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Maryland Board of Pharmacy

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Maryland Board Hosts Medication Errors Task Force

In response to growing public awareness and concern about the serious problem of errors in the medication delivery system, the Maryland Board of Pharmacy formed the Medication Errors Task Force in November 1999. The Task Force is charged with identifying and prioritizing strategies to guide practitioners and permit holders in redesigning medication systems to reduce the incidence and severity of medication errors in Maryland. The Task Force has utilized two approaches to meet its charge: (1) Developing and recommending options for the Board to use in addressing medication errors; and (2) Assisting the Board in developing strategies to implement the options that the Board selects to address the issue.

The first approach entailed soliciting input from broad-based representatives of groups and stakeholders in the pharmacy community, including retail chain, independent community, health system, and academia, along with representation from the Food and Drug Administration and United States Pharmacopeia. These Task Force representatives were educated about medication error issues. To establish a common knowledge base, information was provided that was consistent with current research and literature, as well as with the science of human error. Following this orientation, the Task Force developed strategies to address the problem of medication errors. The strategies were prioritized, based upon impact, ease of implementation, and measurability. The strategies will be crafted into recommendations to the Board.

The second approach, in which the Task Force is currently engaged, involves the development of an action plan and timetable for implementing recommended strategies. Also, the Task Force will assist the Board in drafting language for guidelines and any needed regulations.

Initial recommendations by the Task Force reflect a recognition of the need for broad-based medication and human error education. Most health care professionals, executives, and consumers need this education to set goals, expectations, and responsibilities relating to medication error activities. To this end, Task Force members felt that licensees should be responsible for obtaining continuing education relating to medication errors. Permit holders should also be held responsible for providing education to their staffs and patients/consumers. In addition, the Task Force recommends that the Board attempt to identify underlying system flaws that lead to errors when investigating error-related reports. The Task Force feels that corrective actions should focus on systems improvement rather than a punitive approach against involved pharmacists. This will encourage pharmacists and permit holders to openly examine errors and potential errors and share findings and corrective methods with their peers. Of course, some exceptions, as defined by the Board, state statutes and regulations, will occur even with this approach.

Education must take place before changes may be anticipated in pharmacy practice. Therefore, a phase-in approach to all Task Force recommendations is expected. This approach will allow a gradual transition from education to an improved and safer practice environment. It will also allow for an interim phase for tentative modification of current practices. A second set of Task Force recommendations will address characteristics for medication system quality improvement and error reporting programs to ensure that errors revealed by pharmacists and establishments are non-discoverable in civil cases. Once submitted, the recommendations will be discussed in a future *Newsletter*. Information will also be posted on the Board's Web site at www.MDBOP.com.

Unlicensed Pharmacy Personnel

The regulations in COMAR 10.34.21 will become effective as proposed within the next few weeks. The rules, titled "Standards of Practice," define the responsibilities of licensed pharmacists and permit holders when unlicensed pharmacy personnel work in the pharmacy. The rules also outline the areas of pharmacy practice that unlicensed persons are restricted from performing.

The new regulations are included in the new *Maryland Law Book* being distributed to pharmacy permit holders, and a copy may be obtained by sending a letter or e-mail to the Board, or from the Board's Web site when it is posted. Pertinent points of the regulations follow:

- Permit Holder Responsibilities: The permit holder shall determine which tasks the pharmacist may assign to unlicensed personnel to perform in the prescription process or in the prescription area; must ensure that unlicensed personnel receive appropriate training for the tasks that the pharmacist assigns them; that they maintain their competency; and that they receive training to understand the way confidentiality laws apply to prescriptions. Written policies, procedures, and documentation indicating that the persons have achieved appropriate competency levels are required. A quality assurance program is required as well as documentation of the training. The unlicensed person must be clearly identified to the consumer and have a written job description.

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HHS Releases Final Privacy Regulations

Currently, patient health information and medical records are protected by various state laws, which some privacy advocates and members of the health care industry believe may leave gaps in the protection of patients' privacy and confidentiality. These individuals see a crucial need for national standards that will close these gaps, control the exchange of patient information, and set penalties for the misuse or wrongful disclosure of this sensitive information.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) called upon Congress to develop comprehensive national medical record privacy standards by August 21, 1999. When Congress was unable to meet this deadline, HIPAA required that the US Department of Health and Human Services (HHS) develop the regulations. The HHS published the final regulations in the December 28, 2000 *Federal Register*. These regulations are the nation's first standards for comprehensively protecting the privacy of Americans' personal health records and are designed to protect medical records and other personal health information maintained by health care providers, hospitals, health plans and health insurers, and health care clearinghouses.

For some, this is an important advancement in health care. Former HHS Secretary Donna Shalala commented in a December 20, 2000 press release, "For the first time all Americans – no matter where they live, no matter where they get their health care – will have protections for their most private personal information, their health records. Gone are the days when our family doctor kept our records sealed away in an office file cabinet. Patient information is now accessed and exchanged quickly. With these standards, all Americans will be able to have confidence that their personal health information will be protected."

The final regulations significantly differ from those proposed initially. While the proposed regulations applied only to electronic records and any paper records that existed in electronic format, the final regulations extend protection to all formats of personal health information: paper, electronic, and oral communications. The final rule also requires that patients be provided with detailed written information about their rights to privacy and how their health information will be used. Further, the final regulations give providers full discretion in determining what personal health information to include when sending patients' medical records to other treatment providers. The regulations afford protection against the unauthorized use of medical records for employment-related purposes.

The new regulations, which are expected to go into effect in February 2003, are intended to enhance protection offered by many existing state laws. In situations where the federal rules and state laws are in conflict, the stronger privacy protection would prevail. The final regulations' standards apply to all consumers, whether they are privately insured, uninsured, or participants in public programs such as Medicare or Medicaid.

The new regulations reflect the following principles:

- **Consumer Control:** Consumers are provided new rights to control the release of their medical information, including advance consent for most disclosures of health information; the right to see a copy of their health records; the right to request a correction to their health records; the right to obtain documentation of disclosures of their health information; and the right to an explanation of their privacy rights and how their information may be used or disclosed.
- **Boundaries:** With few exceptions, an individual's health care information should be used for health purposes only, including treatment and payment. For example, a hospital may use personal health information to provide care, teach, train, conduct research, and assure quality. Employers who sponsor health plans may not obtain information for non-health purposes, such as hiring, firing, or determining promotions, without permission from the individual. Similarly, insurers may not use such information to underwrite other products, such as life insurance. Disclosure is to be kept to the minimum information needed.
- **Accountability:** Under HIPAA, for the first time, there will be specific federal penalties if a patient's right to privacy is violated. For noncriminal violations of the privacy standards by the persons subject to the standards, including disclosures made in error, there are civil monetary penalties of $100 per violation up to $25,000 per year, per standard. In addition, criminal penalties are provided in HIPAA for certain types of violations of the statute that are done knowingly: up to $50,000 and one year in prison for obtaining or disclosing protected health information; up to $100,000 and up to five years in prison for obtaining or disclosing protected health information under "false pretenses"; and up to $250,000 and up to 10 years in prison for obtaining protected health information with the intent to sell, transfer, or use it for commercial advantage, personal gain, or malicious harm.
- **Public Responsibility:** The new standards reflect the need to balance privacy protections with public responsibility to support such national priorities as protecting public health, conducting medical research, improving the quality of care, and fighting health care fraud and abuse. For example, when there is an infectious disease outbreak, public health agencies need to obtain important information to better protect the public. The new regulations provide standards for how such information should be released to balance privacy and public health needs.
- **Security:** It is the responsibility of the organizations entrusted with health information to guard against deliberate or inadvertent misuse or disclosure. The final regulations require covered organizations to establish clear procedures to protect patients' privacy, including designating an official to establish and monitor the entity's privacy practices and training.

For more information, visit the HHS Web site at www.hhs.gov.

Compliance News

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FDA Proposes New Prescription Drug Labeling Requirements

The US Food and Drug Administration (FDA) published a proposed rule in the December 21, 2000 *Federal Register* that governs the format and content of labeling for human prescription drug and biologic products. The proposed rule would revise current regulations to require that the labeling of new and recently approved products: 1) include a section containing highlights of prescribing information and a section containing an index to prescribing information, 2) reorder currently required information and make minor changes to its content, and 3) establish minimum graphical requirements. For previously approved drug products, the proposed rule would require that certain types of statements that currently appear on the labeling be removed if they are not sufficiently supported. It would also eliminate certain unnecessary statements that are presently required to appear in the labeling and would move other, less important information to other parts of the labeling.

A recent FDA study demonstrated that practitioners found drug product labeling to be lengthy, complex, and difficult to use. The new requirements are intended to simplify labels, reduce the time spent looking for information, decrease the number of preventable errors, and improve treatment effectiveness.

For further information contact Nancy M. Ostrove, Center for Drug Evaluation and Research (HFD-42), FDA, 5600 Fishers Lane, Rockville, MD 20857, 301/827-2828, Ostrove@CDER.FDA.GOV.

Lotronex Withdrawn from the Market

In late November 2000, pharmaceutical manufacturer Glaxo Wellcome of Research Triangle Park, NC, notified the US Food and Drug Administration (FDA) that it would voluntarily withdraw Lotronex (alosetron hydrochloride) tablets from the market. Lotronex is a prescription medication approved to treat irritable bowel syndrome (IBS) in women.

This action followed FDA analyses of post-marketing reports of serious adverse events involving Lotronex, including reports of patient death. Specifically, FDA had been concerned about reported cases of intestinal damage resulting from reduced blood flow to the intestine (ischemic colitis) and severely obstructed or ruptured bowels (complications of severe constipation). As of November 10, 2000, FDA had received and reviewed a total of 70 cases of serious post-marketing adverse events, including 49 cases of ischemic colitis and 21 cases of severe constipation. Of the 70 cases, 34 resulted in hospitalization without surgery, 10 resulted in surgical procedures, and three resulted in death. In addition, the FDA received two reports of death that the agency did not classify as being cases of ischemic colitis or severe complications of constipation.

The FDA had been closely monitoring Lotronex since its approval on February 9, 2000. Prior to approval, four cases of ischemic colitis were observed in clinical studies. These cases were transient, mild-to-moderate in nature, and reversible upon discontinuation of the drug.

However, between approval and June 1, 2000, FDA received seven post-marketing reports of serious complications of constipation and eight post-marketing reports of ischemic colitis. In response to these developments, on June 27, 2000, FDA convened a public advisory committee meeting where risk management options in response to the serious adverse event reports were discussed. Advisory committee members recommended that physicians and patients be informed of the potentially serious adverse events associated with Lotronex. Following the meeting, FDA updated the health care professional labeling for Lotronex and required Glaxo Wellcome to distribute a Medication Guide that warned patients directly about the risks associated with the drug. In addition, Glaxo Wellcome issued "Dear Healthcare Professional" and "Dear Pharmacist" letters to these groups.

Despite these efforts, FDA continued to receive severe adverse event reports of ischemic colitis and complications of constipation associated with Lotronex. In addition, FDA received reports of death and more serious complications of ischemic colitis that required blood transfusion or surgery. Upon completing its analyses of the 70 cases, FDA met with Glaxo Wellcome to discuss its options, which, as an alternative to market withdrawal, included a restricted drug distribution program. Glaxo Wellcome chose to withdraw Lotronex from the market.

For more information, visit the FDA's Lotronex Information Web page at www.fda.gov/cder/drug/infopage/lotronex/lotronex.htm.

NABP's Survey of Pharmacy Law

NABP's 2000-2001 edition of the *Survey of Pharmacy Law* is now available.

Updated annually, the *Survey* is a compilation of the major state laws and regulations that govern the pharmacy profession. The information is displayed in a chart format with clarifying footnotes for easy reference. Each state board of pharmacy reviews and updates its information yearly to reflect changes in its state's laws and regulations. An educational grant from Wyeth-Ayerst Global Pharmaceuticals enables NABP to provide complimentary copies of the *Survey* to the nation's schools and colleges of pharmacy for distribution to all final-year pharmacy students. The purchase price of the *Survey* is $20.

To purchase the *Survey*, send a request with an accompanying check or money order made payable to NABP, to the NABP Publications Desk, 700 Busse Highway, Park Ridge, IL 60068.

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- Pharmacist Responsibilities: The pharmacist shall ensure that unlicensed personnel are adequately trained for and competent to perform the tasks the pharmacist assigns to them and must provide appropriate supervision. The pharmacist may **not** delegate the following:

  Ensuring the appropriateness of the prescription order and the accuracy of the compounding and preparation of the order; receiving orally transmitted new prescription orders or refill authorizations that include modifications or refill authorizations for prescriptions containing controlled drug substances. The unlicensed person cannot handle transfers of prescriptions between pharmacies or provide pharmaceutical care as described in law, nor provide information to the public or a health care professional about prescription or nonprescription drugs or devices.
- Unlicensed Personnel Duties: This section spells out tasks that the unlicensed person may perform tasks under the supervision of the pharmacist that the person is competent to perform, except for those noted above; it also revisits the confidentiality issue.
- Discipline: These regulations provide for disciplinary action against the pharmacist licensee and permit holder if illegal acts take place. These regulations are intended to allow pharmacies to utilize unlicensed personnel to assist them without additional educational or experiential requirements beyond that which is needed in order to appropriately and accurately perform their assigned duties. The Board does not want to force unlicensed persons who are now acting in a legal manner to curtail their activities. The Task Force now will look at ways to allow appropriately trained unlicensed persons to perform additional tasks for which they may become qualified without the possibility of causing harm to the public. These tasks may require specified education and some form of certification, registration and/or licensing; the titles of pharmacy technician and pharmacist assistant, not presently recognized in Maryland law, may be used in the future to describe persons with specific training. The Task Force may take a year or more to complete its work and will be glad to consider any suggestions from the profession.

Continuing Education

The Board of Pharmacy is considering changes to the continuing education regulations, COMAR 10.34.18, and solicits input from the profession. The Licensing Committee is considering changes, such as requiring a minimum number of credits to be obtained by live presentations, allowing up to a certain number of credits for community service (brown bagging or community lectures), and requiring that credits be obtained in specific subject matters such as medication errors and confidentiality. Hardship problems which might affect persons living in rural areas without access to live programs would be taken into consideration.

Please send suggestions and comments to the Board of Pharmacy by e-mail or a letter, addressed to Wayne Dyke, Licensing Committee Chairman.

Pharmacy Board Statistics: There are 4,741 pharmacists licensed in Maryland who are actively practicing in the state and 1,927 pharmacists licensed in Maryland practicing in other states. Of the pharmacists licensed in Maryland, practicing both in and out of state, 3,189 are female and 3,491 are male. Four hundred eighty-six females and 189 male licensees are under the age of 30. There are 658 chain pharmacies, 257 independent pharmacies, 70 clinic, hospital, and HMO pharmacies, and 201 non-resident pharmacy permits issued. (All figures are current as of January 12, 2001 and are taken from unaudited license and permit applications).

Disciplinary Actions

Jaspal Kocchar (#08257) – Effective November 15, 2001, license to practice pharmacy is revoked.

Martha Okwara (#11549) – Effective February 21, 2001, probation has been terminated.

John Riley (#09173) – Effective February 21, 2001, license to practice pharmacy is indefinitely suspended.

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