MARYLAND BOARD OF PHARMACY
MEDICATION ERROR TASK FORCE REPORT

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PARTICIPANT BACKGROUNDS

State Regulatory	Hospital
Federal Regulatory	Consumer
Home Infusion	Community pharmacy-Chain
Community Pharmacy- Independent	Pharmaceutical Manufacturer
Health Insurance Industry	State Professional Organizations
National Professional Organization	Student

INTRODUCTION

It is the Maryland Board of Pharmacy's sole mission to protect the public health, safety and welfare. In an effort to reduce medication errors to the benefit of the public health and in response to growing public awareness and professional concern about the serious problem of errors in the medication delivery system, the Board of Pharmacy [the Board] formed a Medication Error Task Force in November 1999.[1] Oversight of the Task Force was assigned to the Board's Pharmacy Practice Committee. The Medication Error Task Force was charged with recommending strategies the Board should utilize to guide practitioners and pharmacy permit holders[2] in redesigning medication systems to reduce the incidence and severity of medication errors in Maryland. The Medication Error Task Force 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.

MEMBERSHIP AND ORGANIZATION

In order to globally address the medication error issue in pharmacy practice, the Board's Pharmacy Practice Committee solicited input from a broad base of groups and stakeholders in the pharmacy community. Bruce M. Gordon, Pharm.D., a health care industry consultant who is experienced in medication error prevention, volunteered to act as a facilitator for the Medication Error Task Force. Chain community, independent community, hospital, home infusion, managed care, and long-term care pharmacies were represented on the Task Force. Representatives from the health insurance industry, the

[1] It is should be noted that the Board's decision to dedicate resources to address this issue pre-dated the release of the Institute of Medicine (I.O.M.)report, *To Err is Human*. The I.O.M. report brought national attention to the impact of medical errors on health care and has served as the impetus for many professional and governmental initiatives aimed at addressing medical errors.

[2] Pharmacy permit holders are the individuals or entities that hold a permit to operate a pharmacy. This is different than a pharmacist's license.

Food and Drug Administration and the United States Pharmacopoeia [USP] also participated in the Task Force.

Recognizing the fact that the issue of medication errors in pharmacy practice is impacted by other health care disciplines, the Maryland Hospital Association, the Board of Nursing and the Board of Physician Quality Assurance were invited to participate in the Task Force. Through periodic communications, these organizations were kept abreast of the Task Force's work. On occasion, representatives from the Board of Nursing and the Board of Physician Quality Assurance attended Medication Error Task Force meetings.

The Medication Error Task Force meetings were open to the public and anyone in attendance was allowed to participate in the proceedings. The Task Force met monthly from November 1999 to February 2001 and again from May 2001 to July 2001. From February 2001 to May 2001, a sub-group of the Medication Error Task Force worked on drafting regulations for the Task Force's endorsement and the Board's consideration.

METHODS

The first step towards fulfillment of its charge was the education of Medication Error Task Force members on the numerous issues affecting medical errors. This education included presentations by the group facilitator on how a medication error may be defined, common factors that contribute to errors and an overview of the current literature and trends on medical error prevention. The educational process also included a survey asking how other state boards of pharmacy are addressing medication errors, a review of existing reporting systems and an overview of state and federal legislative initiatives related to medical errors.

Using this newly acquired education and drawing from their collective experiences, the Task Force members worked to identify a range of appropriate strategies to address the issue of medication errors. After considering factors such as potential level of impact of particular strategies on the reduction of medication errors, and the ability to measure that impact, the original list of 23 possible strategies was eventually pared down and translated into the Task Force's recommended strategies for the Board's implementation. Based on the accepted strategies, the Task Force constructed for the Board's consideration, regulations necessary to implement the recommended strategies.

While the Medication Error Task Force has disbanded, its participants continue to assist the Board in carrying out the recommended strategies as needed. It is anticipated that the Task Force will be reconvened in the future to assess the impact of Board's initiatives on medication error prevention and make further suggestions as needed.

MEDICATION ERROR TASK FORCE RECOMMENATIONS AND IMPLEMENTATION

In broad terms, the Medication Error Task Force recommendations fell into three categories, and are as follows:

1. Educational initiatives for consumers and pharmacy practitioners,

2. Non-punitive action in response to errors reported to the Board,[3] and

3. Requirements for mandatory pharmacy quality assurance programs designed to address medication errors.

With the exception of the requirements for mandatory quality assurance programs, the Board has made significant progress in the implementation of the Task Force recommendations. As discussed later in this report, however, legislation will be required to enable the development of meaningful quality assurance and error reporting programs in certain settings.

Educational Initiatives for Consumers and Practitioners

The first recommendation made by the Medication Error Task Force reflects recognition of the need for broad-based medication and human error education for both consumers and health care providers. This recommendation is in line with the concerns discussed by a focus group at the 12th Annual conference of the National Academy of State Health Policy that involved representatives from 20 different states. INSTITUTE OF MEDICINE, *To Err is Human: Building a Safer Health System*, pg 93 (National Academy Press 2000). Education must take place before changes may be anticipated in pharmacy practice. The Task Force recommended, and the Board agreed, that the Board should develop and distribute relevant educational materials for both consumers and members of the pharmacy community. This is one area where Task Force members will likely continue to work with the Board to help identify and select timely information that should be disseminated.

- Practitioner Education

The Task Force determined that a systems-approach[4] to reducing medication errors is an effective way of reducing errors. To that end, and after much heated discussion, the Task Force adopted the National Coordinating Council for Medication

[3] The Task Force did not, nor does the Board of Pharmacy, endorse mandatory reporting to the Board as a means of reducing medication errors.

[4] A "systems-approach" reviews the systems and processes that lead to an adverse event, as opposed to reviewing solely the practitioner's actions. The systems-approach utilizes the "root cause analysis," as is discussed below.

Error Reporting and Prevention's (NCCMERP) definition of medication error that identifies all points within the health care delivery system where an error may occur. The NCCMERP definition is as follows:

> A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

NCCMERP, *About Medication Errors*, (visited October 15, 2001)< http://www.nccmerp.org/aboutmederrors.htm>.

The Medication Error Task Force's own struggle to come to a consensus on how to define a medication error and what practitioners can do to prevent errors demonstrated the need for practitioner training in this area.

Practitioners must understand that in order to reduce errors, whether the error effects the patient or not, the entire medical and medication delivery system must be examined, and practitioners must understand their proper role in error prevention. An error that reaches a patient is not generally the result of one factor in the system, but is the result of multiple breakdowns within the medication system. It is important that the public understand these concepts as well.

Practitioners must be able to identify the process failures, investigate the error, assess their practice settings to identify probable causes for an error or potential error, and respond appropriately. Through the promulgation of regulations, pharmacy permit holders will be required to ensure their pharmacy employees receive annual training in medication error prevention.

The Board's newsletter and website will be used to raise practitioner awareness of the types of medication errors reported in the pharmacy literature, their potential causes and preventative measures that may be adapted to a particular setting. The Board will also make available information on specific training and educational opportunities on medication errors for practitioners. This information may include resources on how to conduct a root-cause analysis[5] of an error or how to establish a quality assurance program.

- Patient Education

[5] A "root cause analysis" focuses on systems and processes to determine why an event occurred. Once the "root" of the problem is identified, an action plan and measurement strategy must be implemented. JCAHO's Framework for a Root Cause Analysis appears in Appendix B.

Patients and their caregivers play a vital role in the delivery of health care. The patient or caregiver is often the last step in the health care delivery system and often the last opportunity to detect or prevent a medication error before harm can occur. Patients who are knowledgeable about their medication, know what questions to ask a health care practitioner and know how to detect a potential medication error.

The Public Relations Committee of the Board is developing two brochures aimed at informing consumers. One will educate and inform consumers of their role in medication safety and error prevention. The second brochure will outline the Board's complaint process and provide instructions on how to file a complaint if the consumer wishes to report an incident to the Board.

The educational materials for consumers will explain:

1. The patient's role in medication error prevention,

2. Steps that may be taken to prevent errors, and

3. What a patient can do if an error is suspected.

The brochures will be posted on the Board's website and distributed at health related consumer events attended by Board staff, Board members, and other pharmacy organizations. The brochures may also be made available to pharmacy permit holders to distribute to their patients. The first brochures are anticipated to be published shortly. Publication and development of additional educational materials for the consumer will be ongoing.

System-Oriented Action in Response to Error Reported to the Board Through the Complaint Process

It was the conclusion of the Medication Error Task Force, and the Board agreed, that medication errors are often the result of a system failure rather than an individual's incompetence.

> Traditional efforts at error reduction have focused on individual practitioners, using training, exhortation, rules and disciplinary action to improve performance. Human factors specialists and error experts reject this approach because it is more effective to change the system as a whole than to target individuals for improvement (Mornay, in *Human Error in Medicine,* 1994). Since most of what people do is governed by the system, the causes of error belong to failures in the system and often lie outside the direct control of the individual work force. Therefore, the way to prevent errors is to redesign the systems and processes that lead to errors rather than focus efforts on correcting the individuals who make errors. Effective strategies for reducing errors include making it impossible or difficult for staff to make an error and promoting the

> detection and correction of errors before they reach a patient and cause harm.

Speech and accompanying handout by Michael Cohen, FASHP, Medication Errors: Prevention and Management Issues (March 13, 2000) *at* The 147th Annual Meeting & Exposition of the American Pharmaceutical Association.

USP states in its "General Principles for Patient Safety Reporting Systems" memorandum that "[t]here should be a nonpunitive culture for reporting healthcare errors that focuses on preventing and correcting system failures and not on individual or organization culpability." USP, *General Principles for Patient Safety Reporting Systems*, (visited October 15, 2001) < http://www.usp.org/frameset.htm?http://www.usp.org/patient_safety.htm>. Such a culture of non-punitive reporting will foster practitioner 'buy-in' and open and complete reporting.

Because the Task Force determined that system failures are often the cause of errors, the committee recommended a non-punitive approach to addressing errors. The Board adopted and has implemented this approach as an initial approach. If, however, an individual's incompetence or knowledge deficit is identified as the likely cause of the error, the Board may pursue remediation, re-education or restrict a license, which may include suspension or revocation. The Board will continue to address complaints involving system-related medication errors in a non-punitive manner.

When a medication error is reported to the Board through a complaint, the pharmacist(s) involved and the pharmacy permit holder are asked to provide a response to the complaint. When the analysis of the incident indicates that a system problem contributed to the error, a plan of corrective action is developed. To assist the pharmacy permit holder and licensee in this task, the Board's Disciplinary Oversight Committee has implemented, and will continue to expand upon, an informal meeting process involving practitioners and permit holders. The process is designed to analyze the contribution of system weaknesses in the commission of errors and develop an action-plan for system changes that will minimize the possibility of a similar error occurring again. One benefit of this process is that the Board and the practitioner work together to identify the problem and possible solutions. The focus is placed on the system's failure rather than an individual's failure. In this manner, the process becomes collaborative and the practitioner and pharmacy permit holder are more receptive to working with the Board to achieve the common goal of improved patient safety.

The end product of this process may be an informal, non-public letter of agreement between the Board and the licensee and/or permit holder. Violation of the agreement, however, may lead to formal disciplinary action by the Board and the issuance of public sanctions. Likewise, if a system defect is sufficiently serious or threatens the public health and safety, the Board may choose to apply a punitive approach in that matter, regardless of whether a medication error is involved. This process has been in place for approximately 6 months, and to date there has been no report of recurrence of a particular error by a consumer or stakeholder.

Requirements for Mandatory Pharmacy Quality Assurance Programs Designed to Address Medication Errors

- Patient Safety Requires Action-Oriented Quality Assurance Programs that include Adverse Medical Events.

Most adverse events are a result of system failures, not the failure of any specific practitioner. Speech and accompanying handout by Michael Cohen, FASHP, Medication Errors: Prevention and Management Issues (March 13, 2000) *at* The 147th Annual Meeting & Exposition of the American Pharmaceutical Association.

In order to reduce the frequency and severity of adverse events, systems within health care entities must be reviewed. This is called the "systems-review approach" to error reduction. Disciplining a health care professional after an event will not prevent the error from occurring again, if the system within the entity is flawed.

Although many entities have quality assurance programs, action-oriented quality assurance programs are necessary to reduce adverse events, as opposed to programs that merely collect information and react to events that have already occurred. Reporting medication errors without proper system-review will not reduce medication errors.

- Sufficient Legal Protection Must be Provided to Health Care Practitioners Who Report

USP states that "[c]onfidentiality protections for patients, healthcare professionals, and healthcare organizations are essential to the ability of any reporting system to learn about errors and effect their reduction." USP, *General Principles for Patient Safety Reporting Systems*, (visited October 15, 2001) < http://www.usp.org/ frameset.htm?http://www.usp.org /patient_safety.htm>.

Congress has attempted to address medical or medication errors and confidentiality or evidentiary privilege, with little progress. USP presented at the February 2001 Task Force meeting, the status of H.R. 3672, S. 2738, S. 2743, S 2378, S. 2038. There has been no formal activity on these bills since June 2000. *Bill Summary & Status for the 106th Congress* (visited October 16, 2001)< http://thomas.loc.gov/home/thomas.html>.

If practitioners are required to report to an entity that is not a recognized medical review committee (sometimes called a peer review committee), MD. CODE ANN., HEALTH OCC., §14-501 (2000), or is not otherwise presently provided protection from discoverability in some other manner, laws would have to be enacted to protect the information from discovery in a lawsuit. *See Appendix B for present statute.*

Additionally, if practitioners are required to report errors internally[6], again some may be exposed to civil liability. Potentially, 88% of the pharmacies in Maryland are not afforded this protection from discoverability.[7]

With respect to discoverability, the applicable Circuit Court rule states that "…[i]t is not ground for objection…that the information will be inadmissible at trial if the information sought appears reasonably calculated to lead to the discovery of admissible evidence." MD. R. CIV. PRO. 2-402. Therefore the net of what may be discovered in a civil proceeding is very wide. Evidence that may be discovered may then be admissible in the proceeding depending on the particular circumstances of a case. *See* MD. R. EVID. 5-803.

Non-institutional pharmacies do not have committees that would meet the definition of a medical review committee and are not provided protection from discoverability. If a non-institutional pharmacy is required to have a highly detailed internal error reporting system in an effort to reduce medication errors, presently, that information would be discoverable in a civil proceeding against that pharmacy and its agents, and depending on the circumstances of the case, admissible as evidence in a trial.

Other states have, or are addressing, the discoverability issue. California is one example of a state that has addressed the issue in its medication error statute. Effective January 1, 2002, pharmacies in California will be required to maintain quality assurance programs aimed at reducing medication errors. *Legislative Counsel's Digest* (visited October 9, 2001) <www.leginfo.ca.gov/cgi-bin/>. California implemented the statute in order to effectuate regulations. The California statute reads as follows.

> **4125**. (a) Every pharmacy shall establish a quality assurance program that shall, at a minimum, document medication errors attributable, in whole or in part, to the pharmacy or its personnel. The purpose of the quality assurance program shall be to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications so that the pharmacy may take appropriate action to prevent a recurrence.
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> (b) Records generated for and maintained as a component of a pharmacy's ongoing quality assurance program shall be considered peer review documents and not subject to discovery in any arbitration, civil, or other proceeding, except as provided hereafter. That privilege shall not prevent review of a pharmacy's quality assurance

[6] "Internal reporting" is the reporting of errors or events within a health care entity. "External reporting" is the reporting of errors or events to a database or agency outside of the reporting entity.

[7] This percent is based on the total number of pharmacies in Maryland, which totals 1,093, and assumes that chain, independent, compounding, long term care, mail order, managed care, mental health, non-resident, respiratory, and specialty pharmacies do not have committees that meet the definition of a peer review committee. The 12 % that does have protection includes institutional pharmacies that are involved in medical review committees.

> program and records maintained as part of that system by the board as necessary to protect the public health and safety or if fraud is alleged by a government agency with jurisdiction over the pharmacy. Nothing in this section shall be construed to prohibit a patient from accessing his or her own prescription records. Nothing in this section shall affect the discoverability of any records not solely generated for and maintained as a component of a pharmacy's ongoing quality assurance program.
>
> (c) This section shall become operative on January 1, 2002.

Id. [citing CAL. BUS.& PROF. CODE § 4125]. The quality assurance program is a program that is established and maintained within the specific entity, and not by a regulatory or other governmental agency. *Id*. The California Board has the authority to review the quality assurance records if "necessary to protect the public health and safety or if fraud is alleged by a government agency with jurisdiction over the pharmacy." *Id.* In the proposed California regulations, the pharmacy must maintain the quality assurance review records for one year. *Proposed Addition of Title 16, Section 1711, Quality Assurance Programs,* (visited October 9, 2001) < http://www. pharmacy.ca.gov/pdfs/1711_15_day_ notice2.pdf>[citing proposed CAL. CODE REGS. tit. 16, § 1711].

California's approach is consistent with the Medication Error Task Force's findings. California requires an on-going quality assurance program within a pharmacy, without requiring mandatory external reporting. The statute allows the California Board of Pharmacy to review the quality assurance records to protect the public health. This is an important point because without this authority the Board would not be able to ensure that a proper quality assurance program was being operated by a pharmacy.

The California statute only protects records generated and maintained as a part of the on-going quality assurance program, and does not protect all records. This too is important because not all pharmacy records should be protected. If an injury is caused by a medication error the patient should be able to obtain her prescription records and use those records in a lawsuit. California's law makes this clear when it states that "[n]othing in this section shall be construed to prohibit a patient from accessing his or her own prescription records." *Id.*

Texas takes a similar approach to the quality assurance programs. *Chapter 554. Board Powers and Duties; Rulemaking Authority*, (visited October 9, 2001) < http://www.capitol.state.tx.us/statutes/oc/oc055400.html#oc002.554.002> [citing TEX.[OCC] CODE ANN §554.002 (West 2001 pamphlet)]. It does not require external reporting. Texas also makes the records generated pursuant to a quality assurance program non-discoverable. *Id.* Many other states are addressing the issue of medication and medical errors as well, including Florida, Massachusetts, Minnesota and New York.

If protection is provided for records that are maintained pursuant to a quality assurance program, the protection should be extended so that if a quality assurance program shares its records with another quality assurance program for the purpose of reducing errors, the protection from discoverability is not lost. The I.O.M. report recommended the following.

> Congress should pass legislation to extend peer review protection to data related to patient safety and quality improvement that are collected and analyzed by healthcare organizations for internal use or shared with others solely for the purpose of improving safety and quality.

INSTITUTE OF MEDICINE, *To Err is Human: Building a Safer Health System*, pgs 111-112 (National Academy Press 2000)[emphasis added]. USP agrees with this position.

> Reporting systems should facilitate the sharing of patient safety information among healthcare organizations and foster confidential collaboration with other healthcare reporting systems.

USP, *General Principles for Patient Safety Reporting Systems*, (visited October 15, 2001) < http://www.usp.org/ frameset.htm?http://www.usp.org /patient_safety.htm>[When information is reported to governmental agencies, USP also advocates exempting error reports from the Freedom of Information Act, to ensure complete confidentiality]. Protection of quality assurance information that is shared with other entities for the purpose of reducing errors is important, whether in federal or state law. Texas attempts to address this issue in several provisions.

> (c) Except as otherwise provided by this section, all proceedings and records of a pharmacy peer review committee are confidential, and all communications made to a pharmacy peer review committee are privileged.

…

> (f) Unless disclosure is required or authorized by law, records or determinations of or communications to a pharmacy peer review committee are not subject to subpoena or discovery and are not admissible as evidence in any civil judicial or administrative proceeding without waiver of confidentiality executed in writing by the committee….

Chapter 554. Board Powers and Duties; Rulemaking Authority, (visited October 9, 2001) <http://www.capitol.state.tx.us/statutes/oc/oc055400.html#oc002.554.002> [citing TEX.[OCC] CODE ANN §554.002 (West 2001 pamphlet)].

It is important to provide protection from certain discoverability for quality assurance records so that pharmacies may document and review, in detail, system flaws in an attempt to reduce medication and other errors. This protection must be provided by the legislature. Without these protections from discoverability, but with the need to

address medication errors, the Board is promulgating limited regulations to address this issue.

- Mandatory Reporting Does Not Reduce Adverse Events

Mandatory reporting programs for adverse events presently exist with consistently low reporting numbers. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has operated a Sentinel Event Program since 1995. If a healthcare organization is accredited by the JCAHO it is "encouraged" to self-report sentinel events to JCAHO. JCAHO, *Facts about The Sentinel Event Policy* (visited October 16, 2001)<www.jcaho.com/ sentinel/se_fact.html>. Health care organizations view this reporting as mandatory because heavy sanctions can be levied if proper procedures are not followed, including sanctions of up to $3,500 a day for "for cause" surveys, and loss of accreditation. *Id.* As of August 30, 2001, JCAHO has reviewed 1,398 sentinel event reports through their national reporting program. JCAHO, *Sentinel Event Statistics-August 30, 2001* (visited October 9, 2001) <www.jcaho.com/sentinel/ se_stats. html>. This is in sharp contrast to the 98,000 estimated fatalities reported by certain studies, as reported in the I.O.M. report, *To Err is Human*. INSTITUTE OF MEDICINE, *To Err is Human: Building a Safer Health System,* pg 26 (National Academy Press 2000).

Requiring that health care professionals report themselves to their own licensing Board will be ineffective. It is analogous to a driver reporting to the police that he has been speeding, so that the police may give the driver a speeding ticket or revoke the driver's license. Licensees will not report speeding, or adverse medical events. The events will not be reported to the licensing Board, and most probably, will not be reported to the health care entity's quality assurance program. If the events are essentially "swept under the rug" the systems-review approach will be ineffective, and the system will not be improved, to the benefit of the patient.

The Task Force does not oppose mandatory reporting but it feels that due to under-reporting, it does not provide an adequate amount of useful information. The Task Force would not recommend mandatory reporting because it believes that it will quell error reporting. If mandatory reporting is required, it must be coupled with protection from discoverability and a non-punitive approach to addressing the reported errors. Additionally, if mandatory external reporting is required, cost of implementing and operating a program must be considered, and structures must be established to collect, analyze and disseminate information in a timely manner.

Open and complete error reporting by those directly involved in the event and review of adverse events by those directly in charge of the particular health care delivery system will cause system improvement to occur. Because systems vary among institutions and pharmacies, reporting to a committee within a health care entity or particular pharmacy is most appropriate because each can modify its particular system to reduce medication errors. This type of reporting is called "internal reporting." It is of tantamount importance that health care practitioners 'buy-in' to the reporting process and

its ultimate goal, otherwise open reporting will not occur. Incentives to report must be established to create 'buy-in'. Incentives can include the lure of creating a safer environment for patients and staff. Showing that the information is used to improve the system can foster practitioner 'buy-in'. Protection from discoverability will encourage practitioner buy-in as well.

Therefore the Medication Error Task Force recommended to the Board that a non-punitive, voluntary, internal reporting approach should be used when addressing medication errors. This does not mean that the Board will take a hands-off approach. Weighing what information the Board may be privy to in order to protect the public health with the need to foster open reporting is a difficult issue. The Board must monitor programs and provide guidance where appropriate. The Board believes it has addressed these issues appropriately in the limited regulations it is presently promulgating based on the Task Force's recommendations.

Present Status of Proposed Regulations

The Medication Error Task Force recommended that the Board implement regulations relating to medication errors with the understanding that a systems-approach to addressing medication errors must be the basis of any regulation. The Medication Error Task Force, along with the Pharmacy Practice Committee of the Board, drafted proposed regulations entitled "Patient Safety Improvement." The regulations, which have been approved by the Board for publication and are in the process of promulgation, include:

- Requiring that pharmacy permit holders provide patients with education related to the patient's role in preventing medication errors;

- Requiring that permit holders ensure that their staff receive annual education and training on their role in preventing medication errors; and

- Requiring permit holders to have:

  —A documented quality assurance program that includes a process to identify, investigate and promote the prevention of medication errors, and

  —Policies and procedures for minimizing the potential for medication errors involving "high alert" medications.

It is important to note that these requirements should only be established in regulation, as opposed to legislation, so that if necessary, particular requirements may be adjusted to improve their effect.

During the development of these regulations, it came to light that certain legislation would be required to fully implement the Task Force's recommendations. The

legislation would address the issue of non-discoverability of quality assurance records in non-institutional pharmacies. Unless quality assurance and internal error reporting program records are protected from discovery, meaningful data collection and error reporting will not occur for the reasons described above.

CONCLUSION

The Medication Error Task Force was charged with recommending strategies that the Board should utilize to reduce the incidence and severity of medication errors in Maryland. After meeting for over two years and considering numerous possible actions that the Board could pursue, the Board accepted three of the Task Force's recommendations.

The first recommendation is that medication error prevention education for both consumers and pharmacy practitioners is essential.[8] The issue of medication errors cannot be properly addressed if the parties affected do not understand the problem. The Board has, and will continue to, dedicate resources to the ongoing dissemination of relevant educational materials.

Secondly, a non-punitive approach should be applied when medication errors are reported to the Board. The Board is resolved to improving medication systems by reviewing each incident to find potential system defects that may have contributed to the error. Through the use of an informal meeting process and exchange of information, the Board ensures appropriate corrective action is taken to reduce the incidence and severity of medication errors. The Board, however, does take disciplinary action when warranted.

The third recommendation of the Task Force is that mandatory pharmacy quality assurance programs designed to address medication errors be required. Medication errors can be reduced by these action-oriented quality assurance programs that focus on a systems-approach, as opposed to a punitive approach. With an effective action-oriented systems approach to reducing medication errors, the system failure that caused the event will be corrected, hopefully before a patient ever receives an inappropriate medication. If a patient does receive an inappropriate medication, a systems-approach will correct the failure before other patients are affected. A punitive approach may remove a pharmacist from the system but will not necessarily correct a systems failure, and patients may continue to be adversely effected by the same system flaw despite the disciplining of a practitioner.

In order to have an effective action-oriented quality assurance program, health care practitioners must 'buy-in' to the system. Practitioner 'buy-in' will not occur if

[8] The recommendation is limited to pharmacies and pharmacy staff, because the Board regulates these aspects of the health care delivery system. The Task Force found that the whole health care delivery system should be reviewed, because errors are the break down of a complete system, not necessarily the fault of a specific practitioner. This is why the Task Force originally recommended to the Board that it request the Secretary of Health and Mental Hygiene to convene a multidisciplinary task force, to review all points within the health care delivery system.

mandatory external reporting is required. Because settings vary greatly, the best approach is to ensure that each pharmacy has, or is involved in, an appropriate action-oriented quality assurance program that is focused on the specific system that gave rise to the error. The program should be operated by the individual pharmacy or health care entity and practitioners should voluntarily report to the program, which is why practitioner 'buy-in' is important. The reporting should be internal to foster full and complete reporting. Sharing of quality assurance information between quality assurance programs should also be fostered, by protecting shared information from discoverability.

In order to allow for 'buy-in' and therefore open reporting and effective quality assurance programs in many pharmacies, non-discoverability laws must be enacted, or existing law must be expanded to address community settings. This requires legislation. Many efforts to address the issue of medication error reduction focus on institutional settings, without addressing the non-institutional settings.[9] Any law that is created must address non-institutional settings and must protect, not only the quality assurance records that are maintained by a pharmacy, but also those records that are shared between programs for the purpose of quality assurance.

Despite these findings, the Board cannot take a hands-off approach. The Board must ensure that appropriate quality assurance programs are established. The Board therefore must require through regulation certain elements of a quality assurance program, and then the Board must be able to review certain records to ensure compliance with the Board's regulations.

The most effective way to reduce adverse medication events is to stop adverse events before they occur, which requires an action-oriented, systems-review approach to reviewing a health care entity's health care delivery system. More than mere data collection must occur. As was discussed above, self-reporting to a licensing Board will not be an effective tool in reducing adverse medical events because practitioners will not self-report all events. This is particularly true because there may be no legal protection of the information collected by a pharmacy, when information is in the pharmacy, prior to any reporting.

The Board of Pharmacy would like to thank the Joint Committee on Health Care Delivery and Financing for the opportunity to address it, and it looks forward to working with the Committee in the future on this and other pharmacy-related issues. The Board would also like to thank all of the dedicated participants on the Medication Error Task Force for working diligently to promote the reduction of medication errors.

cc: The Honorable William H. Cole IV
The Honorable John P. Donoghue
The Honorable Brian K. McHale
The Honorable Mark K. Shriver

[9] Protection is needed in many non-institutional settings, including community pharmacies and potentially physicians' offices. The Task Force did not specifically review the status of physicians' offices.

Josie Ogaitus, Executive Director, Office of Governmental Affairs, Department of Health and Mental Hygiene

APPENDIX A

ERROR DATA COLLECTION FORM

Case# _____
Date _____
Name of person completing form_____
Pharmacy Name (Store #, if applicable)_____
Name(s) of Pharmacists involved with medication error, include license number
_____
_____
_____
Names(s) of Pharmacist(s) that corrected error, include license number
_____
_____
Date and time of day error occurred_____
Date and time of day error was discovered_____
Type of Error (Check any that apply)

__Wrong Drug _____Wrong Strength _____Wrong Directions
____Wrong Dosage Form _____Wrong Patient _____Switched Labels
_____Missed Allergy or Drug Interaction _____ Expired Medication
_____Other
*explain_____
_____

_____New Rx _____Refill Rx

Consequence of Error

_____Patient did not use medication
_____Patient used medication*no harm resulted
_____Patient used medication* treatment or increased monitoring resulted (explain)
_____Patient used medication***..serious harm resulted (explain)

If Patient Used Medication***

1. Describe follow up by pharmacist/pharmacy with patient, physician or prescriber.

_____

_____

_____

_____

2. Briefly describe the prescription-filling process from receiving order/prescription to dispensing. Use diagrams if appropriate. You may attach a copy of the policies regarding dispensing procedures.

3. At what point(s) in the prescription filling process did the error take place?

_____

_____

Causes and Contributing Factors

Please check all that apply. Briefly explain
_____Policies and Procedures not followed
_____Lack of Training of Pharmacist
_____Lack of Training of Support Personnel
_____Knowledge Deficit (lack of clinical intervention/review)
_____Equipment Failure

_____Environmental Factors (lighting, noise, interruptions, distractions, phone calls, lack of workspace)
_____Handwriting/Legibility (please attach photocopy of prescription)
_____Look-Alike-Sound-Alike Medications
_____Increased Rx volume (compared to usual)
_____Insufficient Staff
_____Shift Change
_____Computer Software (defaults, lack of alerts/screening, DUR's)
_____Lack of Adequate Counseling
_____Prescription Pick-Up Procedures (verify name)
_____Medication Storage and Organization

_____ Other

Briefly describe:
_____
_____
_____
_____
_____
_____
_____

Was the error initiated by Pharmacy support personnel ? _____ Yes _____No
If yes, explain:

Was the prescription checked by a pharmacist? _____ Yes _____No
What are the pharmacy operation hours? _____
Number of Rx filled on the day error occurred_____
Number of pharmacists at the time the error occurred_____
Number of support personnel (include technicians and clerks/cashiers)at the time the error occurred_____

Does the pharmacy have an automated dispensing system? _____ Yes _____ No
If yes, describe_____

Was/were the pharmacist(s) responsible for the error a permanent staff member or a "floater" or "relief" pharmacist?_____

How long has the pharmacist(s) responsible for the error been employed by the permit holder?
_____

Does the Pharmacy (or Company) have a written policy that all errors be documented and reported internally? _____
Was an Internal report filed concerning this error?
_____

What processes have been changed to avoid a repeat
error?_____
_____

APPENDIX B

THE PRESENT STATUTE

§ 14-501.

(a) (1) In this section the following words have the meanings indicated.

(2) (i) "Alternative health care system" means a system of health care delivery other than a hospital or related institution.

(ii) "Alternative health care system" includes:

1. A health maintenance organization;

2. A preferred provider organization;

3. An independent practice association;

4. A community health center that is a nonprofit, freestanding ambulatory health care provider governed by a voluntary board of directors and that provides primary health care services to the medically indigent; or

5. Any other health care delivery system that utilizes a medical review committee.

(3) "Medical review committee" means a committee or board that:

(i) Is within one of the categories described in subsection (b) of this section; and

(ii) Performs functions that include at least one of the functions listed in subsection (c) of this section.

(4) (i) "Provider of health care" means any person who is licensed by law to provide health care to individuals.

(ii) "Provider of health care" does not include any nursing institution that is conducted by and for those who rely on treatment by spiritual means through prayer alone in accordance with the tenets and practices of a recognized church or religious denomination.

(5) "The Maryland Institute for Emergency Medical Services Systems" means the State agency described in § 13-503 of the Education Article.

(b) For purposes of this section, a medical review committee is:

(1) A regulatory board or agency established by State or federal law to license, certify, or discipline any provider of health care;

(2) A committee of the Faculty or any of its component societies or a committee of any other professional society or association composed of providers of health care;

(3) A committee appointed by or established in a local health department for review purposes;

(4) A committee appointed by or established in the Maryland Institute for Emergency Medical Services Systems;

(5) A committee of the medical staff or other committee, including any risk management, credentialing, or utilization review committee established in accordance with § 19-319 of the Health - General Article, of a hospital, related institution, or alternative health care system, if the governing board of the hospital, related institution, or alternative health care system forms and approves the committee or approves the written bylaws under which the committee operates;

(6) Any person, including a professional standard review organization, who contracts with an agency of this State or of the federal government to perform any of the functions listed in subsection (c) of this section;

(7) Any person who contracts with a provider of health care to perform any of those functions listed in subsection (c) of this section that are limited to the review of services provided by the provider of health care;

(8) An organization, established by the Maryland Hospital Association, Inc. and the Faculty, that contracts with a hospital, related institution, or alternative delivery system to:

(i) Assist in performing the functions listed in subsection (c) of this section; or

(ii) Assist a hospital in meeting the requirements of § 19-319(e) of the Health - General Article;

(9) A committee appointed by or established in an accredited health occupations school;

(10) An organization described under § 14-501.1 of this subtitle that contracts with a hospital, related institution, or health maintenance organization to:

(i) Assist in performing the functions listed in subsection (c) of this section; or

(ii) Assist a health maintenance organization in meeting the requirements of Title 19, Subtitle 7 of the Health - General Article, the National Committee for Quality Assurance (NCQA), or any other applicable credentialing law or regulation;

(11) An accrediting organization as defined in § 14-501.1 of this subtitle; or

(12) A Mortality Review Committee established under § 5-801 of the Health - General Article.

(c) For purposes of this section, a medical review committee:

(1) Evaluates and seeks to improve the quality of health care provided by providers of health care;

(2) Evaluates the need for and the level of performance of health care provided by providers of health care;

(3) Evaluates the qualifications, competence, and performance of providers of health care; or

(4) Evaluates and acts on matters that relate to the discipline of any provider of health care.

(d) (1) Except as otherwise provided in this section, the proceedings, records, and files of a medical review committee are not discoverable and are not admissible in evidence in any civil action.

(2) The proceedings, records, and files of a medical review committee are confidential and are not discoverable and are not admissible in evidence in any civil action arising out of matters that are being reviewed and evaluated by the medical review committee if requested by the following:

(i) The Department of Health and Mental Hygiene to ensure compliance with the provisions of § 19-319 of the Health - General Article;

(ii) A health maintenance organization to ensure compliance with the provisions of Title 19, Subtitle 7 of the Health - General Article and applicable regulations;

(iii) A health maintenance organization to ensure compliance with the National Committee for Quality Assurance (NCQA) credentialing requirements; or

(iv) An accrediting organization to ensure compliance with accreditation requirements or the procedures and policies of the accrediting organization.

(3) If the proceedings, records, and files of a medical review committee are requested by any person from any of the entities in paragraph (2) of this subsection:

(i) The person shall give the medical review committee notice by certified mail of the nature of the request and the medical review committee shall be granted a protective order preventing the release of its proceedings, records, and files; and

(ii) The entities listed in paragraph (2) of this subsection may not release any of the proceedings, records, and files of the medical review committee.

(e) Subsection (d)(1) of this section does not apply to:

(1) A civil action brought by a party to the proceedings of the medical review committee who claims to be aggrieved by the decision of the medical review committee; or

(2) Any record or document that is considered by the medical review committee and that otherwise would be subject to discovery and introduction into evidence in a civil trial.

(f) A person shall have the immunity from liability described under § 5-637 of the Courts and Judicial Proceedings Article for any action as a member of the medical review committee or for giving information to, participating in, or contributing to the function of the medical review committee.

(g) Notwithstanding this section, §§ 14-410 and 14-412 of this title apply to:

(1) The Board; and

(2) Any other entity, to the extent that it is acting in an investigatory capacity for the Board.

MD. CODE ANN., HEALTH OCC., §14-501 (2000).