) if the permit holder:

(1) Obtains approval from the Board before continuing pharmacy operations from any temporary site; and

(2) Ensures that the temporary pharmacy site complies with State and federal laws.

STATUTE AND/OR REGULATION CHANGES

Procedures for the Maryland Board to Change Statutes and Regulations

To Change Statutes:

Research and write suggested changes in Bill form
Submit proposed changes to potentially affected stakeholders for comments (may be as a taskforce)
Submit proposed changes to DHMH
Submit proposed Bill to Legislature in Annapolis (requires a sponsor)
Testify before the Legislature for the proposed changes

To Change Regulations:

Research and write suggested changes to specified regulation section(s)
Submit proposed changes to DHMH
Submit proposed changes to potentially affected stakeholders for comments (may be as a taskforce)
Submit proposed changes for informal comment period (30 days)
Submit proposed changes for official comment period (30 days)
If Board makes any changes following official comment period, then the proposal must be re-submitted for another 30 day comment period
Post in the Maryland Register

TELEHEALTH

TELEHEALTH

Maryland became one of the latest states to jump on the bandwagon when the governor signed a telehealth parity statute in May 2012.

The Maryland statute has several key provisions, including:

- Telehealth is defined as "interactive audio, video or other telecommunications or electronic technology by a licensed health care provider to deliver a health care service".
  - (Does not apply to audio-only phone conversations, e-mail messages or faxes between providers and patients)
- Insurers are required to provide coverage for health care services provided appropriately using telehealth.
  - Coverage cannot be denied because services are provided via telehealth rather than in-person.
- Insurers can require deductibles, copayments or coinsurance for telehealth services as they would for in-person services.
- Insurers may not differentiate between rural and urban patients to determine coverage for telehealth services.

MARYLAND PRESCRIPTION DRUG MONITORING PROGRAM (PDMP)

Maryland Prescription Drug Monitoring Program (PDMP)

Effective implementation in 2013

Administered by the Department of Alcohol and Drug Abuse Administration ADAA (DHMH)

The PDMP collects and securely stores information on drugs that contain CDS and are dispensed to patients in Maryland. Drug dispensers, including pharmacies and healthcare practitioners, electronically report the information that is stored in the PDMP database.

Access to prescription data is made available at no-cost to physicians, nurse practitioners, pharmacists and others that provide pharmaceutical care to their patients.

By law, healthcare providers may only access information on patients under their care.

Maryland Prescription Drug Monitoring Program (PDMP) (cont)

Who must register?

- Pharmacies
  - In-State
  - Non-resident (if delivering to patients in Maryland)
- Healthcare practitioners that dispense

Is anyone exempt from registering, and if so, who?

- Hospital pharmacies that dispense CDS only to inpatients
  - If dispensing starter doses for discharge or from ER – must register
- Board issued waivered pharmacies:
  - Assisted living facilities
  - Comprehensive care facilities
  - Development disabilities facilities
- Opiod maintenance programs
  - Anonymous participation – condition of enrollment in program
- Veterinarians
- Inpatient hospices

At present – no requirement for Maryland prescribers to utilize program.

2014 – Virginia Statute – requires prescribers to request information prior to initiation of Buprenorphine treatment or prescribing for a benzodiazepine of opiod.

Maryland Prescription Drug Monitoring Program (PDMP) (cont)

What schedules must be reported ?

All drugs in schedules I – II – III – IV – V

Prescription information must be reported within 3 business days.

Maryland does not require zero reports.

At present, Maryland's program is NOT connected to other states' programs – Will be in future (3rd quarter 2014)??

Pharmacy computer MUST allow access to/from CRISP web portal.

Maryland PDMP Questions:
www.hidinc.com/mdpdmp/dispenser.html

PDMP Questions

Who should I contact with questions?

If you need *technical assistance*, please contact the MD PDMP Help Desk by email at mdpdmp-info@hidinc.com or call 1-855-729-8920. Technical assistance is available Monday through Friday (except for holidays) from 9:00 a.m. – 5:00 p.m. Eastern Standard Time.

If you have *non-technical* questions regarding the Maryland PDMP, please send an email todhmh.pdmp@maryland.gov or call 410-402-8686.

I am a pharmacist. How do I access PDMP data for patient care?

Pharmacists will register with CRISP and access data through the CRISP Health Information Exchange query portal. To receive update notifications send an email to dhmh.pdmp@maryland.gov with "Send me PDMP updates" in the Subject line.

REPORTING LOSS OR THEFT OF CDS

Process for Reporting a Loss of a Theft of a Controlled Substance (cont)

What constitutes a loss of a CDS that must be reported?

DEA's requirement to report any theft of controlled substances is fairly ambiguous. The issue of "What Constitutes a Significant Loss" – DEA states "there is no single objective standard which can be established and applied to all registrants to determine whether a loss is significant."

DEA explained that registrants must undertake a case-by-case review of losses "within the context of a registrant's business activity and environment," noting that "what constitutes a significant loss for one registrant may be comparatively insignificant for another."

For example, DEA said that the "loss by a pharmacy of a 100-count bottle of a CDS would be viewed as significant, whereas the same loss by a full line distributor may be viewed differently, particularly if the loss is an unexplained inventory discrepancy that may have resulted from a picking error."

Process for Reporting a Loss of a Theft of a Controlled Substance (cont)

DEA provided the following list of factors to consider when making determinations about whether losses are significant:

- The actual quantity of controlled substances lost in relation to the type of business;
- The specific controlled substances lost;
- Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals;
- A pattern of losses over a specific time period, whether the losses appear to be random or not;
- Whether the specific controlled substances are likely candidates for diversion; and
- Local trends and other indicators of the diversion potential of the missing controlled substance.

Process for Reporting a Loss of a Theft of a Controlled Substance

Breakage or spillage of CDS does not constitute a “loss”. Any breakage or spillage must be reported to DEA on a DEA Form 41.

It is the responsibility of the registrant to use their best judgment to determine what constitutes a significant loss.

In the case of a significant loss of any controlled substance(s) at a pharmacy, the following procedures must be implemented within one (1) business day of the discovery of the theft or loss.

Process for Reporting a Loss of a Theft of a Controlled Substance

1. Notify local police
   - Perform actual investigation
   - May perform polygraph tests
     - Are employees in Maryland required to take a polygraph test?

2. Notify DEA
   - Must promptly complete DEA Form-106 electronically (unless Internet access is not available) through DEA's web portal: https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp

   DEA Form-106 must contain:
   - Name & address of pharmacy; DEA #; Date of theft; name & phone # of local police; type & time of theft; listing of items and quantities missing or stolen

3. Notify Board of Pharmacy

4. Notify Maryland Division of Drug Control

Process for Reporting a Loss of a Theft of a Controlled Substance

In case internet access is not available, a paper copy of DEA Form 106 may be mailed to:

Drug Enforcement Administration
Attn: Regulatory Section/ODG
8701 Morrissette Drive
Springfield, VA 22152

ORDERING CIIs -- DEA FORM 222

How to Order CII Forms

Request forms from DEA:

1-800-882-9539

or

Drug Enforcement Administration

Registration Unit

Central Station

P.0. Box 28083

Washington, D.C. 20038-8083

May request up to 6 books of forms at one time – each book contains 7 forms in numeric order (***should be used in numeric order)

Procedure for Reporting Stolen CII Order Forms

IF CII forms are stolen:

1. Notify local police
   - Perform actual investigation
   - May perform polygraph tests

2. Notify DEA Office
   - Immediately by phone or electronically
   - Follow-up with written notification

OUTSOURCING of PRESCRIPTION ORDERS

OUTSOURCING

Outsourcing means-

The transmitting of a prescription order from a primary pharmacy to a secondary pharmacy that actually prepares the prescription.

Why would a pharmacist need, or want to, "outsource" a prescription?

Primary (original) pharmacy does not have the necessary:

- Personnel
- Training or expertise
- Equipment
- Required (sufficient) temperature storage area

Outsourcing of a Prescription Order

A pharmacist from a primary pharmacy may transmit a prescription order to a secondary pharmacy for preparation and final dispensing to a specific patient or for return to the primary pharmacy for final dispensing to a specific patient if:

A. The label contains the name, address, and phone number of the primary pharmacy;

B. The patient is informed in writing of the name and address of the secondary pharmacy;

C. The patient is informed in writing that the prescription order was prepared at a secondary pharmacy;

D. The original prescription order is filed as a prescription order at the primary pharmacy;

(cont)

Outsourcing of a Prescription Order (cont)

E. The pharmacist from the primary pharmacy documents in a readily retrievable and identifiable manner:

(1) That the prescription order was prepared by a secondary pharmacy;

(2) The name of the secondary pharmacy;

(3) The name of the pharmacist who transmitted the prescription order to the secondary pharmacy;

(4) The name of the pharmacist at the secondary pharmacy to whom the prescription order was transmitted if the transmission occurred in an oral manner;

(5) The date on which the prescription was transmitted to the secondary pharmacy; and

(6) The date on which the medication was sent to the primary pharmacy;

F. Both the primary and secondary pharmacies are licensed in this State, or operated by the federal government; and

G. The primary pharmacy maintains, in a readily retrievable and identifiable manner, a record of preparations received from the secondary pharmacy.

Preparation of Stock and Investigational Medications

Stock medication means-

Medication that is not labeled for, or intended for, use by a specific patient when it leaves the pharmacy, but is intended to be stored and ultimately administered by a licensed health care professional in accordance with applicable laws and regulations.

A. A pharmacist may provide medication for use as stock medication for a licensed health care facility

B. A pharmacist may provide medication for use as stock medication for final dispensing or administration by an authorized prescriber who is permitted by law to administer or dispense medication as long as the pharmacist receives a written stock medication order from the authorized prescriber for each delivery of medication to the authorized prescriber.

C. A pharmacist may prepare, package, and label investigational drugs not destined for a specific individual at the time

of preparation, packaging, and labeling if:

(1) The study for which medications are prepared, packaged, and labeled is approved by an institutional review board; and

(2) The pharmacy permit holder ensures that records disclosing the identity of the subject who eventually receives the medication are:

(a) Received by a pharmacist on duty at the pharmacy within 30 days after being provided to a patient; and

(b) Maintained in the pharmacy

Investigational Medication

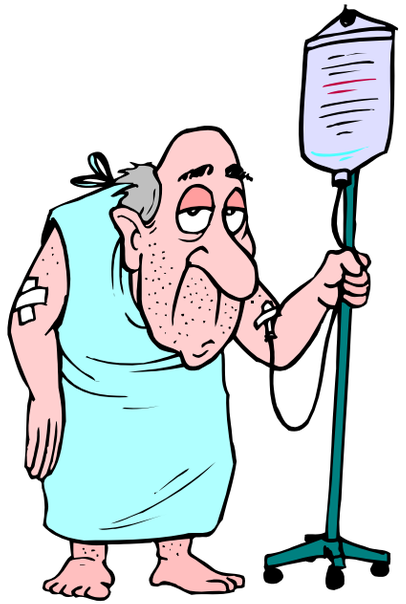
Investigational medication means-

Medication that is under study and is not approved by the FDA for sale in the U.S.

Patients may obtain an investigational medication:

1. By taking part in a clinical trial sponsored under an IND
2. Through an expanded access protocol (allows more patients to potentially benefit from a promising medication)
3. By means of a special or compassionate exception.

INPATIENT INSTITUTIONAL PHARMACY



Inpatient Institutional Pharmacy

Inpatient institutional pharmacy means-

A permit holder that operates a pharmacy that services an inpatient setting (acute care, rehabilitation, transitional care, chronic care, mental health); and

A person or entity that holds a pharmacy permit and operates a pharmacy in or for an impatient institutional facility other than a comprehensive care facility.

Decentralized Pharmacy

Decentralized Pharmacy means an institutional pharmacy which provides services for the population of an institutional facility, and is:

- Dependent on the institutional pharmacy for:
  - Administrative control
  - Staffing
  - Drug procurement
- Is located in the same building or pavilion as the institutional pharmacy.
  - Pavilion means a detached or semi-detatched part of a hospital devoted to a special use.

A decentralized pharmacy must have a pharmacist on site during all hours of operation.

**If dispensing medications to discharge patients, employees, clinic patients or others – must have a full service pharmacy permit.

Agency Regulatory Oversight of Inpatient Institution Pharmacies

Pharmacy operations:

State Board of Pharmacy

Institutional operations:

Office of Healthcare Quality (OHCQ) in Maryland

Joint Commission on Accreditation of Healthcare Organizations (JCAGO) - nationally

Medication Order

Medication order" means a patient-specific order entered on the chart or a medical record of a patient by an authorized prescriber or the authorized prescriber’s designee for a drug or device that is transmitted in writing, verbally or by electronic means and includes the:

(a) Date ordered;

(b) Drug name;

(c) Dosage;

(d) Dosage form;

(e) Patient name with second identifier, such as date of birth or medical record number;

(f) Route and time(s) of administration;

(g) Administration instructions, if appropriate; and

(h) Signature, if appropriate, of an authorized prescriber

Medication Orders (cont)

Medication orders may be:

Verbal

"Verbal order" means a medication order of an authorized prescriber which is recorded in the patient's chart and countersigned by the prescriber within a time period required by the institution

Written

"Written order" means a medication order that is recorded on-site as a written document by an authorized prescriber.

Medication Protocols

The institutional pharmacist may dispense drugs for an approved institutional protocol if conditions designated by the institution are met (without obtaining an actual prescription or drug order first).

The director of pharmacy or designee shall assist in establishing institutional policies and procedures governing the development of order-sets for each individual situation for which medication protocol orders apply to a therapeutic or diagnostic intervention.

An order-set means predefined orders, including medication orders, that are based on an institutionally approved protocol.

The appropriate committee of the institution shall approve the order-sets before the pharmacist may provide the medications based on any protocol.

Emergency Drugs and Supplies

Emergency drugs and supplies means specific drugs and supplies that may be:

(a) Required to meet the emergency needs of patients, and

(b) Are not available from an authorized source in a timely manner.

In other locations, emergency drugs and supplies may be referred to as “emergency drug kits”.

Procedures for Emergency Dispensing of Medications and Supplies

The institutional pharmacy shall furnish emergency drugs and supplies only if:

(1) The emergency drugs and supplies are stored in an environment which maintains the integrity of the drugs and provides accessibility only to authorized personnel;

(2) The institution follows a policy that drugs will be administered from the emergency drugs and supplies formulary only upon written or verbal order by an authorized prescriber;

(3) The emergency drugs and supplies are stored and secured with a tamper evident seal or via electronic means and kept in a secure area;

(4) The emergency drugs and supplies are labeled as follows:

(a) Listing of the expiration dates of the emergency drugs and supplies**;**

(b) Listing of the name or initials of the pharmacist who checked the emergency drugs and supplies; and

(c) Highlighting the expiration date of the medication with the shortest expiration date

(5) When the emergency drugs and supplies are contained within an emergency cart, the pharmacist checking the emergency cart shall ensure that the exterior of the cart is labeled with the contents of the emergency cart and the name or initials of the pharmacist.

Procedures for Emergency Dispensing of Medications and Supplies (cont)

Upon notification that emergency drugs and supplies have been opened, a pharmacist or registered pharmacy technician shall restock the emergency drugs and supplies, or provide a replacement supply.

Inpatient Pharmacy Director Responsibilities

The inpatient institutional permit holder shall hire a director of pharmacy to oversee all pharmacy operations and who will ultimately be responsible for all pharmacy operations.

The director of pharmacy shall establish and operate under a policies and procedures manual.

The director of pharmacy shall provide annual training on the policies and procedures manual to the personnel of the pharmacy.

Requirements of Inpatient Repackaging of Medications

A licensed pharmacist shall verify the selection of medication to be packaged and verify the completed packaging of medication performed by a registered pharmacy technician.

The pharmacy shall use a lot number and expiration date assigned by the pharmacy documented in a master log with respect to drugs that are packaged within the pharmacy facility from the original manufacturer's container.

Unless the licensed pharmacist has reason to reduce the time period, the expiration date of the medication is the lesser of:

(1) Twelve months from the date of packaging;
(2) The manufacturer's or distributor's listed expiration date; or
(3) The maximum time period allowed for the specific packaging used for the medication.

CDS Accountability in an Inpatient Institutional Pharmacy (cont)

The director of pharmacy is responsible for establishing procedures and maintaining adequate written or electronic records regarding dispensing and accountability of CDS which specify at least the following:

(a) Name and strength of the drug;

(b) Dose;

(c) Dosage form;

(d) Prescriber;

(e) Patient name with second identifier;

(f) Date and time of administration; and

(g) Individual administering the drug

CDS Accountability in an Inpatient Institutional Pharmacy (cont)

The director of pharmacy shall be responsible for establishing and maintaining adequate procedures for documentation of:

(a) Recording receipt of delivery to the pharmacy;

(b) Entering into the pharmacy inventory;

(c) Entering into Schedule II inventory; and

(d) Dispensing of controlled dangerous substances

CDS Accountability in an Inpatient Institutional Pharmacy (cont)

The director of pharmacy or designee shall be responsible for establishing and maintaining adequate procedures for documenting partially administered controlled dangerous substances

(a) For disposal by hospital policy; and
(b) Return of unused drugs to the pharmacy.

The director of pharmacy or designee shall establish procedures to ensure that CDS records include the handwritten or electronic signature of the individual authorized:

(a) By the institution to dispose of drugs or to return them to the pharmacy; and
(b) To witness the disposal, as defined by the institution's policies and procedures.

Drug Recalls

If a recall has been initiated for a drug that has been purchased by the institution, the director of pharmacy or designee shall issue a notice in a timely manner informing affected departments of the institution that the drug shall be returned to the pharmacy for proper return or disposal.

The institutional pharmacy is responsible for the timely retrieval of affected drugs.

Reporting of Adverse Drug Events

Reporting of ADRs in the institutional setting:

The director of pharmacy or designee shall immediately report adverse drug events to the prescriber, or the prescriber's designee, make a written or electronic report to the appropriate committee or committees and record in the patient's chart.

The director of pharmacy shall participate in the deliberations of the institutional committee charged with the development of the programmatic and operational changes that may result from the analysis of medication errors or other adverse events.

The director of pharmacy in collaboration with the medical staff and other appropriate departments and services shall develop and maintain a process for training staff regarding detecting and reporting medication errors to prevent future occurrences.

The director of pharmacy or designee shall make further reports of adverse reactions as required by federal or State law.

Pharmaceutical Care Functions of the Pharmacist

The pharmacist shall be available as necessary to provide pharmaceutical care to individual patients including, but not limited to:

A. Participating in decisions about medication use for patients including decisions not to use medication therapy as well as judgments about:

(1) Medication selection;

(2) Dosages;

(3) Routes and methods of administration;

(4) Medication therapy monitoring; and

(5) The provision of medication-related information and counseling to individual patients;

B. Cooperating directly with health care professionals and the patient in designing, implementing, and monitoring a therapeutic outcome.

C. Providing care directly to the patient to improve a patient's quality of life through achieving definite and predefined, medication-related therapeutic outcomes.

D. Identifying potential and actual medication-related problems, resolving actual medication-related problems, and preventing potential medication-related problems.

Medication Reconciliation

Medication reconciliation is the process in which health care providers review a patient's medication regimen at transitions in care (such as admission or discharge from a hospital and transfers to a long-term are or home care).

The process has been shown to be effective in preventing medication errors by:

- Avoiding inconsistencies
- Adverse affects
- Duplicative or unnecessary medications

New CMS Rule

In June 2012, CMS announced that inpatient hospitals will no longer be reimbursed for treating their Medicaid patients for illnesses, injuries or re-admissions that could and should have been prevented.

May mean that hospital pharmacies may now have to provide their discharged patients a sufficient supply of medication to give them time to obtain a regular supply elsewhere.

How some hospitals are trying to meet this requirement?

Using outpatient dispensing to provide the first fill of a prescription – subsequent refills must be obtained at the patient's regular community pharmacy.

REMOTE PHARMACY MANAGEMENT

Remote Pharmacy Management

Remote pharmacy management, in this context, means:

The review of patient medication orders to ensure safe medication use -- from an off-site location by a pharmacist.

Review of patient profile

Clarification of medication orders

Communication of clarified orders or changes to orders

Remote Pharmacy Management (cont)

ASHP Guidelines:

Quality assurance and safety guides must be followed

Access to drug information resources and hospital policy resources is essential

The remote site must be able to access and use the client information system and order transmittal system

All federal and state regulatory provisions must be met

The remote site must establish and maintain effective communication channels.

STERILE PHARMACEUTICAL COMPOUNDING

Sterile Pharmaceutical Compounding Definitions (cont)

Anteroom

Means the area, room, or rooms where personnel perform hand hygiene and garbing immediately adjacent to the designated clean room where the compounding of sterile preparations is actually performed.

Batch

Means a preparation compounded in advance of receipt of a prescription, or a preparation compounded in a supply that will be used on more than one dispensing to one patient or several patients, or any preparation compounded in excess of the filling of an individual prescription.

Biological Safety Cabinets

Biological safety cabinet (BSC) - Means a containment unit that is:

Suitable for work involving agents that pose higher risk of exposure to operators during compounding; and

Used when there is a need for protection of the preparation, personnel, and environment.

The bio-safety cabinet is similar to the conventional fume hood in providing protection for the operator.

It differs from the conventional fume hood by offering extra protection for the person performing the work in progress and the environment.

Biological Safety Cabinets (cont)

They act as primary barriers to prevent the escape of biological aerosols into the laboratory environment.

This is an important function, because most laboratory techniques (e.g., pipetting, vortexing, sonicating) are known to produce inadvertent aerosols that can be readily inhaled by the laboratory worker.

High Efficiency Particulate Air (HEPA) filters are present in all classes of BSCs. A HEPA filter removes only particulates (including microorganisms), not vapors or gasses, from the air.

Depending on its quality, a HEPA filter is able to trap 99.97% of particles equal to and greater than 0.3 microns.

Beyond-Use Dating

Beyond-use-dating identifies the time by which the preparation –once mixed- must be used before it is at risk for chemical degradation, contamination or permeability of the packaging.

The pharmacist shall use "beyond-use dating" as determined by USP 797 Standards and appropriate reference materials.

Sterile Pharmaceutical Compounding Definitions (cont)

Clean room -

Means an International Standards Organization (ISO) Class 7 environment inside which compounding occurs within an ISO Class 5 engineering control device such as a laminar airflow workstation or a biological safety cabinet.

The particle count per cubic meter must be no more than 352,000 particles/m^3 in a size of 0.5 micrometers or larger

ISO Class 5 --- Laminar air flow workstation or Biological Control Cabinet

The particle count per cubic meter must be no more than 3520 particles/m^3 in a size of 0.5 micrometers or larger.

Sterile Pharmaceutical Compounding Definitions (cont)

Media fill verification

Means a process of practical examination to verify the aseptic technique of personnel or an aseptic process by manual manipulation of microbiological growth media which simulates compounding processes and techniques used in actual compounding procedures.

Pyrogen testing

Means an analysis of sterile preparations for the presence of cell material from microbiological organisms in sufficient quantity to elicit a febrile reaction.

Sterile drug product

Means a drug product free from living microorganisms or any other contaminants prepared using aseptic techniques and is not required to be prepared in response to a patient specific prescription. Usually means that the compounding facility must be registered with the FDA as a manufacturer, or be granted a waiver permit by the Board.

Sterile Pharmaceutical Compounding Definitions (cont)

Risk Level

Means a risk level in the compounding process of low, medium or high as defined in USP 797 Standards.

Sterile Compounding Facility

Means a pharmacy, a health care practitioner's office of any other setting in which sterile compounding is performed.

Sterile Drug Product

Means a drug product that:

a. Is prepared using aseptic techniques; and

b. Is not required to be prepared in response to a patient specific prescription

Sterile Drug Product Waiver

Sterile Drug Compounding Waivers may be issued by the Maryland Board of Pharmacy if:

The specified size or strength is listed as current drug shortage

The absence would result in a patient care or patient safety risk

There is an identified clinical need

If the Board determines to issue a waiver based on the Board's review of information submitted with application and fee

New Regulation of Compounding Pharmacies

New England Compounding Center (Massachusetts)

Were registered with the Maryland Board as a compounding pharmacy. Our regulations require an inspection by another state or federal agency.

NECC was inspected by the Mass. Board and given a clean rating.

They were also inspected by the FDA, and although written up for various infractions, were allowed to continue operations and the identified infractions were not reported to any State Board.

Maryland's regulations also state that prescriptions must be compounded for an individual patient. The Maryland Board considers mass compounding to be manufacturing and under the purview of the FDA.

NECC's Maryland pharmacy license has been surrendered following the fungal meningitis outbreak.

General Requirements for Sterile Pharmaceutical Compounding

2013 - HB 986 - A sterile compounding facility shall hold a sterile compounding permit issued by the Board before the facility may perform sterile compounding in Maryland.

A licensed pharmacist who has appropriate practical and didactic training in compounding sterile preparations, clean room technology, laminar flow technology, quality assurance techniques, and clinical application of intravenous drug therapy shall control and supervise the section of the pharmacy that prepares compounded sterile preparations and is responsible for, at a minimum, the following:

A. Preparation of compounded sterile preparations within the pharmacy

B. Storage of materials pertinent to the preparation of compounded sterile preparations, including drugs, chemicals, and biologicals, and the establishment of specifications for procurement of the materials;

C. Labeling of containers of compounded sterile preparations compounded within the pharmacy;

D. Recording of transactions of the pharmacy as may be necessary to maintain accurate control over, and accountability for, pharmaceutical materials; and

E. Ensuring that only licensed pharmacists or registered pharmacy technicians under direct supervision, prepare, compound, and dispense compounded sterile preparations.

Special Handling, Packaging, Labeling Required for Sterile Pharmaceutical Compounding

A. The compounding pharmacy shall make available special handling and packaging materials to maintain container integrity and drug stability of the prepared prescription orders, including anti-neoplastic or other hazardous sterile preparations, during delivery to the patient including:

(1) A reasonable effort to provide tamper-evident packaging;

(2) Delivery from the pharmacy to the patient within a reasonable time; and

(3) Proper in-transit storage consistent with preparation labeling

(cont)

Special Handling, Packaging, Labeling Required for Sterile Pharmaceutical Compounding

B. The dispensed container for any compounded sterile preparation shall include labeling according to Maryland law and regulations, in addition to the following information that is required by federal law:

(1) The date of preparation unless otherwise readily retrievable from prescription records;

(2) Time prepared, if applicable;

(3) The requirements for proper storage;

(4) The name of the base solution for infusion preparations;

(5) The name and concentration or amount of active drugs contained in the final sterile preparation;

(6) The beyond-use/expiration dating and time of the compounded sterile preparation, and if no time is stated, the time is presumed to be at 11:59 p.m. of the stated beyond use date;

(7) A pertinent warning that cytotoxic preparations are biohazardous, when applicable

C. A pharmacy compounding sterile infusion preparations shall provide a 24-hour telephone number to allow its patients or other health care providers who may be administering its prescriptions to contact its pharmacists.

Record Keeping Requirements

A. Patient Prescription Records.

5 Years

B. Compounded Sterile Preparations Records.

5 Years

Minimum Equipment

The permit holder shall provide at least the following equipment that is maintained in working order:

(1) Adequate refrigerator and freezer space;

(2) A sink and wash area in the anteroom;

(3) Appropriate waste containers for:

(a) Used needles and syringes; and

(b) Cytotoxic waste including disposable apparel used in its preparation;

(4) Laminar air flow workstation or compounding aseptic isolator that meets USP 797 Standards, dedicated for products other than antineoplastics;

(5) If applicable to compounded sterile preparations compounded, biological safety cabinet, or compounding aseptic isolator that meets USP 797 Standards, dedicated for use with antineoplastics or other hazardous sterile preparations;

(6) Appropriate filters and filtration equipment; and

(7) A device for light/dark field examination.

Proper Attire

Must wear clean room garb inside the designated area at all times, which consists of:

(a) A low-shedding coverall or gown;
(b) Head and facial hair covers;
(c) A face mask; and
(d) Shoe covers;

Clean room garb shall be donned and removed outside the designated clean room area;

Hand, finger, and wrist jewelry shall be eliminated, unless it cannot be removed, and then it shall be thoroughly cleaned and covered with a sterile glove;

Gloves made of low-shedding materials are required; and

Make-up may not be worn in the clean room.

Quality Assurance

The permit holder shall ensure that the compounded sterile preparation retains its potency and sterility throughout the assigned "beyond use" dating period through a written quality assurance program that includes:

A. A reasonable effort by the pharmacist to assure that compounded sterile preparations shall be kept under appropriate controlled conditions before dispensing, during transport, and at the location of use by providing adequate labeling and verbal or written instructions regarding proper storage and administration, as set forth by the product manufacturer and established standards and literature, with each compounded sterile preparation dispensed;

B. Environmental sampling for microbial organisms in laminar air flow workstations and clean rooms is performed according to methods and schedules specified by USP 797 Standards any time microbial contamination is suspected, for example, positive media fill verification results;

(cont)

Quality Assurance (cont)

C. Laminar air flow workstations, biological safety cabinets, and compounding aseptic isolators and are certified by a trained and qualified operator;

D. Clean room and anteroom which are certified by an independent certification company that meets the standards of the USP 797 Standards;

E. The proper disposal in accordance with accepted professional standards and applicable State and federal laws of unused drugs and materials used in the preparation of compounded sterile preparations, including anti-neoplastic agents and hazardous materials;

F. A process that complies with applicable USP 797 Standards for performing sterility checks or pyrogen testing, or both, for applicable compounded sterile preparations.

COMPREHENSIVE CARE PHARMACY FACILITIES

Comprehensive Care Facility Definitions

Comprehensive Care Facility

Means a facility, other than an inpatient institution, which admits patients suffering from disease, disabilities, or advanced age, and requiring medical service and nursing service rendered by or under the supervision of a registered nurse.

"hospital in denial"

Comprehensive Care Pharmacy

Means a pharmacy that provides pharmaceutical services to a comprehensive care facility. It may be on-site or off-site.

Comprehensive Care Pharmacy (cont)

Medication and device distribution:

The director of pharmacy or designee shall be responsible for:

(1) The preparation of medications compounded in the pharmacy;
(2) The proper preparation, storage, and distribution of compounded sterile preparations;
(3) The packaging and/or repackaging and labeling of medications;
(4) Record keeping related to pharmaceuticals;
(5) Participation in aspects of the facility's quality assurance program which relate to pharmaceutical care and effectiveness (includes patient chart reviews).

A pharmacy servicing a comprehensive care facility may allow the facility to have an emergency drug supply on-site to provide for emergency administration of a drug that is not readily available from the pharmacy.

A licensed pharmacist must perform the final check of the contents of any emergency drug supply prior to delivery to the comprehensive care facility.

Comprehensive Care Pharmacy (cont)

Labeling of Patient Medications:

The director or the director's pharmacist designee shall ensure that all medications dispensed by the pharmacy and intended for use within the facility are dispensed in appropriate containers and are labeled with the:

(1) Name and address of the pharmacy;
(2) Date of dispensing;
(3) Prescription number assigned by the pharmacy;
(4) Name of the resident;
(5) Name, quantity, and strength of the drug;
(6) Name of the prescriber;
(7) Expiration date of the drug when required by law;
(8) Required precautionary information regarding controlled substances; and
(9) Further cautionary information as may be required or desirable for proper use of the medication.

Labeling of Patient Medications (cont)

A. Labeling requirements for medication provided per dosing period in a single container, slot, blister package, or any other method of delivering an entire single dosing unit may be established as policies and procedures of the comprehensive care facility.

B. The director of pharmacy or designee shall be responsible for the safe and efficient dispensing, delivery, control of, and accountability for medications and devices dispensed or distributed by the permit holder.

C. The director of pharmacy or designee shall work in cooperation with the other professional staff of the comprehensive care facility in meeting the responsibilities in ordering, storing, and accounting for pharmaceutical materials.

D. Compounded Sterile Preparations. When compounding sterile preparations, a licensed pharmacist or a registered pharmacy technician under the licensed pharmacist's supervision, shall comply with tall compounding and labeling requirements.

Comprehensive Care Pharmacy (cont)

Drug control and accountability:

The director of pharmacy or designee shall develop a process for the pharmacy to be notified of medications which have been discontinued.

Medications may be accepted for return if:

(1) The returned medication is properly labeled and properly sealed in the manufacturer's package or an individually labeled unit dose of a drug or a device;

(2) The licensed pharmacist determines that the returned medication has been handled in a manner which preserves the strength, quality, purity, and identity of the drug or device during an interim period between the sale of the drug or device and its return to the pharmacy

Drug Control and Accountability (cont)

Discontinued Medications — Controlled Dangerous Substances.

(1) Drugs classified as Schedule II, Schedule III, Schedule IV, and Schedule V may not be returned to the inventory of the pharmacy.

(2) Schedule III, Schedule IV, and Schedule V medications may be returned to inventory of a pharmacy when the pharmacy uses a distribution system that classifies medications as pharmacy inventory until the utilization of the medication by the patient.

A compounded sterile preparation may not be returned to the inventory of a pharmacy.

Drugs requiring refrigeration may not be returned to the inventory of a pharmacy.

Drug Control and Accountability (cont)

Discontinued and returned drugs must be credited:

To the facility, or

To the individual patient (i.e. Medicare Part D)

Procedure for Destruction of Controlled Substances in a Comprehensive Care Facility

Any controlled substance medications to be destroyed must be:

- Inventoried
- Destroyed by administrator or nurse
- Witnessed by administrator or nurse
- Reported to DEA as destroyed

New 2012 rule:

- Allows the pharmacy servicing a comprehensive care facility to maintain a collection receptacle at the facility for:
  - CDS and other discontinued medications
  - Unused medications following a patient's death

Recent Comprehensive Care Issue (cont)

The DEA specified the following "circumstances in which an agent may assist the practitioner in communicating prescription information to a pharmacy":

1. An authorized agent may prepare the prescription for the signature of the DEA-registered practitioner.

2. For a Schedule III-V medication, an authorized agent may transmit a practitioner-signed prescription orally, or by fax, to a pharmacy.

3. An authorized agent may transmit a prescription for a Schedule II medication by fax for a patient in a hospice or long-term care facility.

CII Faxing Policy

The DEA policy statement made it clear that Schedule II prescriptions may NOT be transmitted to the pharmacy by fax except for the exceptions made for:

- Hospice
- Comprehensive care

Just as a reminder, the strip containing the identification of the transmission must be retained as part of the original faxed prescription to qualify that prescription as a valid prescription.

Comprehensive Care

Consulting pharmacists should be familiar with all CMS F-Tags pertaining to pharmacy

CMS federal Nursing home F-Tags:

F-Tags (primarily related to pharmacy)

- F 176 Resident Self Administer Drugs if deemed Safe
- F 329 Drug Regimen is Free From Unnecessary Drugs
- F 332 Free of Medication Error Rates of 5% or More
- F 333 Residents Free of Significant Med Errors
- F 425 Pharmaceutical SVC – Accurate Procedures, RPh
- F 428 Drug Regimen Review, Report Irregular, Act On (Monthly, by pharmacist)
- F 431 Drug Records, Label/Store Drugs & Biologicals

Affordable Care Act of 2010 Affecting Medicare Part D Rxs

Proposed Rule – Effective January 1, 2013

The Affordable Care Act of 2010 requires Medicare Part D plan sponsors to use uniform dispensing techniques such as weekly, daily or automated dose dispensing.

Requires LTC pharmacies to provide Medicare Part D residents' branded medications in 7 or14-day fills.

Affects any resident with Medicare part D

Designed to cut waste associated with 30-day fills and improve efficiency

It is expected that the Medicare rules will eventually change to cover all medications.

HOSPICE REGULATIONS

Hospice Regulations

May have in-house pharmacy or contract with an outside pharmacy to provide pharmaceutical services.

Requirements:

Pharmacist must serve as a consultant to the interdisciplinary team.

Ensure that all medications are prescribed, administered, stored, and disposed of in accordance with all applicable laws and regulations.

Must have a system that provides drugs on an emergency basis – 24/7

Must maintain a drug profile for each patient, conduct periodic drug reviews and patient monitoring

Must keep interdisciplinary team and the patient's family informed about each medication prescribed and any specific administration information

Hospice Regulations (cont)

Storage:

- All medications must be stored in locked compartments.
- All medications must be stored under proper temperature controls.
- All Schedule II medications must be stored separately from other medications and must be secured by 2 separate locks.

Disposal:

- Discontinued medications must be destroyed in the presence of 2 witnesses, OR
- The pharmacy may maintain a drop box disposal system within the hospice.

ASSISTED LIVING FACILITIES

Assisted Living Facilities

Assisted Living program - a residential or facility-based program that provides housing and supportive services, supervision, personalized assistance, health-related services or a combination of those services 24/7 to meet the needs of individuals who are unable to perform, or who need assistance in performing, the activities of daily living in a way that promotes optimum dignity and independence for the individuals.

Group home – a residence owned, leased or operated by a licensed provider that provides residential services for individuals who, because of a developmental disability, require specialized living arrangements

- Limited to 2-8 persons
- Must offer at least 10 hrs of supervision per week

Assisted Living Facilities (cont)

Medication Review Upon Admission

A medication review must be done for each new resident within 14 days of admission to:

- Include all current medications
- Assure that medications are not designed to act as chemical restraints
- Ascertain any potential for adverse drug interactions
- Identify any medication errors that may have occurred since admission

This review may be completed by a:

- Primary care physician
- Certified registered nurse practitioner
- Certified registered nurse midwife
- Registered nurse
- Licensed pharmacist

Assisted Living Facilities (cont)

Pharmacy Review

A licensed pharmacist must conduct an on-site review of physician prescriptions, physician orders and resident records at least every 6 months for any resident receiving 9 or more medications, including OTC and prn medications for:

- Compliance with labeling, packaging and storage requirements
- Timeliness of medication delivery and admission to residents
- Determination that desired effectiveness of medications are achieved (notify appropriate prescriber with questions)
- Undesired side effects, potential or adverse reactions and medications errors (report to appropriate prescriber)
- Interactions with OTCs and herbal mediations
- Correct administration times and adherence

Assisted Living Facilities (cont)

Permit holder must appoint a pharmacist who:

Is responsible for the operations of the pharmacy and for compliance with statutes and regulations regarding pharmaceuticals.

Is responsible for the safe and efficient dispensing, delivery, control of, and accountability for medications and devices dispensed or distributed by the contracted pharmacy.

Will work in cooperation with other facility professional staff in meeting the responsibilities for ordering, storing and accounting for pharmaceuticals.

Will develop a process for the pharmacy to be notified of medications which have been discontinued.

AUTOMATED MEDICATION SYSTEMS

Automated Medication System

Automated medication system means a robotic or computerized device and that device's components designed to:

(a) Distribute medications in a licensed health care facility; or

(b) Prepare medications for final dispensing by a licensed pharmacist to a patient or a patient's agent.

A pharmacy may install an automated medication system in a comprehensive care facility if the pharmacy:

- Applies for & registers each automated unit with the DEA if the system contains any CDS
- Follows all other federal & state statutes and regulations

Theoretically, more than one pharmacy could have automated medication system in the same facility.

Automated Medication Systems (cont)

Centralized automated medication system:

Means an automated medication system located in a pharmacy from which medication is distributed or prepared for final dispensing by a licensed pharmacist for a specific patient.

Decentralized automated medication system

Means an automated medication system that is located outside of the pharmacy in a health care facility with an on-site pharmacy and in which medication is stored in a manner that may be, but need not be, patient specific.

Remote automated medication system

Means an automated medication system that is located in a health care facility that does not have an on-site pharmacy and in which medication is stored in a manner that may be, but need not be, patient specific.

Automated Medication Systems (cont)

Starter dose

Means a dose of medication removed from a remote or decentralized automated medication system within the first 24 hours after it is ordered, and before the pharmacy can supply the patient's regular medication supply.

Automated Medication Systems (cont)

Usage Requirements:

An automated medication system shall only be used if:

(1) Records concerning transactions or operations are maintained;

(2) A licensed pharmacist controls access to the system and defines a method for delegating access to the system to qualified pharmacy personnel under the licensed pharmacist's supervision or to individuals permitted by law to administer medication;

(3) A licensed pharmacist:

(a) Reviews:

(i) Each order for medication before the medication is removed from the remote or decentralized automated medication system, except if the order is for a starter dose; or

(ii) The order for a starter dose within 24 hours of removal of the starter dose from the remote or decentralized automated medication system, if the patient is still under the care of the facility when the review is to be performed; or

(b) Makes a final check of the prescription before dispensing the medication to the patient;

(cont)

Usage Requirements (cont)

(4) The permit holder ensures that:

(a) Patients have prompt access to all pharmacy services necessary for the provision of good pharmaceutical care;

(b) The system maintains the integrity of the information in the system and protects patient confidentiality; and

(c) A comprehensive program of quality assurance for the system is in place; and

(5) The permit holder and licensed pharmacist responsible for the automated medication system shall:

(a) Maintain policies and procedures related to:

(i) The operation of the system;

(ii) Training of personnel using the system; and

(iii) Operations during system downtime; and

(b) Establish a process to:

(i) Ensure the security of the system; and

(ii) Account for medication added to and removed from the system.

Usage Requirements (cont)

All remote or decentralized automated medication systems shall operate in a manner which:

(1) Limits simultaneous access to multiple:

(a) Drug strengths;

(b) Dosage forms; or

(c) Drug entities; and

(2) Minimizes the potential for misidentification of medications, dosages, and dosage forms by those accessing the automated medication system.

Automated Medication Systems (cont)

Procedures for filling (refilling)automated medication systems:

A. Except as provided in B of this regulation, only a licensed pharmacist may fill an automated medication system.

B. Systems that possess sufficient safeguards to ensure accuracy of the replenishment may be filled by:

(1) Personnel supervised by a licensed pharmacist; or

(2) Health care professionals licensed under the Health Occupations Article and permitted access to an automated medication system due to the health care professionals' privileges to administer medication.

Automated Medication Systems (cont)

Record keeping:

A. The permit holder and the licensed pharmacist responsible for the automated medication system shall maintain records regarding the system in a readily retrievable manner for at least 2 years.

B. The records shall include:

(1) Maintenance records and service logs;

(2) System failure reports;

(3) Accuracy audits and system performance audits;

(4) Copies of reports generated as part of the quality assurance program;

(5) Reports or databases related to level of access and changes in the level of access to the system; and

(6) Training records

C. The permit holder and the licensed pharmacist responsible for the automated medication system shall maintain transaction records for all prescription drugs or devices dispensed or distributed for the preceding 5 years

DRUG THERAPY MANAGEMENT

Drug Therapy Management Definitions

Emergency first care

Means triage of emergent conditions

Or treatment of the condition in those cases in which a protocol specifies treatment for the emergent condition.

Drug therapy management agreement

Means a contract between a pharmacist, or group of pharmacists, and a physician, or group of physicians, that allow the pharmacist(s) to work collaboratively with that physician(s) in the drug therapy management of a patient or group of patients in a specific location.

Drug Therapy Management Definitions (cont)

Drug therapy management protocol

Means a written and disease-state specific condition; that contains the following:

(a) The condition that the protocol is designed to manage;

(b) A list of medications that may be used under the auspices of the protocol;

(c) Monitoring parameters including laboratory tests for the:

(i) Condition; and

(ii) Medication used;

(d) A list of circumstances requiring contact with the physician;

(e) A statement prohibiting substitution of a chemically dissimilar drug product by the pharmacist for the product prescribed by the physician unless permitted in the therapy management contract;

(cont)

Drug Therapy Management Definitions (cont)

(f) A list of circumstances under which the pharmacist may alter doses, modify the treatment regimen, or switch the agent under the terms of the therapy management contract;

(g) Information to be documented;

(h) A listing of provisions within the protocol that may be customized within a therapy management contract;

(i) An action plan for situations when the pharmacist encounters a situation that is not addressed in the protocol;

Approval Process for a Drug Therapy Management Protocol

Approval of Pharmacist (only requirement that now must be verified by the Board – 2013 HB 716/SB 617)

(1) The pharmacist shall submit signed documentation that:

(a) The pharmacist has completed advanced training required

(b) The pharmacist possesses a Doctor of Pharmacy degree or has met the additional training requirements

(c) Must be certified as a specialist by:

The Board of Pharmacy Specialties

The American Society of Consultant Pharmacist's Certified Geriatric Practiontier certification program

Another credentialing body approved by the Board of Pharmacy

or

Completion of:

Residency accredited by a Board approved body or approved by ACPE

A certificate program approved by the Board

A NABP credentialing examination

A Board approved examination

(2) Must be in "good standing" with the Board

(3) May not have a public final order for discipline within the 5 years immediately preceding the application

Guidelines for Use of Protocols

A. On receipt of specific instructions from the physician regarding a specific patient, the pharmacist may execute the physician's specific instructions.

B. The protocol may not prohibit the pharmacist from providing other pharmaceutical services that are within the pharmacist's scope of practice.

C. Documentation of activities performed under a protocol or the physician's specific instructions shall be maintained in such a manner that it is accessible to the:

(1) Physician; and

(2) Pharmacist.

D. Oral communications between the physician and pharmacist shall be summarized in the documentation maintained by the pharmacist and forwarded to the physician.

E. Unless an alternative time period is stated in the physician-pharmacist agreement, the pharmacist shall inform the physician within 48 hours if the pharmacist:

(1) Modifies the dose or agent under the therapy management contract; or

(2) Detects an abnormal result from an assessment activity.

PHARMACIST VACCINATIONS

Pharmacist Vaccinations (cont)

Estimated that approximately 145,000 pharmacists nationwide have qualified as immunizers

Different states have different regulations affecting pharmacist vaccinations

- Delaware = all injectable immunizations
- Maryland = all CDC recommended vaccinations >age11 (9 for influenza with protocol)
- Virginia = all vaccinations

Primary Training Programs (as of 2012)

- APhA
- Company-based

CDC Requirements for Vaccinations

Every person administering vaccinations must be trained in basic cardiopulmonary resuscitation (CPR).

Every patient should be observed for 15 – 20 minutes for signs of syncope or adverse reactions to the vaccination.

Every patient must be given:

- A consent form (allergy information*)
- A VIS (vaccine information statement)
- Credentials of person administering the injection

Pharmacist Vaccinations (cont)

Registration.

(1) A licensed pharmacist shall submit a registration to the Board on the form that the Board requires and that verifies:

(a) Successful completion of a certification course approved by the Board of Pharmacy that includes the current guidelines and recommendations of the CDC.

(b) Possession of an active certification in basic cardiopulmonary resuscitation obtained through in-person classroom instruction.

(2) A registration authorizing a licensed pharmacist to administer vaccinations expires with the expiration of the license to practice pharmacy unless the licensed pharmacist has also completed:

4 hours of continuing education credits related to vaccinations

RPH VACCINATIONS

2013 - Maryland Senate Bill 401 - Pharmacists – Administration of Vaccinations –Expanded Authority and Reporting Requirements ------ Maryland RPhs may administer any vaccination listed in the Centers for Disease Control and Prevention's recommended immunization schedule to:

1. Any individual (minor) who:
   - Is at least 11 years old, but under 18
   - Has a prescription from an authorized prescriber
2. Any adult for:
   - Vaccines listed in the Center for Disease Control and Prevention recommended immunization schedule, or
   - Vaccines recommended for international travel
3. The RPh must:
   - Have a written protocol that is vaccine specific
   - Report all vaccinations to ImmuNet
   - Document at least one effort to inform the individual's primary care provider

RPH VACCINATIONS

Partial listing of approved immunizations – Children (11+)

- Tetanus, Diphtheria, Pertussis (Tdap)
- Human Papillomavirus (HPV)
- Meningococcal (MCV)
- Influenza
- Pneumococcal
- Hepatitis A
- Hepatitis B
- Polio
- Measles, Mumps, Rubella (MMR)
- Varicella
- Travel vaccines (required and country specific)

RPH VACCINATIONS

Partial listing of approved immunizations – Adult

- Influenza
- Tetanus, Diphtheria, Pertussis (Td, Tdap)
- Varicella
- Human Papillomavirus (HPV)
- Zoster
- Measles, Mumps, Rubella (MMR)
- Pneumococcal
- Meningococcal
- Hepatitis A
- Hepatitis B
- Travel vaccines (as required and country specific)

VACCINATIONS

Maryland now has over 3000 pharmacists certified to give vaccinations.

HealthMap Vaccine Finder

- Lists 47,000+ locations for patients to be able to obtain certain vaccinations (mainly adult).

PHARMACISTS' POINT-OF-CARE TESTING

CLIA Waived Tests

All facilities in the United States that perform laboratory testing on human specimens for health assessment or the diagnosis, prevention, or treatment of disease are regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

Although CLIA requires that waived tests must be simple and have a low risk for erroneous results, this does not mean that waived tests are completely error-proof.

Errors can occur anywhere in the testing process, particularly when the manufacturer's instructions are not followed and when testing personnel are not familiar with all aspects of the test system.

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm

CLIA Certificate of Waiver

Pharmacists must enroll by obtaining a CLIA Certificate of Waiver

Must have a CLIA certificate for each site at which testing will be performed

Must follow manufacturers' instructions for the CLIA-waived tests performed

Must permit inspections by CMS agents

Obtain certificate:

Maryland Dept. of Health and Mental Hygiene
Office of Health Care Quality – Bland Bryant Building
Spring Grove Hospital Center
55 Wade Ave – Catonsville, Md. 21228
410-402-8025 or (fax) 410-402-8213

Maryland Regulations

COMAR 10.10.03.02

- Must register as a laboratory and obtain a "letter of exception" (allows approx. 35 different tests) - $100 biennially

Requires:

- CLIA Certificate of Waiver - $150 biennially
- Completion of application for Maryland laboratory license and complying with "good laboratory practices" (i.e. lot #s, training of personnel, record keeping, specimen handling procedures, QA program, etc)
- Complying with all applicable OSHA standards and training requirements (i.e. annual live training, observe universal precautions, exposure control plan, gloves, etc)

COMAR 10.10.06.02 (requesting tests)

A pharmacist may request tests that qualify for a letter of exception under COMAR 10.10.03.02 and for glucose, A1c, lipids (including total cholesterol, HDL, LDL, and triglycerides), AST, and ALT.

Testing Sites (other than a pharmacy)

Must notify OHCQ by phone or in writing of the date, time, location and supervisor's name at least 14 days prior to holding event (i.e. health screening) - $100 general permit fee.

Once site is approved by OHCQ, must display approval form throughout the testing event.

May not be in a restaurant (must be located at least 12 feet from any produce, meat or diary).

Site must:

- Have access to water and disinfectant supplies
- Have telephone access for emergency assistance
- Maintain temperature, humidity and ventilation to comply with manufacturers' instructions
- Maintain partitions (tape/ropes) around 3 sides of any area where blood is drawn or processed

Records

Evaluation and verification

- 2 levels of quality control tests prior to starting
- Complete the comparison worksheet required by OHCG quarterly

Testing logs

- Names of persons tested and results
- Name, address and phone number of pharmacy
- Date of testing
- Signature of employee(s) involved
- Maintain for 2 years

Reporting of results

- Written testing results submitted to OHCQ
- Referral of patient(s) for medical care when indicated
- Written patient informal of test limitations

WHOLESALE DISTRIBUTION

Wholesale Distribution Definitions

Authorized distributor of record

Means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug.

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.

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

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.

Wholesale Distribution Definitions (cont)

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

(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.

Wholesale Distribution Definitions (cont)

Pedigree

Means a document or electronic file containing information that records each wholesale distribution of a prescription drug.

Maryland requires a pedigree accompany the drug for any drug that has ever left the normal distribution channel.

Why??

Gray Market
Less reputable suppliers

The Gray Market is a parallel market that deals with goods sold outside of their "authorized channels".

Obtain goods in short supply and resell them for whatever price the market will pay
Have, on occasion, been able to obtain and hoard a product that will soon be a "short supply" item.

Gray Market

"Gray market" selling, in which small wholesalers identify drugs either in a shortage situation or likely to experience one, purchase as much of the drug's stock as possible to further exacerbate the shortage, and then take advantage of the increased demand by increasing the price of the drugs.

Hospitals and pharmacies have been increasingly reporting receiving unsolicited offers from wholesalers.

Most troubling of all, their investigation found some wholesalers (pharmacies) purposefully obtaining additional licensing just to be able to obtain greater supplies of drugs experiencing shortages with intent to sell the medicines to hospitals or physicians (at hugely increased prices), thereby worsening the shortage and further increasing prices.

Still other companies appeared to set up shell partners or subsidiaries to funnel short-supply drugs to other gray-market distributors for greater financial gain.

Gray Market (cont)

Use of Gray Market is NOT recommended, but if it is used:

1. Understand the risks of possible counterfeit, stolen, diverted, mislabeled or adulterated merchandise
2. Confirm wholesaler or distributor license
3. Confirm receipt of drug pedigree(s)
4. Compare and scrutinize purchases – Don't use if:
   - Product label appears altered (font, color, size, markings)
   - Content or appearance appear inconsistent with previous purchases
5. Report any suspect suppliers to appropriate authorities and organizations

Wholesale Distribution Case (cont)

This case coined a relatively new term:

Corporate Social Responsibility

It is defined as an obligation of an organization to pursue long-term goals that are good for society.

Deals with the obligation to conduct business in an ethical manner (self-policing).

DEA has greatly increased its actions against various wholesalers over the last year.

Wholesale Distribution Definitions (cont)

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; and

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

Virtual manufacturer –

Means an entity that engages in the manufacture of drug or device products for which it:

- Owns the NDA or ANDA number;
- Contracts with a contract manufacturing organization for the physical manufacture of the drug or device;
- Is not involved in the physical manufacture of the drug or device product;
- Directs the sale and or distribution of drug or device; and
- Does not take physical possession of drug or device

Wholesale Distribution Definitions (cont)

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) Transfers of prescription drugs or devices by a retail pharmacy to another retail pharmacy;

(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;

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

(vi) 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;

(viii) 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.

Wholesale Distribution Definitions (cont)

Wholesale Distributor.

(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.

Wholesale Distributors' Requirements for Application

Must have a designated representative responsible for the operations of the entire operation

Must have a supervisor for the designated representative

Must have an adequate storage area and separate areas for quarantine of damaged, adulterated, out-of-date or returned merchandise

Must have security system

Must maintain records of transactions for 3 years

Must post surety bond made payable to Maryland Board of Pharmacy

- $100,000 if sales over $10,000,000
- $50,000 if sales less than $10,000,000

A wholesale distributor's permit is good for a 2 year period and expires on May 31st of odd numbered years. It may be renewed for an additional 2 years.

Returned, Damaged, and Outdated Prescription Drugs or Devices

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 items are destroyed or returned to their supplier for proper disposal.

(2) Prescription Drugs and devices:

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.

Required Records

(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 must include drug pedigrees.

(3) The wholesale distributor shall make available inventories and records for inspection and copying for a period of 3 years after their date of creation.

(4) 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.

(5) 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.

Wholesale Distributor Closure (cont)

Upon closure, a wholesale distributor shall:

- Notify manufacturers, wholesale distributors and licensed pharmacies that supply or receive drugs and devices at least 30 days in advance of closure

- Comply with all federal regulations

- Request a closing inspection within 72 hours

- Return or dispose of medications in accordance with State and federal regulations

- Provide the Board all required records, licenses, permits, etc.

STATE LAWS - DELAWARE

2004 Delaware Seal

Members of Delaware Pharmacy Board

The Delaware Board consists of nine members who are appointed by the Governor and who are residents of the State.

Six members are pharmacists who have been engaged in the practice of pharmacy in Delaware for at least 5 years and who are representative of the various practice settings in the field of pharmacy.

Three members are public members, 1 from each county.

Each member serves a 3 year term and may reappointed for one additional term.

All Delaware professional boards are under the Division of Professional Regulation.

The Director of the Delaware Board must be a pharmacist.

Main Differences Between Delaware and Maryland Pharmacy Laws/Regulations

Pharmacy building standards:

Must have an area which assures patient privacy provided to facilitate counseling.

Security:

When the pharmacist is not physically present and the operation is open for business, the pharmacy department shall be physically or electronically secured from floor to ceiling.

A conspicuous sign with letters not less than three inches in height, reading "PRESCRIPTION LABORATORY TEMPORARILY CLOSED, NO PROFESSIONAL SERVICES RENDERED," or words of similar import, must be posted in the front section of the operation or in front of the prescription area, room or partitioned off section where it can be seen by the public.

Main Differences Between Delaware and Maryland (cont)

The pharmacy will be managed by a pharmacist-in-charge (PIC) who is licensed to practice pharmacy in the State and who will serve as a pharmacist-in-charge in only that pharmacy.

All applicants for the pharmacist-in-charge designation must be interviewed by the Board prior to appointment (accompanied by permit holder).

The pharmacist-in-charge, whose name is on the application, will comply with pharmacy, controlled substance, and other applicable statutes and regulations

Pharmacists-in-charge (PIC) must complete an annual PIC Self-Inspection Report by February 1, of each year. New PICs must complete a PIC Self-Inspection Report within 30 days of becoming a new PIC.

Main Differences Between Delaware and Maryland (cont)

The Board interprets the responsibilities of the Pharmacist-in-Charge to include, but not be limited to the following:

- Maintain necessary pharmaceutical equipment and reference texts in accordance with the State Board of Pharmacy requirements.
- Maintain records required by the Uniform Controlled Substances Act and other relevant State and Federal regulations.
- Maintain proper security of particular pharmacy operation during and after normal business hours.
- Establish procedures within operation that maintain standard of practice as it relates to the dispensing of pharmaceuticals and refusal to dispense pharmaceuticals. These procedures shall include proper supervision of supportive personnel and delegation of authority to another pharmacist when not on duty.
  - The pharmacist on duty is directly responsible for his own actions and for the supportive personnel under his supervision.
- Must notify the Board of Pharmacy in writing within 10 days of termination as pharmacist-in-charge.

Main Differences Between Delaware and Maryland (cont)

Technician Support:

At all times that the pharmacy department is open for business, there shall be at least one technician immediately available in the facility to assist in the pharmacy at the pharmacist's request.

Main Differences Between Delaware and Maryland (cont)

Schedule II medications must be kept in a safe

The safe must be locked at all times and may only be opened by a pharmacist or other authorized personnel.

Schedule III-V medications may be stored in a securely locked, substantially constructed cabinet OR dispersed with regular medications.

Main Differences Between Delaware and Maryland (cont)

Patient Counseling:

A pharmacist, or a pharmacy intern or student working under the direct supervision of a pharmacist shall, with each new medication dispensed, provide verbal counseling to the patient or the patient's agent on pertinent medication information. The counseling may include, but not be limited to the following:

1 .The name and description of the prescribed drug;

2. The dosage and the dosage form;

3. The method and route of administration;

4. The duration of the prescribed drug therapy;

5. Any special directions and precautions for preparation, administration, and use by the patient that the pharmacist determines are necessary;

6 . Common severe side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, how to avoid them, and what actions should be taken if they occur;

7. Patient techniques for self-monitoring of the drug therapy;

8. Proper storage and appropriate disposal methods for unwanted or unused medications;

9. Prescription refill information;

10. The action to be taken in the event of a missed dose

Main Differences Between Delaware and Maryland (cont)

A pharmacist MUST dispense the brand name medication if the prescriber writes:

Brand Medically Necessary (BMN)

Dispense As Written (DAW)

Do Not Substitute (DNS)

OR:

Signs the prescription blank on a signature line labeled “May not Substitute” or “Dispense as Written”

Main Differences Between Delaware and Maryland (cont)

A prescription for a Schedule II or III medication becomes void unless dispensed within 7 days from date of issue.

Schedule II and III medications may not be written nor dispensed for more than 100 dosage units or a 31 day supply whichever is greater.

Schedule II medications for a terminally ill or LTCF patient shall be valid for 60 days from the issue date.

Main Differences Between Delaware and Maryland (cont)

Requirement for photo ID:

Every bearer and receiver presenting a CDS must show ID verification by:

1. Presentation of a photo ID on pick-up of prescription
   - Valid driver's license (photo)
   - Passport
   - Delaware photo ID card

The pharmacy must obtain & retain the photographic ID of any person picking up a prescription.

The unique number associated with the photo ID must be made part of the prescription record.

The person picking up a prescription for a CDS must be >18 years of age.

Main Differences Between Delaware and Maryland (cont)

Delaware's mandatory identification law is the only one in the U.S. that applies universally, stating that:

> "*The pharmacist and/or an employee under his/her direct supervision must verify the identification of the receiver of the controlled substance prescription by reference to valid photographic identification,"*

without specifying circumstances under which pharmacists should request identification.

Drive-thru Schedule II CDS Scripts

This Law, which took effect on December 11, 2011, bars Delaware pharmacies from dispensing Schedule II controlled drugs from their drive-thru windows unless the pharmacy has been authorized by the Delaware Office of Controlled Substances.

Authorization to permit the receipt of filled Schedule II controlled substance prescriptions at a drive through window may be granted only if the pharmacy can demonstrate all of the following:

1. A security camera system that captures clear images of the driver's face and the license plate of the vehicle receiving any filled prescription; and
2. A written policy indicating that when picking up a Schedule II controlled substance at a drive through window, the driver must be recorded as the person picking up the prescription; and

3 A written policy requiring staff to review the identification of the driver, capture an image of the identification of the driver, and store that image in the pharmacy's records for at least three years for every filled Schedule II prescription picked up at the drive through window.

Main Differences Between Delaware and Maryland (cont)

The Delaware State Board of Pharmacy now requires pharmacies to post signage advising patrons that they may request the lot number and expiration date of their dispensed medication at the time a prescription is dropped off at the pharmacy.

The regulation requires a conspicuous sign, reading “patients may request the lot numbers and expiration dating for their dispensed medication at the time of prescription drop-off” which must be posted in the front section of the operation, or in front of the prescription area, room, or partitioned-off section where it can be seen by the public.

OUTSTANDING PHARMACY ISSUES

Some Outstanding Issues

3rd Class of drugs

Dextromethorphan

Medical marijuana

Death with dignity

Hydrocodone Scheduling

Pharmacy Provider Status

Continuing Professional Development

3rd CLASS OF DRUGS

Third Class of Drugs

FDA is weighing over-the-counter switching for key drugs as announced March 8, 2012

Some of the most widely used prescription drugs, including those to treat cholesterol and high blood pressure, could be available over the counter under a new proposal being weighed by government regulators.

The shift comes as drug companies and their allies in Congress have pressured the agency to speed up approvals, complaining that U.S. requirements are more burdensome than those in Europe and elsewhere.

Also in 2012, the American College of Obstetricians and Gynecologists published an opinion that oral contraceptives should be sold as OTCs. They cited their long history of safety and said that having increased availability would reduce unintended pregnancies.

Third Class of Drugs (cont)

In some cases, patients would still need to see a doctor to obtain an initial prescription before getting over-the-counter refills.

In other cases, patients would need to speak with a pharmacist but would not need a prescription to receive medication.

Drug manufacturers would have to request a switch for each drug individually, and the FDA would judge the safety of each proposal on a case-by-case basis.

FDA officials stress that the idea is still in the early stages and public meetings will be scheduled to gather comments.

DEXTROMETHORPHAN

Some Outstanding Issues Dextromethorphan (cont)

Approx. 10% of teenagers report having used dextromethorphan to get high.

California:

- Prohibits sale to anyone <18
- Requires pharmacies to check ID at point of sale

Virginia:

- 2014 Statute – Retailers may NOT sell any product containing dextromethorphan to any minor – effective January 2015.

Some Outstanding Issues Dextromethorphan (cont)

U.S. Legislature

2009 - A bill was introduced in U.S. House to control sale and distribution of unfinished dextromethorphan.

That bill passed the House, but died in the Senate

2010 – A bill was introduced in U.S. Senate to restrict sale of dextromethorphan to adult >18

That bill died in the Senate

2012 -- A bill was introduced in U.S. Senate to restrict sale of dextromethorphan to adult >18

That bill died in the House

2014 – A bill introduced in U.S. House

Some Outstanding Issues Dextromethorphan

Maryland Legislature

2008 – Maryland Legislature debated a bill that would have

placed dextromethorphan behind the pharmacy counter and required that:

Sale must be by a pharmacist

Patient must show photo ID

That bill died in Committee

Has not been re-introduced in Maryland

MEDICAL MARIJUANA

Some Outstanding Issues Medical Marijuana

2005 Supreme Court handed down its latest decision regarding marijuana.

They stated that "the CSA is a valid exercise of federal power". That ruling effectively still invalidates all state marijuana laws.

Some Outstanding Issues Medical Marijuana (cont)

In October 2009, the Department of Justice issued a memorandum that:

Emphasized that the prosecution of trafficking in illegal drugs, including marijuana, continues to be a "core priority" of the Department's efforts.

Stated that the priority should not focus federal resources on those individuals in "clear and unambiguous compliance" with state laws providing for the medical use of marijuana.

Some Outstanding Issues Medical Marijuana (cont)

Maryland has passed one bill (2005) that states "the use of marijuana for approved medical purposes will be taken into account in sentencing" (no jail time, but does permit fines to be levied).

2013 - HB 180/SB 580 - Caregiver – Affirmative Defense – Passed

Allows an affirmative defense for the possession of marijuana or specified drug paraphernalia intended for medial use of an individual with a specified debilitating medical condition for whom the defendant is a qualified caregiver.

Some Outstanding Issues Medical Marijuana (cont)

2013 - HB 1101 - Medical Marijuana – Academic Medical Centers - Passed

Establishes a Medical Marijuana Commission to oversee the "program".

Program – means an investigational use-type program overseen by an academic medical center through which marijuana is made available to specified, enrolled patients for medical use. The program is slated to be operational July 1, 2014.

Academic medical center means a hospital that:

- Operates a medical residency program for physicians; and
- Conducts research that is overseen by the Federal Department of Health and Human Services and involves human subjects
- Must report participating patients and caregivers daily
- Must obtain marijuana only from:
  - The Federal Government
  - Licensed Maryland medical marijuana growers

Some Outstanding Issues Medical Marijuana (cont)

On January 1, 2014, Illinois became the twenty-first jurisdiction since 1996 to enact legislation to decriminalize the use of marijuana for medical purposes. The other jurisdictions are:

Alaska, Arizona, California, Colorado, Connecticut, District of Columbia, Delaware, Hawaii, Maine, Massachusetts, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, Oregon, Rhode Island, Vermont and Washington.

Some Outstanding Issues Medical Marijuana (cont)

Overview of State Medical Marijuana Laws

Of the 21 jurisdictions, only six – Arizona, Connecticut, Delaware, Illinois, Maine, and Rhode Island – explicitly prohibit employers from discriminating against qualifying medical marijuana patients or their primary caregivers.

Arizona, Delaware, Illinois and Maine provide an exception to their prohibition against discrimination only if employing or taking other adverse employment action (i.e., disciplining) against qualifying medical marijuana patients or their primary caregivers would cause the employer to lose a federal contract or federal funding.

Many states' medical marijuana laws, including those in Arizona, Colorado, Connecticut, Delaware, Hawaii, Maine, Michigan, Montana, New Jersey, New Mexico, Rhode Island and Vermont, provide that employers are not restricted from prohibiting the use of marijuana in the workplace or from prohibiting employees from working while under the influence of marijuana.

Some Outstanding Issues Medical Marijuana (cont)

A June 2011 memo from the U.S. Department of Justice in Washington says state laws allowing medical marijuana opened the door to abuses and calls for legally targeting "large-scale, privately operated industrial marijuana cultivation centers" as well as distribution operations known as dispensaries.

The memo -- which arrived June 29, 2011 in the email inboxes of U.S. attorneys nationwide, -- says that no patient or other user is shielded from federal prosecution by state laws.

Some Outstanding Issues Medical Marijuana (cont)

Colorado has legalized marijuana:

Banks currently not allowed to do business with marijuana growers/sellers (violates federal banking laws).

Traffic deaths where driver tested positive for marijuana has doubled from 27% to 56%.

Marijuana related businesses have sky-rocketed (now rated as the number 3 industry in Colorado).

Some Outstanding Issues Medical Marijuana (cont)

A British company, GW Pharma, is in advanced clinical trials for the world's first pharmaceutical developed from raw marijuana instead of synthetic equivalents -- a mouth spray it hopes to market in the US as a treatment for cancer pain.

It hopes to see FDA approval by the end of 2013."

"Sativex contains marijuana's two best known components – delta 9-THC and cannabidiol

The product already has been approved in Canada, New Zealand and eight European countries for a different usage, relieving muscle spasms associated with multiple sclerosis."

DEATH WITH DIGNITY

Death With Dignity

At this time, affects primarily compounding pharmacies:

- May pharmacies compound and then supply medications intended to end life?:
  - Incurable diseases
  - Compassionate death issues
  - Prison inmates on death row

HYDROCODONE SCHEDULING

Hydrocodone Scheduling

The FDA is planning to revisit a benefit:risk assessment for hydrocodone subject to escalating amounts of addiction and abuse after the agency was pressed by the DEA.

FDA said it had been petitioned by the DEA to look at how the government classifies hydrocodone, which is subject to restrictions under the Controlled Substances Act (CSA).

The product class is often subject to "misuse, abuse and addiction" as a result of its properties. As a result of the substance control issues, the DEA requested the FDA conduct a new scientific and medical evaluation to support a scheduling recommendation for the product class.

One month after an FDA advisory panel voted 19-to-10 to place Vicodin and other prescription painkillers that contain hydrocodone under greater restrictions, a bipartisan group of members of Congress have written the FDA to demand the agency take "swift action" to follow their recommendation.

> And in their letter, they note it has been 14 years since the FDA was first asked to reclassify prescription painkillers containing hydrocodone.

Hydrocodone Scheduling

2013- 2014 U.S. Congress

H.R.1285: To amend the Controlled Substances Act to make any substance containing hydrocodone a schedule II drug.

S. 621: To amend the Controlled Substances Act to make any substance containing hydrocodone a schedule II drug.

Hydrocodone Scheduling

February 27, 2014 -- the DEA published in the Federal Register a Notice of Proposed Rulemaking to move hydrocodone combination products from Schedule III to Schedule II, as recommended by the Assistant Secretary for Health of the U.S. Department of HHS, and as supported by the DEA's own evaluation of relevant data.

This proposed rule would impose the same regulatory controls and sanctions applicable to Schedule II substances on those who handle or propose to handle HCPs

PHARMACY PROVIDER STATUS

Pharmacy Provider Status

Pharmacy Provider Status would allow pharmacists to expand their medical roles to:

- Administer some classes of drugs
- Administer some biologics
- Prescribe smoking cessation drugs
- Order and interpret tests to monitor and manage efficacy and toxicity of drug therapies
- Perform patient assessments
- Refer patients to other providers

Provider status would allow pharmacists to bill for services (not just products) and be reimbursed

California – Pharmacist obtain provider status (Jan. 2014) – Establishes a new category – Advanced Practice Pharmacists (APPs). So far, this does not affect pharmacists getting paid for services, but does allow for contract negotiations.

Maryland is part of a coalition (with other states and pharmacy companies) to push for pharmacy provider status on the national level.

PHARMACY CERTIFICATION

Pharmacy Certification

Organizations approved to accredit pharmacies:

- Board of Pharmacy Specialties (BPS)
- Specialty Pharmacy Certification Board (SPCB)

Certifications - current:

- Ambulatory Care
- Nuclear
- Nutrition Support
- Oncology
- Pharmacotherapy

Certifications – additional proposed:

- Pain and Palliative Care
- Pediatric
- Critical Care
- Infectious Disease
- Cardiology

Continuing Professional Development

ACPE is promoting the adoption of continuing professional development (CPE) as a required enhancement to current pharmacist continuing educational programs.

CPE is currently utilized in several countries (such as):

- Great Britain
- Canada
- New Zealand

And is being piloted in several states:

- Indiana
- Iowa
- North Carolina
- Washington
- Wisconsin

One concern still outstanding is the liability issue and whether expanded, credentialed learning would be protected from discovery in the case of a legal proceeding.

PHARMACIST CODE OF ETHICS

Pharmacist Code of Ethics

I. A pharmacist respects the covenantal relationship between the patient and pharmacist.

Considering the patient-pharmacist relationship as a covenant means that a pharmacist has moral obligations in response to the gift of trust received from society. In return for this gift, a pharmacist promises to help individuals achieve optimum benefit from their medications, to be committed to their welfare, and to maintain their trust.

II. A pharmacist promotes the good of every patient in a caring, compassionate, and confidential manner.

A pharmacist places concern for the well-being of the patient at the center of professional practice. A pharmacist is dedicated to protecting the dignity of the patient. With a caring attitude and a compassionate spirit, a pharmacist focuses on serving the patient in a private and confidential manner.

III. A pharmacist respects the autonomy and dignity of each patient.

A pharmacist promotes the right of self-determination and recognizes individual self-worth by encouraging patients to participate in decisions about their health. A pharmacist communicates with patients in terms that are understandable. In all cases, a pharmacist respects personal and cultural differences among patients.

IV. A pharmacist acts with honesty and integrity in professional relationships.

A pharmacist has a duty to tell the truth and to act with conviction of conscience. A pharmacist avoids discriminatory practices, behavior or work conditions that impair professional judgment, and actions that compromise dedication to the best interests of patients.

Pharmacist Code of Ethics (cont)

V. A pharmacist maintains professional competence.

A pharmacist has a duty to maintain knowledge and abilities as new medications, devices, and technologies become available and as health information advances.

VI. A pharmacist respects the values and abilities of colleagues and other health professionals.

When appropriate, a pharmacist asks for the consultation of colleagues or other health professionals or refers the patient. A pharmacist acknowledges that colleagues and other health professionals may differ in the beliefs and values they apply to the care of the patient.

VII. A pharmacist serves individual, community, and societal needs.

The primary obligation of a pharmacist is to individual patients. However, the obligations of a pharmacist may at times extend beyond the individual to the community and society. In these situations, the pharmacist recognizes the responsibilities that accompany these obligations and acts accordingly.

VIII. A pharmacist seeks justice in the distribution of health resources.

When health resources are allocated, a pharmacist is fair and equitable, balancing the needs of patients and society.

PHARMACIST OATH

Pharmacist Oath

Oath of a Pharmacist

At this time, I vow to devote my professional life to the service of all humankind through the profession of pharmacy.

I will consider the welfare of humanity and relief of human suffering my primary concerns.

I will apply my knowledge, experience, and skills to the best of my ability to assure optimal drug therapy outcomes for the patients I serve.

I will keep abreast of developments and maintain professional competency in my profession of pharmacy. I will maintain the highest principles of moral, ethical and legal conduct.

I will embrace and advocate change in the profession of pharmacy that improves patient care.

I take these vows voluntarily with the full realization of the responsibility with which I am entrusted by the public.

SUMMARY

Keep in Mind

KNOWLEDGE

Comes fast

WISDOM

Comes slow

It Is YOUR Responsibility To Stay Current With Legislation/Regulations

Federal Register

Maryland Register

Newsletters

- Board of Pharmacy
  - Hard copy to Establishments
  - Electronic copy to pharmacists and technicians (Requires current email address)
- MPhA
- MSHP
- Other professional organizations and professional publications

REVIEW