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Maryland Board of Pharmacy

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2001 Legislation

The Maryland General Assembly ended the 2001 Session in April. After considering more than 30 bills that would have had an effect on pharmacy, the legislature passed relatively few, including:

- HB 807/SB 686 the Health Insurance Benefit Cards, Prescription Benefits Cards, or other Technology require insurers and HMOs, which come under the jurisdiction of the Insurance Commissioner, to place specific information on the identification card to provide the necessary data entry elements for pharmacists to efficiently process claims.
- HB 418 allows the Department of Health and Mental Hygiene to impound drugs and prescription records of a pharmacy or authorized prescriber if their permit or license has expired, been revoked, or suspended; an application has been denied; or the entity has otherwise ceased operation without following procedures, after notice has been provided by the department. Impounding can also occur if there is imminent danger to the public or a danger that patient confidentiality may be breached. The Division of Drug Control and the Maryland Board of Pharmacy will jointly develop regulations.
- HB 1274 requires the Maryland Health Care Commission to study the feasibility of developing a system for reducing the incidences of preventable adverse medical events in the state, including a system of reporting. The Board of Pharmacy Medication Error Task Force anticipates providing information for this report.
- HB 1032 increases the provider assessment that is used to fund the Maryland Health Care Commission from $8.25 million to $10 million. The commission will be reviewing which providers will be required to participate in the funding. This may require a change in the fee that health care providers, including pharmacists, pay with their license renewals. The change will not affect renewals this year.
- HB 6/SB 236 is a complex bill titled Senior Prescription Drug Relief Act that is intended to provide some relief from high prescription prices to seniors through various programs including a Maryland Pharmacy Discount Program.

SB 772, Therapy Management Agreements and Cooperative Procedures, is a bill that was supported by most of the Maryland pharmacy community. Although it was not passed, the legislature has directed the Board of Pharmacy and the Board of Physician Quality Assurance to study the issue and provide the legislature with language for a bill they anticipate will be passed in the next session.

Regulations

- New regulations (COMAR 10.34.14) are in effect now, governing the procedures required for a permit holder to close a pharmacy. The changes generally affect the flow of information between the Board of Pharmacy and the Division of Drug Control, which performs the closing inspection.
- The Portable Drug Kits regulation (COMAR 10.34.16), which has been in effect since September 1999, has been amended to include home infusion providers licensed as residential service agencies to lawfully utilize the kits under the same regulations that govern the use by licensed home health agencies and hospices.
- Outsourcing, the process whereby one pharmacy utilizes the services of another pharmacy to prepare products for them, is now addressed by COMAR 10.34.04. This provides the legal framework for both outsourcing and the transferring of prescriptions and prescription information from one pharmacy to another.
- Provisions of the Code of Conduct regulation, 10.34.10.01, will be changed to include unprofessional conduct as grounds for discipline. Additionally, the regulation may be changed to address sanitation.
- Sanitation regulations are being considered that would make licensees responsible for maintaining proper sanitation, hygiene, biohazard precautions, and infection control when performing tasks in the prescription process, as well as making permit holders responsible for the actions of unlicensed personnel.
- The Board is responding to comments on the proposed Record of Drug Inventory Acquisition regulations. The proposal would require pharmacies to maintain records of drug inventory acquisitions received from any source, with some limitations.
- The regulations proposed to govern the delivery of prescription medications have been reworded in response to comments and will be published again for further comments.
- The Board has voted to publish automation regulations for comments.
- Regulations that will clarify the reinstatement of expired licenses for pharmacists regulations are presently being reviewed.

Board Activities

Summertime does little to limit Board of Pharmacy activities. Currently, the Board is hosting a Drug Therapy Management Workgroup that meets once a month and comprises representatives of the legislature, other boards, chain and independent community pharmacy, Med-Chi, the School of Pharmacy, Pharmaceutical Research and Manufacturers of America, and others to comply with a request from the legislature to meet and bring back a consensus bill, which hopefully will pass in the next session.

A group is being formed under the auspices of the secretary of health and mental hygiene to review and report on the pharmacy manpower shortage in Maryland.

Work is continuing on the Medication Error Task Force. Additional suggestions to address error problems and recommendations have been brought to the Board for implementation. The Board has had informal meetings with several permit holders when multiple complaints related to errors at their pharmacies were received. The Board reviews their policies and makes suggestions. If necessary,

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Study Shows Sharp Increase in Prescription Drug Misuse Costs and Morbidity

A study published in the March/April 2001 issue of the *Journal of the American Pharmaceutical Association* estimates that prescription drug misuse costs the health care system $177.4 billion and results in 218,000 deaths each year; a significant increase over the findings of a 1995 study conducted by Jeffrey A. Johnson, PhD, and J. Lyle Bootman, PhD, of the College of Pharmacy, University of Arizona, which estimated such costs to be $76 billion and the number of deaths approximately 198,000.

Study authors Frank R. Ernst, PharmD, and Amy J. Grizzle, PharmD, of the College of Pharmacy, University of Arizona, Tucson, found that of the $177.4 billion spent, hospital and long-term care facility admissions accounted for $121.5 billion (69%) and $32.8 billion (18%), respectively. Another 13.8 billion (8%) was spent on physician visits, $5.8 billion (3%) on emergency department visits, and $3.5 billion (2%) on additional treatments.

According to the study, the majority of the cost increases appeared to result from estimates of hospital and long-term care admission costs, which were more than twice the 1995 estimates. Further, Ernst and Grizzle estimated the mean cost of treatment failure to be $977. For new medical problems, the mean cost was estimated at $1,105, and the cost of a combined treatment failure and resulting new medical problem was $1,488. They identified the most significant drug-related problems to be untreated indication, improper drug selection, subtherapeutic dosage, failure to receive drugs, overdosage, adverse drug reactions, drug interactions, and drug use without indication.

The authors' research of prior literature demonstrated that "costs associated with drug-related morbidity and mortality exceed the expenditures for initial drug therapy; that is, the total cost of drug-related morbidity and mortality exceeds the cost of the medications themselves."

They concluded that "drug-related morbidity and mortality continue to pose a serious medical and economic problem for society" and recommended that "more attention be directed toward developing solutions that reduce preventable morbidity, mortality, and costs associated with drug-related problems."

DEA Clarifies CII Prescription Faxing

The US Drug Enforcement Administration (DEA) published a final rule in the January 11, 2001 *Federal Register*, which clarifies that prescriptions for Schedule II narcotic substances for patients enrolled in hospice care certified by Medicare under Title XVIII or licensed by the state may be transmitted by facsimile. 21 CFR 1306.11(g) originally provided that a pharmacy could dispense a Schedule II narcotic substance pursuant to a prescription transmitted via fax for a patient "residing in a hospice certified by Medicare. . . or licensed by the state."

According to the DEA, this language was perceived by many as requiring that the patient reside in a hospice facility to the exclusion of other health care settings, such as home hospice care. The new language clarifies that fax transmission is allowed for a patient "*enrolled in a hospice care program* certified by Medicare. . . ," [italics added] making it clear that Schedule II narcotic prescriptions may be faxed for patients enrolled in recognized hospice programs, regardless of where the patient resides.

This amendment became effective February 12, 2001. For further information, contact Patricia M. Good, chief, Liaison and Policy Section, Office of Diversion Control, DEA, Washington, DC 20537, 202/307-7297.

FDAMA Compounding Legislation Ruled Unconstitutional

On February 6, 2001, the United States Court of Appeals for the Ninth Circuit ruled the pharmacy compounding section of the Food and Drug Administration Modernization Act of 1997 (FDAMA) unconstitutional and, therefore, unenforceable. The court upheld the US district court's ruling that restrictions on commercial speech found in Sections 353A(a) and (c) violate the First Amendment.

Sections 353A(a) and (c) of the FDAMA allowed the compounding of drugs as long as the compounding pharmacy, pharmacist, or physician did not advertise or promote the compounding of any particular drug, class of drug, or type of drug. The advertising of compounding services in general was not prohibited. The lawsuit, which was filed by several compounding pharmacies, claimed the advertising provisions violated the First Amendment.

"NABP is reviewing the court decision to understand its impact on current state and federal regulations," states NABP Chairman Jerry Moore. "In the most dramatic sense, it could be a return to the situation that existed prior to the compounding legislation's adoption. If this is the case, NABP would advise states to continue their efforts to distinguish compounding from manufacturing and work cooperatively with the Food and Drug Administration (FDA) to resolve manufacturing complaints."

Section 353A was intended to curtail the manufacturing of products under the guise of compounding. In addition to placing advertising restrictions on compounding services, it regulated the types and characteristics of bulk drug substances and ingredients that may be used in compounding and limited the amount of compounded product that may be distributed out of state. The law specifically designated NABP as a consultant to the Secretary of the Department of Health and Human Services (HHS) in developing a memorandum of understanding for states to use when compounded drugs are distributed across state lines and mandated that an NABP representative be appointed to an advisory committee to assist HHS in developing regulations.

CybeRx-Smart Coalition Offers Tips for Online Rx Safety

Adhering to a few simple, common sense precautions, such as looking for the Verified Internet Pharmacy Practice Sites™ (VIPPS™) seal, offers consumers significant protection when purchasing prescription medicines online, says the CybeRx-Smart Safety Coalition. Organized by the US Food and Drug Administration (FDA) and comprised of 14 government, professional, and industry related organizations, including NABP, the Coalition has launched a national public service campaign featuring public service radio announcements, news releases, and an information brochure that appears on the FDA Web site at www.fda.gov.

Through the efforts of the Coalition, FDA has made a significant commitment to educating consumers about the "do's and don'ts" of buying prescription medication online. Consumers are advised to:

- Meet with their doctors to obtain any new prescription;
- Look for the VIPPS seal to ensure they are dealing with a legitimate pharmacy;
- Buy only from US-based sites;
- Look for easy-to-find and understandable privacy and security policies; and
- Use the same standards when purchasing prescription medications online as you would when selecting any reputable pharmacy.

Consumers are also encouraged to report any site they believe to be unlicensed or a problem to the FDA.

FDA's future plans to widely promote the Coalition brochure include the distribution of a card with every tax refund check listing the new brochure; radio public service announcements (an audience of over five million has been reached to date); a banner page on the FDA Web site; and an exhibit booth at several professional meetings during 2001.

Member organizations of the CybeRx-Smart Safety Coalition are the American Pharmaceutical Association, American Society of Consultant Pharmacists, American Society of Health-System Pharmacists, CornerDrugstore.com, CVS.com, drugstore.com, Federal Trade Commission, NABP, National Association of Chain Drug Stores, National Community Pharmacists Association, National Council on Patient Information and Education, National Patient Safety Foundation, PlanetRx.com, and the FDA.

The Coalition brochure is posted at www.fda.gov/cder/drug/consumer/buyonline/guide.htm.

DEA Offers New Controlled Substance Regulation Manual for Pharmacists

The US Drug Enforcement Administration (DEA) announced the availability of a new publication for pharmacists entitled *Pharmacists Manual, An Information Outline of the Controlled Substances Act of 1970.*

The publication is available on DEA's Web site at www.deadiversion.usdoj.gov or from DEA Diversion Field Offices.

"DEA is hopeful that this manual will prove to be a valuable resource and will assist pharmacists in understanding the Controlled Substances Act of 1970 and its implementing regulations as they pertain to pharmacy practice," says Patricia M. Good of the DEA Office of Diversion Control.

For further information contact the Liaison Unit of the DEA Office of Diversion Control at 202/307-7297.

Continuing Education Available on FDA Web Site

The US Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) now offers free continuing education programs for pharmacists and physicians via its Web site.

The first program, entitled *New Drug Development in the United States*, provides an overview of the FDA's role in the new drug development process by discussing various aspects of the Investigational and New Drug Application (IND/NDA) process, including drug testing in the laboratory and in patients, the importance of the Prescription Drug User Fee Act, the FDA Modernization Act, generic drugs, and post-marketing surveillance.

Interested individuals may access this one-credit hour program at www.fda.gov/cder/learn/CDERLearn/default.htm.

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the Board sends a representative to view the systems used for filling prescriptions. The intent is to minimize prescription errors by a systems approach.

The Unlicensed Pharmacy Personnel Task Force continues its monthly meetings that will lead to regulations allowing more efficient use of appropriately trained pharmacy technicians while continuing to guard the safety of the public.

Internal board committees are reviewing all regulations, as required periodically by state law, to determine if they are still necessary and whether changes are required due to changes in practice.

The Board is undergoing the second phase of a Sunset Review by the legislature. This review is performed periodically on 68 state agencies to ensure that the agencies are carrying out their mandates appropriately. A preliminary review last year concluded that the Board has "acted conscientiously in protecting the public through promoting a high level of quality in pharmacy care." The reviewers recommended a full evaluation to determine if the rapid changes in the pharmacy industry are being addressed appropriately; whether the Board fully meets its current responsibilities; and whether the Board has sufficient administrative support to fulfill its obligations.

Strategic Plan

The Board of Pharmacy has completed a five-year strategic plan that will guide it through the next several years of operation. The plan includes a program description, mission, vision, and four measurable goals:

- Goal 1: accurate and timely licensure procedures that will reduce the time it takes to process licenses;
- Goal 2: provide efficient, fair, and consistent compliance processes by standardizing recommendations for some actions based on defined categories and database information; and to reduce the time it takes to close cases.
- Goal 3: requires the Board to establish professional working relationships with key stakeholders to advance legislative initiatives, as well as track trends, practices, and philosophies in pharmacy in order to determine necessary regulatory or legislative changes; and
- Goal 4: ensure that the public is informed about the availability of pharmaceutical services and how appropriate medication use can enhance the quality of care and safety.

Continuing Education Regulations

In the April issue of this *Newsletter*, readers were solicited to offer their opinions on changes that were being considered by the Board concerning requirements for continuing education credits. We were gratified by the number of respondents and thank the licensees for their interests. After reviewing the wide range of opinions from the e-mails received and the varying views of the board members, the Board decided to retain the regulations and not make any changes at this time. Thirty continuing education credits must be earned during the two-year period immediately preceding the applicant's renewal date. At this time there are no specific topics required, and any form of programming that has American Council on Pharmaceutical Education or Maryland Board of Pharmacy approval is acceptable. For complete information, refer to Health Occupations Title 12-309 and COMAR 10.34.18.

Newsflash

Look out for our **new** *Newsletter* format in our next issue. The Maryland Board of Pharmacy will be expanding its quarterly *Newsletters* to include a variety of topics pertaining to consumers, pharmacists, and pharmacies.

Staff

Sharon Cornish will be retiring after 31 years of dedicated service to the State of Maryland. Sharon has demonstrated innovative leadership, professionalism and noteworthy contributions as a Personnel/Contract/Budget Officer and Licensing Supervisor with the Maryland Board of Pharmacy and as the Board's administrative assistant. The Board extends its best wishes for Sharon's future endeavors.

Disciplinary Actions by the Maryland Board of Pharmacy

Effective Date	Licensee/Permit Holder/Action Taken
February 12, 2001	Donald Ullman (#05762) Voluntary Surrender
March 20, 2001	Gerald Freedenberg (# 06162) Termination of Probation
April 18, 2001	Melvin Chaiet (#05958) Voluntary Surrender
April 18, 2001	David Drugs Inc/KayCee Drugs Probation for one year (P00357)
April 18, 2001	Moslem Eskandari (#14714) Suspended
April 26, 2001	John Hoelscher (#11115) Summary Suspension

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