



**Report on Analysis of
Quality Related Events (Medication Errors)**

**Reviewed by the
Massachusetts Board of Registration in Pharmacy
January 1, 2004 - December 1, 2004**

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Table of Contents

I. Introduction.....	3
II. Historical Perspective.	5
A. Best Practice Initiative	
B. New Pharmacy Board Regulations Requiring Continuous Quality Improvement Programs	
III. Analysis and Findings.....	6
A. Results by Category of Event	
B. Results by Type of Error	
C. Corrective Actions	
IV. Conclusions and Recommendations.....	11
A. Conclusions	
B. Recommendations	
V. Acknowledgements.....	13
VI. Appendices.....	13
Appendix A	
Best Practice Recommendations to Promote Optimum Pharmaceutical Care in the Commonwealth of Massachusetts - Massachusetts Board of Registration in Pharmacy	14
Appendix B	
247 CMR 15.00: Continuous Quality Improvement Program	24
Appendix C	
Massachusetts Board of Registration in Pharmacy, August 2004 newsletter article: “Mix-ups in Zantac/Zyrtec”	27
Appendix D	
Analysis of Quality Related Events (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy January 1, 2004 - December 1, 2004	28

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I. Introduction

The mission of the Massachusetts Board of Registration in Pharmacy (Board) is to promote, preserve, and protect the public health, safety, and welfare by promoting the provision of quality pharmaceutical care to the citizens of Massachusetts through the regulation of pharmacy practice, community pharmacies, and the distribution of prescription drugs in the public interest. The Board assumes a leadership role in regulating the practice of pharmacy and acts in accordance with the highest standards of ethics, accountability, efficiency, effectiveness, and openness.

Chapter 149 of the Acts of 2004 (Fiscal Year 2005 Budget) requires the Board to prepare a compilation of cases involving preventable medical error reports received by the board that resulted in harm to a patient or health care provider for the purpose of assisting health care providers, hospitals and pharmacies to modify their practices and techniques to avoid error. The Board is statutorily mandated to protect the public health, safety and welfare through the licensure of community pharmacies and pharmacists, registration of pharmacy interns and technicians, and regulation of the practice of pharmacy. The Board licenses community pharmacies pursuant to M.G.L. c. 112, ss. 37-39 and 247 CMR 6.00. The Board currently licenses approximately 1,042 community (retail) pharmacies; seven nuclear pharmacies; 9,940 pharmacists; 6,200 pharmacy technicians and 65 wholesale drug distributors.

Community pharmacies are not required by statute to report medication errors to the Board; therefore, the analysis presented in this report is of consumer complaints received and reviewed by the Board between January 1, 2004 and December 1, 2004. Complaints were reviewed to identify those that involved a medication error meeting the definition of a Quality Related Event as set forth in the Board regulation 247 CMR 15.01. A Quality-Related Event or QRE means the incorrect dispensing of a prescribed medication that is received by a patient, including:

- (a) a variation from the prescriber's prescription order, including, but not limited to:
 - 1. dispensing an incorrect drug;
 - 2. dispensing an incorrect drug strength;
 - 3. dispensing an incorrect dosage form;
 - 4. dispensing the drug to the wrong patient; or
 - 5. providing inadequate or incorrect packaging, labeling, or directions; or
- (b) a failure to identify and manage:
 - 1. over-utilization;
 - 2. therapeutic duplication;
 - 3. drug-disease contraindications;
 - 4. drug-drug interactions;
 - 5. incorrect drug dosage or duration of drug treatment;
 - 6. drug-allergy interactions; or
 - 7. clinical abuse/misuse.

Complaints that involved regulatory violations such as continuing education deficiencies, controlled substance violations, or allegations of unprofessional conduct, or any other complaint that did not include practice issues meeting the definition of a QRE were excluded from analysis for this report. Reports involving hospital/institutional and clinic pharmacies were also excluded from the analysis since those pharmacies are licensed by the Massachusetts Department of Public Health Division of Health Care Quality and operate under a separate regulatory framework with different reporting requirements administered by the Division of Health Care Quality.

Thirty-nine (39) consumer complaints were found to involve a QRE, as defined above. Those thirty-nine (39) cases were separated into the following four Categories of Events:

1. **Potential to Cause Harm (P):** Dispensing error that reached the patient with no ingestion.
2. **Ingestion with No Harm (I):** Dispensing error that reached the patient with ingestion and no harm resulting.
3. **Ingestion with Harm (IH):** Dispensing error that reached the patient with ingestion and harm resulting.
4. **Sentinel Event (S):** Dispensing error that reached the patient with ingestion and serious permanent harm or death to the patient resulting.

After being separated by Category of Event, the complaints were classified by the Type of Error made during prescription preparation and/or dispensing. Each complaint (hereinafter referred to as “case”) was also examined to gain a broader understanding of the error and to determine corrective measures taken by the pharmacy and pharmacist(s) in response to the error.

The Board believes the findings of this report provide valuable insights into the nature of medication errors which occurred within community based pharmacies licensed by the Board. The findings of this report will also be useful in guiding the Board in its efforts to protect the public health, safety and welfare through the development and promotion of initiatives that educate pharmacy professionals as to the need for and benefits of Continuous Quality Improvement (CQI) programs.

We wish to recognize the thousands of community pharmacy professionals who provide Massachusetts citizens with vitally important pharmaceutical services every day and who provide clinical leadership in the movement to develop safer practices and better pharmaceutical therapies. More than eighty-three million prescriptions were dispensed in Massachusetts in 2003¹ and certainly the vast majority of those services were delivered without incident. The thirty-nine (39) complaints involving medication errors that form the basis of this report are miniscule in comparison to the millions of prescriptions dispensed, without incident, in Massachusetts every year. Nevertheless, we hope that the findings of this report provide a greater understanding of issues involved in prescription preparation and delivery and lead to development of strategies to prevent errors. To that end, we urge pharmacy profession leaders to not only review this report for their own benefit, but to widely distribute it within their pharmacies so that all staff may benefit from knowledge of factors contributing to the medication errors discussed in this report. These case analyses should be used as a benchmark from which pharmacists examine current practices in their particular pharmacy to identify areas where changes or additional safeguards may be appropriate to prevent the occurrence of similar errors.

¹ Pharmacy Journal of New England, Volume 2, Number 2, 2005.

This report may be accessed on the Board's web site at www.state.ma.us/dph/boards/. Notice of the release of this report will be sent to Massachusetts community pharmacies, hospitals, pharmacy associations and patient safety organizations, including the Betsy Lehman Center for Patient Safety and Medical Error Reduction and the Massachusetts Coalition for the Prevention of Medical Errors.

II. Historical Perspective

Patient safety is at the forefront of concern for all healthcare providers and institutions providing services to patients. The spotlight on patient safety evolved from lessons learned from tragic events that resulted in a call for cultural change throughout the healthcare industry. The benchmark report TO ERR IS HUMAN: Building a Safer Health System issued by the Institute of Medicine (IOM) Quality of Health Care in America Committee² (the "IOM Report") in 1999 identified and quantified the need to focus on preventable medical errors and system processes as the cause of many errors. In Massachusetts, the Betsy Lehman Center for Patient Safety and Medical Error Reduction and the Massachusetts Coalition for the Prevention of Medical Errors were established to improve patient safety and reduce the incidence of medical errors by developing and disseminating best practices and by facilitating the exchange of information about initiatives under development to improve patient care.

The IOM Report and other studies have focused on medical errors (including medication errors) that occurred in hospitals, which represents only a portion of the varied settings where health care services are provided. Community pharmacies are an integral part of the health care delivery system providing patients with critically important services and counseling for safe and proper medication use.

Major initiatives of the Board that promote the highest standards of pharmacy practice in the Commonwealth include:

A. Best Practice Initiative

In 2000, the Board convened an advisory committee to make recommendations to the Board regarding CQI initiatives that could be implemented in all pharmacy practice settings to promote optimum pharmaceutical care. Participants in the Board's CQI Advisory Committee included Board members and representatives from institutional and retail pharmacy settings, professional associations, and schools/colleges of pharmacy, the Massachusetts Coalition for the Prevention of Medical Errors, the Department of Public Health and related regulatory agencies.

The CQI Advisory Committee developed a set of **Best Practice Recommendations** that could be implemented in various pharmacy settings according to the particular needs, available resources, and community served by the pharmacy. These recommendations were developed following a review of current literature on medication dispensing systems and research on the incidence and causes of medication errors, as presented by the Board's Quality Assurance Surveyor and CQI Advisory Committee Chairman (a member of the Board). The Board has disseminated the Best Practice Recommendations to the regulated community at various educational forums statewide and continuously updates the recommendations as additional pharmacy practice patterns, high-risk error areas, and technology benefits/challenges are identified.

A summary of the Best Practice Recommendations issued by the Board is provided in Appendix A of this report and may be viewed at www.gov/dph/boards/ph/index.htm

² Institute of Medicine, *To Err is Human: Building a Safer Health System*, National Academy Press, 2000

B. New Pharmacy Board Regulations Requiring Continuous Quality Improvement Programs

The Board believes that establishing CQI Programs in pharmacies is key to reducing the incidence of errors. Consequently, the Board promulgated new regulations (247 CMR 15.00) that require pharmacies licensed by the Board to establish CQI Programs for the purpose of detecting, documenting, assessing and preventing Quality Related Events (QREs). Pharmacies licensed by the Board are required to implement CQI Programs by December 31, 2005. CQI Program regulations are provided in Appendix B of this report and may be viewed at http://www.mass.gov/dph/boards/ph/rule_reg.htm

At a minimum, as required by 247 CMR 15.02(1), a pharmacy CQI program must include provisions to:

1. designate an individual or individuals responsible for monitoring CQI Program compliance with the requirements of 247 CMR 15.00;
2. identify and document QREs;
3. minimize impact of QREs on patients;
4. analyze data collected in response to QREs to assess causes and any contributing factors;
5. use the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs; and
6. provide ongoing professional education at least annually in the area of CQI to pharmacy personnel.

III. Analysis and Findings

A. Results by Category of Event

A breakdown by Category is presented below for the thirty-nine (39) consumer complaints analyzed.

Category 1: Potential to Cause Harm (P) - Dispensing error that reached the patient with no ingestion.

Seven (7) of thirty-nine (39) cases reviewed were characterized as involving Potential To Cause Harm to the patient. Three (3) of these cases involved the dispensing of incorrect medication; three (3) involved incorrect strength; and one (1) involved incorrect directions. In all of these cases, the QRE was discovered prior to any ingestion by the patient. Actual impact on patient(s) was determined to be at a level of minimal inconvenience that did not cause disruption in planned treatment for the patient. In one case (Case #1/Appendix D), Lipitor 10mg was prescribed and Lisinopril 10mg was dispensed. Lipitor is used to lower cholesterol levels and Lisinopril 10mg is used to control elevated blood pressure levels (hypertension). Although the patient did not ingest the medication, the potential for harm existed because ingestion of the incorrect medication for an extended period of time would have compromised the intended prescribed treatment for this patient.

Category 2: Ingestion with No Harm (I) - Dispensing error that reached the patient with ingestion and no harm resulting.

Seven (7) of the thirty-nine (39) cases reviewed were characterized as involving Ingestion With No Harm to the patient. Five (5) of these cases involved ingestion of the incorrect medication for a range

of 2 to 30 days and two (2) cases involved ingestion of the incorrect strength of the prescribed medication for a range of 1 to 30 days. All of these cases involved a temporary impact on the intended treatment but did not require a medical intervention. For example, a prescription for Zantac Syrup was dispensed with Albuterol Syrup to a four-month-old infant (Case #11/Appendix D). Zantac is a medication utilized for gastrointestinal conditions and Albuterol is used to treat asthma. Although ingestion occurred for a three-day period without negative consequences in this case, the intended therapy was disrupted and the patient was exposed to an unintended medication with potential risk.

Category 3: Ingestion with Harm (IH) -Dispensing error that reached the patient with ingestion and short term reversible harm resulting.

Twenty-three (23) of the thirty-nine (39) cases reviewed were categorized as involving Ingestion With Harm requiring treatment intervention. The ingestion resulted in reversible short-term harm that adversely affected intended treatment or required medical intervention. Medical interventions included emergency room visits or revisits to the physician's office to address mild to moderate side effects resulting from disruption in planned treatment. Nine (9) of these cases involved ingestion of the incorrect medication for a range of 1 to 30 days; nine (9) cases involved the dispensing of a prescription with the incorrect strength with ingestion for a range of 1 to 60 days; two (2) cases involved the dispensing of a medication with incorrect directions with ingestion for 7 and 14 days; one (1) case involved ingestion of an incorrectly labeled prescription with ingestion for 14 days; one (1) case involved dispensing a medication to the incorrect patient with ingestion for one (1) day; and one case involved dispensing a prescription to a patient with a known allergy to medication. In one case (Case #13/Appendix D), a prescription for Tegretol 100mg was incorrectly dispensed with Tegretol 200mg to a six-year old. Tegretol is an anticonvulsant medication indicated for the treatment of seizures. Ingestion of a two-fold increased dose occurred over a two-day period. On the third day, a 911 call was placed for severe toxicity symptoms requiring admission to an emergency room for observation and treatment. Patients involved in these events received medical interventions and appropriate treatment in time to avoid any long-term adverse health affects.

Category 4: Sentinel Event (S) - Dispensing error that reached the patient with ingestion and serious permanent harm or death to the patient resulting.

Two (2) of the thirty-nine (39) cases reviewed were categorized as involving a Sentinel Event. In one case (Case #2/Appendix D), a prescription for Cardura (doxazosin) 4mg was incorrectly dispensed with Coumadin (warfarin) 4mg. Cardura is indicated for the control of hypertension and Coumadin is used for anticoagulation (blood thinning). A 69-year-old patient incorrectly received a blood thinning medication instead of high blood pressure medication for approximately one (1) month. The patient was admitted to an emergency room and hospitalized for five (5) days for side effects related to Coumadin toxicity. The second case in this category involved the dispensing of medication to a patient with a known allergy to the dispensed medication involving an anti-inflammatory agent. All cases in this category resulted in extended hospitalization with long-term health consequences for the patients.

A more detailed summary of each case is provided in Appendix D of this report.

B. Results by Type of Error

Cases were also classified by Type of Error, which includes incorrect medication, incorrect strength, incorrect directions, incorrect labeling, incorrect patient, and failure to verify allergy. Additionally, the cases were analyzed to identify the probable contributors to the error, such as sound-alike or look-alike medications, failure to correctly verify prescription, or failure to perform an adequate drug utilization review (DUR). The breakdown of cases by Type of Error follows:

1. Incorrect Medication – eighteen (18) cases were classified as a prescription dispensed with the incorrect medication.

- Ten (10) of these eighteen (18) cases involved sound-alike or look-alike medications as follows:
 - Amaryl 2mg rather than Avandia 2mg
 - Chlorpropamide rather than Chlorpromazine
 - Coumadin 4mg rather than Cardura 4mg
 - Lisinopril 10mg rather than Lipitor 10mg
 - Neurontin rather than Zarontin
 - Prilosec 10mg rather than Prozac 10mg
 - Sprintec rather than Tri-Sprintec
 - Zantac Syrup rather than Zyrtec Syrup
 - Zyrtec Syrup rather than Zantac Syrup (2 cases)

- Eight (8) of these eighteen (18) cases involved a failure to correctly verify prescription as follows:
 - Albuterol Syrup rather than Zantac Syrup
 - Alprazolam rather than Vioxx
 - Dilantin 100mg rather than Phenytoin 100mg
 - Doxycycline rather than Darvocet
 - Methocarbamol rather than Relafen
 - Monopril rather than Serzone
 - Toprol XL 100mg rather than Seroquel 100mg
 - Trihexyphenidyl rather than Fluphenazine

- Five (5) of these eighteen (18) cases (also included in the above categories) involved age specific dosing for children that resulted in the child receiving higher than recommended doses of the incorrectly dispensed medication. They include:
 - Albuterol Syrup rather than Zantac Syrup
 - Neurontin rather than Zarontin
 - Zantac Syrup rather than Zyrtec Syrup
 - Zyrtec Syrup rather than Zantac Syrup (2 cases)

2. Incorrect Strength – Fourteen (14) cases were classified as a prescription dispensed with the incorrect strength.

- Nine (9) of these fourteen (14) cases involved a drug with the same name as the prescribed drug but the incorrect strength of the medication was dispensed, as follows:
 - Atenolol 50mg rather than Atenolol 25mg
 - Ativan 1mg rather than Ativan 0.5mg
 - Clonazepam 1mg rather than Clonazepam 0.5mg
 - Epi-Pen Adult 0.3mg rather than Epi-Pen Junior 0.15mg
 - Haldol 5mg rather than Haldol 0.5mg
 - Zonegran 100mg rather than Zonegran 25mg
 - Phenobarbital 64.8mg rather than Phenobarbital 32.4mg
 - Tegretol 200mg rather than Tegretol 100mg
 - Wellbutrin SR 150mg rather than Wellbutrin 100mg

- Five (5) of these fourteen (14) cases involved failure to correctly verify prescription before dispensing, as follows:
 - Augmentin Suspension inadequate reconstitution
 - Cefzil Suspension inadequate reconstitution
 - Hydroquinone 4% with sunscreen rather than Hydroquinone 4% plain
 - Nitroglycerin 2% ointment rather than Nitroglycerin 0.2% ointment
 - Zithromax Suspension inadequate reconstitution

- Five (5) of these fourteen (14) cases (also included in the above categories) involved age specific dosing for children resulting in the child receiving the incorrect strength of the prescribed medication, as follows:
 - Augmentin Suspension inadequate reconstitution
 - Epi-Pen Adult 0.3mg rather than Epi-Pen Jr. 0.15mg
 - Tegretol 200mg rather than Tegretol 100mg
 - Zithromax Suspension inadequate reconstitution
 - Zonegran 100mg rather than Zonegran 25mg

3. Incorrect Directions – Three (3) cases were classified as a prescription dispensed with incorrect directions. All three (3) of these cases involved failure to correctly verify prescription directions, as follows:

- Allopurinol 300mg, Take 4 tablets daily rather than 1 tablet daily
- Clonazepam 0.5mg, Take 4 tablets at bedtime rather than 6 tablets at bedtime
- Paxil 40mg, Take 2 tablets daily rather than 1 tablet daily

4. Incorrect Labeling – Two (2) cases were classified as incorrect labeling of a prescription. One case involved a failure to correctly verify two prescriptions for the same patient. Specifically, a Carafate prescription was labeled with Protonix directions and vice versa for the Protonix prescription. As a result, the patient ingested both medications in incorrect amounts for a two-week period prior to discovery. The second case (Case #9/Appendix D) involved two types of errors, specifically, incorrect labeling on a prescription that was also dispensed to the incorrect patient. In this case, the medication Zithromax suspension was both incorrectly labeled and incorrectly dispensed to a 5-year old patient.

5. Incorrect Patient - One (1) case was classified as a prescription dispensed to the incorrect patient. This case involved a failure to perform an adequate drug utilization review (DUR) involving a prescription with age specific dosing; specifically, a prescription for Zithromax suspension with a 600mg dose (adult dose) was dispensed rather than the prescribed 190mg (pediatric dose) to a 5 year-old child. Although the correct labels specific to the adult and child patients were generated, an error occurred during the label placement process resulting in the correct label being placed on the packaging box (child's label) and an incorrect label being placed on the actual suspension bottle inside the box (adult label). As a result, the medication was administered as directed on the incorrect label affixed to the bottle, leading to vomiting by the child.

6. Failure to Verify Allergy – Two (2) cases involved a failure to perform an adequate drug utilization review (DUR) which resulted in the dispensing of a prescription to a patient with known allergy to medication. Both patients had documented allergies to the prescribed medication; one involved an anti-inflammatory agent (naproxen) and the other involved a benzodiazepine (lorazepam).

C. Corrective Actions

As part of its complaint review, the Board requires involved pharmacists and pharmacies to conduct a QRE post-event analysis and describe corrective actions taken to prevent recurrence. In addition, each pharmacist involved in an error is required to complete a Board approved continuing education course in medication error prevention. The involved pharmacies are required to submit a medication error report to a nationally recognized reporting program, such as the reporting systems operated by U.S. Pharmacopoeia (USP), the Institute for Safe Medication Practices (ISMP), and the U.S. Food and Drug Administration (FDA).

Corrective action plans submitted to the Board in response to the cases reviewed in this report address the factors identified by the pharmacists and pharmacy as related to the QRE and detail the actions taken by the pharmacists and pharmacy to prevent recurrence. When developing a plan for corrective actions, pharmacists and pharmacies commonly review pharmacy policy and procedures pertaining to:

1. Prescription data entry;
2. Prescription verification, including review of technologies available such as bar code scanning and medication imaging;
3. Drug utilization review; and
4. Patient counseling procedures.

A summary of corrective actions taken in response to specific cases analyzed in this report is provided in Appendix D of this report.

IV. Conclusions and Recommendations

A. Conclusions

This report analyzes thirty-nine (39) consumer complaints involving medication errors that were reviewed by the Massachusetts Board of Registration in Pharmacy from January 1, 2004 to December 1, 2004. More than eighty-three million prescriptions were dispensed in Massachusetts in 2003.² The numbers of complaints involving medication errors that form the basis of this report are miniscule in comparison to the millions of prescriptions dispensed, without incident, in Massachusetts every year. Nevertheless, we hope the analysis presented in this report provides a greater understanding of issues in prescription preparation and delivery. This is the Board's most comprehensive effort to date to analyze and compile complaints reviewed by the Board as part of its ongoing efforts to identify and address the causes and contributors to the occurrence of medication errors in community setting. A common reason cited by a patient or consumer in filing a complaint with the Board in the aftermath of an error is the desire for pharmacies and pharmacists take necessary corrective action after an error to prevent recurrence. Communicating our analysis and findings with the pharmacy community is intended for use in the development of effective strategies to prevent errors from occurring. The identification of medication error QREs through the complaint review process also underscores the importance of developing a "partnership in care" relationship between consumers, pharmacists and prescribing practitioners to reduce the incidence of errors. There is a pressing need to establish CQI programs in community-based pharmacies, similar to the quality assurance and error prevention initiatives that have been widely implemented in hospital pharmacies. Patients deserve and expect safe and accurate pharmacy practices across the Commonwealth.

Efforts to communicate with licensees and the public about specific patient safety issues identified by the Board are ongoing. When the Board identifies a high-risk error pattern, the Board has published newsletter articles highlighting the specific medications involved in those types of errors. A recent article written by Board members warning of concerns about the sound-alike drugs Zantac (ranitidine) and Zyrtec (certirizine) was published in the August 2004 Board newsletter (see [Appendix C of this report](#)). The Board notes that the National Association of Boards of Pharmacy, the FDA, drug manufacturers, state, local and specialty pharmacy associations, and patient safety organizations also have recognized the importance of developing effective strategies to reduce the incidence of errors. Advancements in technology, prescription labeling, manufacturing processes and regulatory policy will also assist in the elimination and reduction of errors.

Errors in drug dispensing that involve factors such as sound-alike and look-alike drugs, failure to perform adequate drug utilization review (DUR), missed opportunities for correction of error at final verification, factors such as failure of pharmacy personnel to utilize available technology specifically designed to reduce errors, and significant gaps in providing direct and effective patient counseling by the pharmacist, are a few of the root contributors that must be addressed to prevent errors from occurring and recurring. Micro bar coding implemented during the manufacturing process to identify individual tablets may also provide a double check to ensure that the labeled vial correlates with the contents, thus reducing errors involving incorrect medication and incorrect strength. Improved standards for the appearance and names of products at the drug approval phase may also prevent medication errors related to sound-alike, look-alike medications. Pharmacists must also be diligent in providing patients and their caregivers with effective counseling and key information about the proper use and administration of their medications. Involving patients in their care and educating them about their prescribed medications is absolutely necessary to reduce the overall incidence of medication errors.

The important process of implementing CQI programs in community pharmacies that include methods for identifying and understanding root causes of errors is a critically important initiative that will improve internal pharmacy systems and build greater consumer confidence in the pharmaceutical services provided by Massachusetts pharmacists and community pharmacies. In conjunction with this effort, community pharmacies are encouraged to establish non-punitive medication error reporting systems that promote the reporting of errors and “near misses” by employees to allow for follow up review in order to gain an understanding of what happened and what steps can be taken to prevent a recurrence. A collaboration of health care providers dedicated to the identification, prevention and education of root causes of error will achieve the safest pharmaceutical services for patients.

B. Recommendations

In furtherance of its goal to promote safe practice and improve the delivery of pharmacy services in the Commonwealth, the Board will seek to:

1. Assist and advise pharmacists and community pharmacies in implementing Continuous Quality Improvement Program Regulations (247 CMR 15.00), requiring community pharmacies to establish CQI programs by December 31, 2005. CQI programs must identify, document and analyze data collected in response to QREs; assess causes and any contributing factors; formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs; provide ongoing professional education at least annually in the area of CQI to community pharmacy personnel; and designate an individual or individuals responsible for monitoring CQI Program compliance.
2. Develop a Quality Related Event (Medication Error) Prevention Training Program to educate and assist pharmacists and community pharmacies in complying with new CQI program regulations. This training program will address methods and techniques for conducting a root cause analysis, as well as the design, implementation and monitoring of corrective action plans.
3. Explore options for convening an expert consensus group in collaboration with the Betsy Lehman Center for Patient Safety and Medical Error Reduction and the Massachusetts Coalition for the Prevention of Medical Errors to study medication errors in community-based settings for purposes of developing best practice guidelines.
4. Collaborate with the Betsy Lehman Center for Patient Safety and Medical Error Reduction to consider development of methodologies for collecting and analyzing medication error and “near miss” reports for all pharmacy settings.
5. Continue to circulate “Best Practice Recommendations to Promote Optimum Pharmaceutical Care in the Commonwealth of Massachusetts” and encourage pharmacists and pharmacies to implement the recommendations. These Best Practices are posted on the Board’s website and are updated periodically to address emerging issues pertaining to the practice of pharmacy.
6. Communicate with the colleges/schools of pharmacy to develop curriculum content that incorporates continuous quality improvement and patient centered risk management theories as well as techniques for quality related event discovery, analysis and reporting.

V. Acknowledgements

We wish to acknowledge the members and staff of the Board of Registration in Pharmacy for their ongoing commitment to fulfilling the Board's mission to protect the health, safety and welfare of Massachusetts citizens and thank them for their assistance and guidance in preparing this report.

Board Members

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VI. Appendices

Appendix A – Best Practice Recommendations to Promote Optimum Pharmaceutical Care in the Commonwealth of Massachusetts, - Massachusetts Board of Registration in Pharmacy

Appendix B – 247 CMR 15.00: Continuous Quality Improvement Program

Appendix C – Board of Registration in Pharmacy, August 2004 newsletter article: “Mix-ups in Zantac/Zyrtec”

Appendix D – Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy January 1, 2004 – December 1, 2004

Appendix A:

Best Practice Recommendations to Promote Optimum Pharmaceutical Care in the Commonwealth of Massachusetts

In 2000, the Massachusetts Board of Registration in Pharmacy (Board) convened an advisory committee to make recommendations to the Board regarding continuing quality improvement (CQI) initiatives that could be implemented in all pharmacy practice settings to promote optimum pharmaceutical care. Participants in the Board's CQI Advisory Committee included Board members, representatives from institutional and retail pharmacy settings, professional associations, colleges of pharmacy, the Massachusetts Coalition for the Prevention of Medical Errors, the Department of Public Health and related regulatory agencies.

The CQI Advisory Committee developed a set of **Best Practice Recommendations** (Recommendations) that could be implemented by the various pharmacy settings according to the particular needs, available resources, and community served by the pharmacy. The Recommendations developed by the CQI Advisory Committee were based on a review of current literature on medication dispensing systems and recent research on the incidence and causes of medication errors, as presented by the Board's Quality Assurance Surveyor and CQI Advisory Committee Chairman (a member of the Board). The CQI Advisory Committee provided comment and direction regarding the Recommendations and forwarded the proposed Recommendations to the Board for adoption.

The Board adopted these Best Practice Recommendations on September 25, 2001 (amended on various dates thereafter) as recommended standards of professional practice to be considered for implementation as appropriate by pharmacies to promote optimum pharmaceutical care outcomes in the Commonwealth.

The Recommendations cover most pharmacy settings and include a variety of measures that can be implemented immediately and other processes that involve technological and training topics that can be instituted over a longer period of time to improve medication delivery systems. This list is **not** exclusive of other improvements that may be necessary to a particular pharmacy setting and may be supplemented by the Board from time to time.

The Board urges all pharmacies to make review of these recommendations a high priority and to consider implementation of those measures that are appropriate to the particular pharmacy setting. The Board believes that adoption and institution of these practices will result in improved performance, increased patient safety, a reduction in medication errors, and enhanced pharmacy medication delivery systems in general.

MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

Best Practice Recommendations To Promote Optimum Pharmaceutical Care in the Commonwealth of Massachusetts

- 1. Develop policies and procedures providing that incident reports will be completed and submitted to a national database, such as the USP Medication Errors Reporting Program (MERP), for each quality-related event (QRE) occurrence. A QRE is defined as any departure from the appropriate dispensing of a prescribed medication that is not corrected prior to the delivery of the medication.**

The term “quality-related event” includes variations from the specifications of a prescription, such as wrong drug, wrong strength, wrong directions, and wrong dosage form. The term also includes packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, and the failure to detect and appropriately manage a significant actual or potential problem with a patient’s drug therapy.

- **Recommended Actions**

- ✓ Create a system for reporting medication errors to a national database to promote analysis of the occurrence of the QRE and prevent similar events from recurring.
- ✓ Promote a non-punitive atmosphere for reporting of medication errors.
- ✓ Voluntarily report QRE to the USP Medication Error Reporting Program.

- 2. Institute a system to quarterly review incident reports generated at the pharmacy. Perform root cause analysis and include information from such review in quality improvement programs. Reviewers should include pharmacists, pharmacy technicians, and appropriate management personnel.**

- **Recommended Actions**

- ✓ Evaluate the QREs that occurred in the pharmacy on a quarterly basis and identify the root cause of the QREs.
- ✓ Implement improvements/interventions based on the information gathered as part of the root cause analysis.
- ✓ Publicize changes to pharmacy staff.

- 3. Develop and implement an effective workflow plan that is evaluated periodically to maximize effective use of space, equipment and staff.**

- **Recommended Actions**

- ✓ Develop policies and procedures to ensure that the appropriate individuals are completing appropriate tasks.
- ✓ Consider the use of automated devices to aid staff.
- ✓ Explore ways to optimize patient care services, i.e. providing separate area for confidentiality when counseling patients.
- ✓ Evaluate the size of the pharmacy to determine optimum dispensing area.

4. Routinely poll customers regarding quality of care and satisfaction with service.

▪ **Recommended Actions**

- ✓ Develop a customer-focused survey to identify areas of improvement.
- ✓ Review the findings of the survey with pharmacy staff to develop solutions to improve patient satisfaction.

5. Develop and implement a comprehensive technician-training program that requires pharmacy technician trainees to demonstrate competence in functioning as pharmacy technicians and to qualify for registration as pharmacy technicians.

▪ **Recommended Actions**

- ✓ Develop a comprehensive pharmacy technician training program and provide a copy of the technician training program to the Board's Technician Training committee for Board approval.
- ✓ Encourage pharmacy technicians registered by the Board to meet and maintain certification requirements.
- ✓ Provide continuing education opportunities for pharmacy technicians.

6. Implement a policy requiring that counseling be offered to every patient receiving a prescription, regardless of whether the prescription is new or a refill. During patient counseling, the pharmacist should verify that the patient understands the purpose, proper use and expected outcomes of their drug therapy. Counseling should also include information as to the safe and accurate use of prescribed medications. Educating patients about the safe and effective use of medications promotes patient involvement in their own care and is an important component of any medication error reduction strategy. Patient counseling may have a beneficial impact by reducing the incidence of quality-related events.

▪ **Recommended Actions**

- ✓ Dispense or recommend proper measuring device (e.g., oral dosing spoon) with all liquid medications. Instruct patients or caregivers on how to use the measuring device.
- ✓ Provide written patient drug information materials with all new outpatient prescriptions dispensed.
- ✓ Develop standard counseling procedures that include checks for the following:
 - Right patient
 - Right drug
 - Right drug for this patient
 - Appropriate dosing schedule
 - Appropriate route of administration
 - Correct route of administration for this patient
 - Verification that the patient understand why they are taking the drug
 - Verification that the patient understands how to use the drug

7. Develop policies and procedures that insure patient profiles are periodically updated for drug allergies, patient weight, adverse reactions, over-the-counter (OTC) medication usage, and alternative medication/herbal remedy usage.

▪ **Recommended Actions**

- ✓ Develop a policy that requires that allergy information be updated when filling or refilling a prescription.

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- ✓ Require all new prescriptions include allergy information.
 - ✓ Develop a policy of updating patients weight periodically
 - ✓ Ask patients about their use of OTC medications and herbal remedies and document responses in the patient profile.
 - ✓ Update patient profiles periodically. Updates should include information on newly developed allergies even if patient is not filling a new prescription.

8. Utilize available age and weight adjusted dosing guidelines when appropriate.

▪ **Recommended Actions**

- ✓ Verify pediatric dosing to ensure proper dose.
- ✓ Develop pediatric and geriatric specific guidelines for age and weight adjusted dosing.
- ✓ Consider acquiring or utilizing reference materials, textbooks and/or computer software that directly address pediatric and geriatric dosing.
- ✓ When appropriate and necessary, verify that doses are appropriate for the patient.

9. Provide adequate and easy access to appropriate reference materials.

▪ **Recommended Actions**

- ✓ Provide Internet access to pharmacists to research clinical information.
- ✓ Establish a clinical department to serve as a resource for dispensing pharmacists.
- ✓ In addition to required reference texts, provide additional reference materials, such as computer software programs, relevant to particular practice setting.

10. When necessary and appropriate, question adherence to prescriber directions when a medication intended for chronic use is filled more than three days late or when the medication is reordered substantially earlier than expected.

▪ **Recommended Actions**

- ✓ Monitor prescription drug usage among chronic disease state patients to ensure compliance.
- ✓ Ask the patient if a drug therapy change has occurred and if needed contact the prescriber to obtain updated information.
- ✓ Ask patients how they are feeling, paying attention to improvements in the patient's condition as well as adverse effects.

11. Develop written policies and procedures to assure that outdated stock or stock with an expiration date that does not allow sufficient time for dispensing by the pharmacy or use by the patient is segregated from other stock and either prepared for return to the manufacturer or destroyed and documented.

▪ **Recommended Actions**

- ✓ Periodically inspect the expiration date on the medication stock bottles.
- ✓ Periodically inspect the expiration date on the medication containers in the refrigerator or freezer.
- ✓ Identify short dated items with a colored label indicating expiration date.
- ✓ Check expiration dates on all products prior to completing the filling and dispensing of medication.

12. Adopt written policies and procedures pertaining to the handling of filled prescription orders waiting for pick-up by a patient or patient representative.

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- **Recommended Actions**
 - ✓ Verify the patient's name, address, and date of birth when prescription orders are picked up.
- 13. Adopt written policies and procedures relating to the return of unclaimed prescriptions to stock.**
- **Recommended Actions**
 - ✓ Adopt a policy that only a pharmacist may return medication to the stock with appropriate checks.
- 14. Develop procedures to ensure drug recalls are acted upon in a timely manner.**
- **Recommended Actions**
 - ✓ Adopt procedure that personnel receiving recall notice are required to immediately bring the recall notification to the pharmacist's attention.
- 15. Explore the reasons for out of stock items.**
- **Recommended Actions**
 - ✓ Collect data and analyze trends related to out of stock items.
 - ✓ Utilize a computer program to determine inventory employing maximum/ minimum strategy.
 - ✓ Consider auto replenishment technology.
 - ✓ Refer to the FDA shortage list
- 16. Adopt a policy allowing for continuation of therapy for out of stock or unavailable items.**
- **Recommended Actions**
 - ✓ Inform patient or caregiver that the medication is out of stock or unavailable.
 - ✓ If known, inform patient or caregiver when the medication would be available.
 - ✓ Offer to make arrangements for the patient or caregiver to pick up the medication at another location.
 - ✓ If the availability from manufacturer will result in interruption of therapy, offer to call the physician to discuss a change in therapy.
- 17. Adopt a policy allowing pharmacists up to a thirty-minute lunch break when they work six or more hours in a day.**
- **Recommended Actions**
 - ✓ Develop policies and procedures regarding the operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods, in accordance with policies of the Board of Registration in Pharmacy.
 - ✓ Develop policies and procedures detailing the authorized duties of ancillary staff during temporary absences of the pharmacist; the pharmacist's responsibilities for checking all work performed by ancillary staff; and the pharmacist's responsibility for maintaining the security of the pharmacy.
- 18. Develop policies and procedures regarding proper staffing.**
- **Recommended Actions**
 - ✓ Periodically review staffing requirements to assure adequate availability of professional, technical and clerical staff.
 - ✓ Ensure that available and competent staff is available during periods of high activity.

19. Utilize interpreters as necessary.

▪ Recommended Actions

- ✓ Employ individuals who can speak a second language.
- ✓ Learn a second language.
- ✓ Engage an interpreter service (such as AT&T).

20. Develop policies and procedures, which continually improve pharmacy, practice by incorporating strategies to optimize therapeutic outcomes.

▪ Recommended Actions

- ✓ Consider disease state management programs and certification programs to enhance delivery of pharmaceutical care.
- ✓ Initiate a program to monitor HbA1C levels of diabetic patients.
- ✓ Counsel patients with diabetes regarding the proper use of glucose monitoring equipment, insulin, syringes, injection techniques, and insulin pens.
- ✓ Implement a program to encourage high-risk patients to have cholesterol levels evaluated.
- ✓ Encourage patients with asthma to demonstrate proper use of Metered Dose Inhalers (MDIs), spacers, and peak-flow meters.
- ✓ Institute and promote procedures to determine if patients utilizing chronic care medications are adhering to prescribed medical regimens.
- ✓ Develop a plan for the acquisition of adherence software within an acceptable time frame.
- ✓ Provide counseling and conduct activities to help increase immunization rates for patients at high risk for pneumonia and influenza.

21. Develop policies and procedures, which continually insure the integrity of Biologicals and Pharmaceuticals.

▪ Recommended Action

- ✓ Consider maintaining a daily temperature log on file to insure proper storage of biologicals and refrigerated pharmaceuticals

22. Develop and implement written policies and procedures that enhance anti-counterfeiting measures regarding the receipt, storage and security of controlled substances.

▪ Recommended Actions

- ✓ Visually examine all deliveries promptly on receipt to identify contents and determine if any contaminated, damaged, misbranded, expired and or suspected counterfeit drugs or devices are included in the shipment.
- ✓ Quarantine any drugs or devices found to be unacceptable for further examination and determination.
- ✓ Inspect medication during final verification to assure product accuracy and integrity.
- ✓ Request wholesalers to certify that all medications delivered to the pharmacy, not accompanied by a pedigree, are purchased directly from the manufacturer.
- ✓ Report suspected counterfeit medications to **MedWatch** (the FDA Safety Information and Adverse Event Reporting Program), the Board and appropriate law enforcement authorities within three business days.
- ✓ Educate consumers about the risks of counterfeit medications.

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- ✓ Encourage consumers to promptly consult with health care professionals if they suspect that their medication is counterfeit.
 - ✓ Remind consumers to be aware of noticeable differences in their medications or packaging and the occurrence of any adverse events.
 - ✓ Alert consumers to the important role pharmacists play in identifying, reporting and responding to counterfeit drug events.
 - ✓ Advise consumers to make online medication purchases from pharmacies that have obtained the Verified Internet Pharmacy Practice Site (VIPPS) seal from the National Association of Boards of Pharmacy (NABP).
 - ✓ Maintain records of counterfeit reports from manufacturers and other sources for a minimum three-year period.
 - ✓ Consult NABP's "National Specified List of Susceptible Drug Products" available for reference at www.nabp.org and the Board's website under "Board News" at www.mass.gov/reg/boards/ph.

23. Develop and implement written policies and procedures regarding the identification of medication when requested by a consumer/patient or medical professional.

Resources for Non-Emergency Product Identification Requests
[If emergency call poison control center at 1-800-222-1222]

▪ **Recommended Actions**

1. When a prescription is associated with the medication to be identified.

- ✓ Verify the prescription content with the original copy of the prescription dispensed making sure that the markings on the unidentified medication match the prescription medication dispensed and identified from the original prescription.
- ✓ If unidentified medication can not be verified then refer to procedure #2.

2. Identification of a medication with manufacturer's code and/or NDC code or other markings on the product.

- ✓ Utilize available resources and references (see Attachment A) to identify medication by manufacturers' identification codes, NDC code, or drug name.
- ✓ If medication cannot be identified then refer to procedure #3.

3. Identification of a medication that has no markings and/or is a formulation (liquid) that is not positively identifiable.

- ✓ Call the poison control center and describe medication and indication for use if known.
(EMERGENCY SITUATION)
- ✓ In non-emergency situations, obtain services for laboratory product analysis, <http://www.bostonanalytical.com> or <http://www.bio-concept.com>

Attachment A

Online resources for identifying prescription and non-prescription drugs:

- <http://www.drugdigest.org> click on to Drug library then pill images. *
- <http://www.drugs.com/> identifies by, name, codes and/or description. *
- <http://www.rxlist.com/interact.htm> identifies by code, drug name, or Manufacturer. *
- <http://www.drugs.com/manufacturers.html> links to Medication manufacturers. *
- *PDRhealth*, The Drug Information Directory. *
 - Prescription drugs http://www.pdrhealth.com/drug_info/rxdrugprofiles/alphaindexa.shtml *
 - OTC drugs http://www.pdrhealth.com/drug_info/otcdrugprofiles/alphaindexa.shtml *
- www.mcphs.edu/altmed Center for Complementary and Alternative Pharmacotherapy. *
- <http://www.micromedex.com/> Micromedex
 - <http://www.cp.gsm.com/> *Clinical Pharmacology* Product Identification
 - <http://www.identadrug.com/> by Pharmacist Newsletter

* information accessed without charge

Books for identifying drugs may be available at your local public or university library:

- *Ident-A-Drug Reference*; identifies drugs by the numbers, letters and images.
- *Mosby's DrugConsul*
- *Physicians' Desk Reference (PDR)*
- Facts and Comparisons

REFERENCES

All websites listed were accessed August 2001.

1. Massachusetts Board of Registration in Pharmacy Regulations 247 CMR 1.00-14.00. Available at: <http://www.state.ma.us/reg/boards/ph>.
2. United States Pharmacopoeia (USP) Quality Review. Available at: <http://www.usp.org>.
3. Lesar TS. Recommendations for reducing medication errors. Medscape Pharmacists, 2000. Available at: <http://www.medscape.com/Medscape/pharmacists/journal>.
4. The Pharmacy Society of Wisconsin. PSW Medication use practice standards to maximize patient safety. Available at: <http://www.pswi.org>.
5. American Society of Hospital Pharmacists. ASHP guidelines on preventing medication errors in hospitals. Am J Hosp Pharm. 1993; 50: 305-314.
6. American Society of Hospital Pharmacists. ASHP guidelines on pharmacist conducted patient education and counseling. Am J Health-System Pharm. 1997; 54: 431-434.
7. American Society of Consultant Pharmacists. Guidelines for pharmacist counseling of geriatric patients. Available at: <http://www.ascp.com/member/policy/guidelines/1998/geriatric.shtml>.
8. Agency for Healthcare Research and Quality. Twenty tips to help prevent medical errors. Available at: <http://www.ahrq.gov/consumer/20tips.htm>.
9. Institute for Safe Medicine Practices. ISMP Medication Safety Self-Assessment™. Huntingdon Valley, PA; 2000. Available at: <http://www.ismp.org>.
10. Massachusetts Board of Registration in Pharmacy. Policy 2000-03: [Policy on Pharmacy Operations During the Temporary Absence of a Pharmacist](#). Available at: <http://www.state.ma.us/reg/boards/ph/pol00003.htm>.
11. Cohen MR. Why error reporting systems should be voluntary. BJM. 2000; 320: 728-729.
12. Grasha AF. Into the abyss: Seven principles for identifying the causes of and preventing human error in complex systems. Am J Health-System Pharm. 2000; 57: 554-564.
13. Aviation Safety Reporting System (ASRS). Available at: <http://human-factors.arc.nasa.gov/ihs/activities/ASRS.gif>.
14. Brushwood DB. Regulating for pharmaceutical care outcomes: A report submitted to the National Association of Boards of Pharmacy. (Date to be inserted)
15. Massachusetts Hospital Association. MHA best practice recommendations to reduce medication errors. Available at: http://mhalink.org/mcpme/mha_best_practice_recommendation.htm.
16. American Pharmaceutical Association. Quality Improvement in Pharmacy: Report Cards, Continuous Quality Improvement, and Peer Review. Available at: www.aphanet.org/govt/policycomm2000/qualityassessbackground.html.
17. Veterans Administration (VA) National Center for Patient Safety. VA NCPS root cause analysis. Available at: <http://www.va.gov/ncps/tools.html>.
18. Rex JH et al. Systematic root cause analysis of adverse drug events in a tertiary referral hospital. Jt Comm J Qual Improv 2000. October 2000; 26(10): 563-75.
19. American Society of Health-System Pharmacists. ASHP guidelines on a standardized method for pharmaceutical care. Am J Health-System Pharm. 1996; 53: 1713-1716.
20. MacKeigan LD and Larson LN. Development and validation of an instrument to measure patient satisfaction with pharmacy services. Medical Care. 1989; 27: 522-536.
21. American Society of Consultant Pharmacists. ASCP guidelines on the role of pharmacy technicians in long term care. Available at: <http://www.ascp.com>.

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22. Pharmacy Technician Certification Board. Video: Enhancing Pharmaceutical Care: Certified Pharmacy Technicians. Available at: <http://ptcb.org/PTCBVideo.asp>.
 23. Grasha AF et al. A cognitive systems perspective on human performance in the pharmacy: Implications for accuracy, effectiveness, and job satisfaction. Department of Psychology University of Cincinnati. October 2000.
 24. American Society of Hospital Pharmacists. AHSP guidelines for selecting pharmaceutical manufacturers and suppliers. AM J Hosp Pharm. 1991; 48: 523-524.
 25. U.S. Food and Drug Administration. Drug Shortages. Available at: <http://www.fda.gov/cder/drug/shortages/#Current>.
 26. Washington State Department of Health. Medication errors report and recommendations. December 2000.
 27. American Society of Consultant Pharmacists. Guidelines on preventing medication errors in pharmacies and long term care facilities through reporting and evaluation. Available at: <http://www.ascp.org/member/policy/guidelines/1997/guidelines-errors.shtml>.
 28. Cerulli J. The role of the community pharmacist in identifying, preventing, and resolving drug-related problems. Medscape Pharmacists 2001. Available at: <http://www.medscape.com/Medscape/pharmacists/journal>.
 29. American Society of Hospital Pharmacists. AHSP guidelines on managing drug product shortages. AM J Health-Syst Pharm. 2001; 58: 1445.
 30. Epstein D. Med-error minder. Drug Topics. April 6, 1998: 32-37 passim.
 31. Kirby Lester, Incorporated. The growth in dispensing errors and its effects. Available at: <http://www.kirbylester.com/disperr.html>.
 32. United States Pharmacopoeia (USP) Medication Error Reporting Program. Available at: <http://www.usp.org>.

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Appendix B

247 CMR 15.00: CONTINUOUS QUALITY IMPROVEMENT PROGRAM

Section

15.01: Definitions

15.02: Continuous Quality Improvement Program

15.03: Quality Related Event Discovery, Notification and Documentation

15.04: Records

15.01: Definitions

Continuous Quality Improvement Program or CQI Program means a system of standards and procedures to identify and evaluate quality-related events and improve patient care.

Quality-Related Event or QRE means the incorrect dispensing of a prescribed medication that is received by a patient, including:

- (a) a variation from the prescriber's prescription order, including, but not limited to:
 - 1. dispensing an incorrect drug;
 - 2. dispensing an incorrect drug strength;
 - 3. dispensing an incorrect dosage form;
 - 4. dispensing the drug to the wrong patient; or
 - 5. providing inadequate or incorrect packaging, labeling, or directions; or
- (b) a failure to identify and manage:
 - 1. over-utilization;
 - 2. therapeutic duplication;
 - 3. drug-disease contraindications;
 - 4. drug-drug interactions;
 - 5. incorrect drug dosage or duration of drug treatment;
 - 6. drug-allergy interactions; or
 - 7. clinical abuse/misuse.

Pharmacy, as referenced in 247 CMR 15.00, means a pharmacy, or a group of pharmacies under common ownership and control of one entity, licensed by the Board pursuant to M.G.L. c. 112.

Pharmacy Personnel means pharmacist, pharmacy intern, pharmacy technician and pharmacy support personnel.

15.02: Continuous Quality Improvement Program

(1) Continuous Quality Improvement Program Requirements. Each pharmacy shall establish a Continuous Quality Improvement (CQI) Program for the purpose of detecting, documenting, assessing and preventing Quality-Related Events (QREs). At a minimum, a CQI program shall include provisions to:

- (a) designate an individual or individuals responsible for monitoring CQI Program compliance with the requirements of 247 CMR 15.00;
- (b) identify and document QREs;
- (c) minimize impact of QREs on patients;
- (d) analyze data collected in response to QREs to assess causes and any contributing factors;

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- (e) use the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs; and
 - (f) provide ongoing education at least annually in the area of CQI to pharmacy personnel.

(2) Implementation Date. The CQI Program requirements of 247 CMR 15.00 shall be implemented by each pharmacy by December 31, 2005.

15.03: Quality Related Event Discovery, Notification and Documentation

(1) QRE Discovery and Notification. All pharmacy personnel shall be trained to bring any QRE to the attention of the pharmacist on duty or the pharmacist Manager of Record immediately upon discovery. The pharmacist who has discovered or been informed of a QRE shall immediately provide:

- (a) notification to the patient or patient's representative, the prescriber (if indicated in the professional judgment of the pharmacist) and other members of the healthcare team;
- (b) directions for correcting the error; and
- (c) instructions for minimizing the negative impact on the patient.

(2) QRE Documentation.

(a) A QRE shall be initially documented by the pharmacist who has discovered or been informed of the QRE on the same day the QRE is discovered by or described to the pharmacist.

(b) QRE documentation shall include a description of the event that is sufficient to permit categorization and analysis of the event. QRE documentation shall include:

1. the date when the pharmacist discovered or received notification of the QRE and the name of the person who notified the pharmacy;
2. the names and titles of the persons recording the QRE information and performing the QRE analysis;
3. a description of the QRE reviewed; and
4. documentation of the contact with the patient, or patient's representative, and prescribing practitioner (if indicated in the professional judgment of the pharmacist), and other members of the healthcare team.

(3) QRE Analysis and Response.

(a) QRE Analysis. The investigative and other pertinent data collected in response to QREs shall be analyzed, individually and collectively, to assess the cause and any contributing factors such as system or process failures. The QRE analysis and assessment shall include:

1. a consideration of the effects on quality assurance related to workflow processes, technological support, personnel training and staffing levels;
2. any recommended remedial changes to pharmacy policies, procedures, systems, or processes; and
3. the development of indicators that identify means against which a pharmacy's program intends to measure its standards over a designated period of time.

(b) Response. Each pharmacy shall inform pharmacy personnel of changes to pharmacy policies, procedures, systems, or processes resulting from recommendations generated by the CQI Program.

15.04: Records

- (1) Each pharmacy shall maintain a written copy of its CQI Program description on the pharmacy premises. The CQI Program description shall be readily available to all pharmacy personnel.
- (2) Each pharmacy shall maintain a record of all QREs for a minimum period of two years from the date of the QRE report.
- (3) QRE records shall be maintained in an orderly manner and filed by date.
- (4) QRE records may be stored at a site other than the pharmacy where the QRE occurred.

REGULATORY AUTHORITY

247 CMR 15.00: M.G.L. c. 112, §§ 37 through 39 and 42A.

CQI Regulations are available at <http://www.mass.gov/dpl/boards/ph/cmr.htm>

Appendix C

Article Written by Board Members and Published in the Massachusetts Board of Registration in Pharmacy August 2004 Newsletter

Mix-ups in Zantac/Zyrtec By Karen Ryle and Donna Horn

In Massachusetts, as well as other parts of the country there have been numerous errors that have occurred in the pediatric population where **ZANTAC** (ranitidine) syrup (Glaxo Wellcome) has been prescribed but **ZYRTEC** (cetirizine) syrup (Pfizer) has been dispensed. Zantac is an H2 receptor blocker and Zyrtec is an H1 antihistamine. Although these medications do not have overlapping dosage strengths, both are available in the syrup dosage form: Zantac as 150 mg/10 mL and Zyrtec as 5 mg/5 mL. Since a different company manufactures each drug, the container labels look dissimilar. However, the syrups of both drugs are available in 480 mL amber glass bottles. Zyrtec syrup is also available in a 120 mL bottle. The proprietary names look and sound alike, increasing the potential for medication errors.

Errors occurred most frequently in patients ranging in ages from 7 days to 15 months. In one case, a 12-month-old male patient was prescribed 120 mL of Zantac syrup but was given 120 mL of Zyrtec. The error occurred when the incorrect stock bottle of Zyrtec syrup was chosen by the technician and poured into the dispensing bottle labeled as Zantac. The mother noticed that the baby became "violently ill" but the doctor did not find any serious injury after examining the baby. In another case, a 15-month-old patient was given Zyrtec instead of Zantac for 6 weeks before the error was discovered. The patient's reflux-induced sinusitis continued until the error was corrected. Other patients experienced sleep disturbances, increased thirst, decreased appetite, diarrhea, vomiting, and decreased weight as a result of the errors. Thankfully, none of the symptoms caused serious harm to patients.

SAFE PRACTICE RECOMMENDATION:

- Separate stock bottles of Zantac and Zyrtec syrups in pharmacy dispensing areas and any other areas in the healthcare facility where the drugs are stored* (e.g., automated dispensing cabinets).
- Encourage prescribers to include the drug's indication to differentiate these look-alike drug names and reduce the risk of selecting the wrong drug due to poor handwriting*.
- As with all liquid oral medications, physicians should include the desired mg/mL concentration to guide proper drug selection, especially since the drug concentrations differ*.
- The dose should also be expressed in mg, not just volume (mL or teaspoonfuls). Place reminders on stock bottles and install pharmacy computer alerts to advise staff of the risk for errors*.
- It's also helpful to warn patients about the risk of confusing these two products so they can detect possible errors when filling prescriptions.
- As a final check, immediately before the patient or caregiver leaves the pharmacy department with the filled prescription, open the bottle and sniff the liquid. Does it smell like mint? Then it must be Zantac. What does the label indicate it is supposed to be?

*Institute for Safe Medication Practices. Action needed to prevent dangerous Zyrtec-Zyprexa mix-ups. ISMP Medication Safety Alert! Volume 5, Issue 22 November 1, 2000. Similar sound-alike, look-alike mix-ups have occurrence with Zyrtec and Zyprexa™ tablets – be mindful

<http://www.mass.gov/dpl/boards/ph/forms/ma082004.pdf>

Appendix D

Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy January 1, 2004 – December 1, 2004

A. Definitions of Column Headings in Appendix D

Column 1 **Case #.** Case number identifier of particular case.

Column 2 **Category of Event.** Each Quality Related Event (QRE) is classified in one of the following four (4) categories:

P - Potential to Cause Harm. Medication error that reached the patient with no ingestion.

I - Ingestion with No Harm. Medication error that reached the patient with ingestion and no harm resulting.

IH - Ingestion with Harm. Medication error that reached the patient with ingestion and harm resulting.

S - Sentinel Event. Medication error that reached the patient with ingestion and serious permanent harm or death to the patient resulting.

Column 3 **Date.** The date the case was entered into the information technology databank system utilized by the Board.

Column 4 **Case Description.** Summary description of the specific medication and details of the error involved in the particular QRE.

Column 5 **Type of Error.** Further description of the specific type of error involved in the QRE, such as:

- Incorrect Directions
- Incorrect Labeling
- Incorrect Medication
- Incorrect Patient
- Incorrect Strength
- Failure to Verify Allergy

Column 6 **Patient Outcomes.** Summary description of the specific patient outcomes in the QRE.

Column 7 **Corrective Action.** Summary description of the information provided to the Board by the pharmacists and pharmacies involved in the QRE regarding specific actions taken after identification of the error. For example, a root cause analysis may have been performed by involved personnel to determine why the event occurred and how to prevent the event from recurring. Information on contributing factors to the QRE as well as corrective action plans focused on prevention of similar events in the future may also be submitted to the Board. Pharmacies also submit a medication error report to a national data bank such as the reporting

systems operated by the Institute for Safe Medication Practices (ISMP) (<http://www.ismp.org>) and the United States Pharmacopoeia (USP) (<http://www.usp.org>). Pharmacists complete Accreditation Council for Pharmacy Education (ACPE) approved continuing education units on medication error prevention and provide continuing education compliance history for the previous licensure cycle.

B. Glossary of Terms and Acronyms used in Appendix D

ACPE. Accreditation Council for Pharmacy Education.
(<http://www.acpe-accredit.org>)

Board. Massachusetts Board of Registration in Pharmacy.

CEU or Continuing Education Unit. A unit of measure of educational credit equal to ten contact hours or its equivalent, as determined by the Board, of satisfactory participation in a Board-approved program of continuing education. (247 CMR 2.00)

CQI Program or Continuous Quality Improvement Program. A system of standards and procedures to identify and evaluate quality-related events and improve patient care.
(247 CMR 2.00)

DUR or Drug Utilization Review. A medication profile review performed by a pharmacist to verify drug indications, drug allergies, dose, route, amount, drug-drug/drug food interactions and appropriate lab monitoring of medications prescribed.

IOM or Institute of Medicine. A nonprofit organization established to act as adviser to the nation to improve health. (<http://www.ism.org>)

ISMP or Institute for Safe Medication Practices. A nonprofit organization that works closely with healthcare practitioners and institutions, regulatory agencies, professional organizations and the pharmaceutical industry to provide education about adverse drug events and their prevention.
(<http://www.ismp.org>)

ITD. An information technology databank system utilized by the Board.

NDC or National Drug Code Number. The nationally recognized standard that identifies drug products using a unique number issued by the U. S. Food and Drug Administration. The NDC has three components: the first component identifies the drug manufacturer ("Labeler No."); the second component identifies the product ("Product No."); and the third component identifies the package size ("Pkg."). (247 CMR 2.00)

Prescription. An order for a drug, chemical, device or combination thereof, either written, given orally or otherwise transmitted to a registered pharmacy by a practitioner or his or her expressly authorized agent, to be dispensed or compounded in a registered pharmacy and dispensed by a registered pharmacist to a patient or his or her agent with necessary and appropriate counseling.
(247 CMR 2.00)

Prescription Drug. Any and all drugs which, under federal law, are required, prior to being dispensed or delivered, to be labeled with the statement: "Caution, Federal law prohibits dispensing without prescription" or "Rx only" and a drug which is required by any applicable Federal or State law or regulation to be dispensed pursuant only to a prescription drug order. (247 CMR 2.00)

QRE or Quality Related Event. The incorrect dispensing of a prescribed medication that is received by a patient, including:

- (a) a variation from the prescriber's prescription order, including, but not limited to:
 - 1. dispensing an incorrect drug;
 - 2. dispensing an incorrect drug strength;
 - 3. dispensing an incorrect dosage form;
 - 4. dispensing the drug to the wrong patient; or
 - 5. providing inadequate or incorrect packaging, labeling, or directions; or
- (b) a failure to identify and manage:
 - 1. over-utilization;
 - 2. therapeutic duplication;
 - 3. drug-disease contraindications;
 - 4. drug-drug interactions;
 - 5. incorrect drug dosage or duration of drug treatment;
 - 6. drug-allergy interactions; or
 - 7. clinical abuse/misuse. (247 CMR 15.01)

Root Cause Analysis. A process to determine the factors that contributed to the QRE. By repeatedly asking why at each level of the cause and effect to determine what processes, procedures or training contributed to the event, changes can be made to prevent medication errors.

USP/ISMP Medication Error Report. Reports of QREs may be provided to the national USP Medication Errors Reporting (MER) Program operated by the United States Pharmacopoeia (USP) (<http://www.usp.org>) and the Institute for Safe Medication Practices (ISMP). This voluntary error reporting program seeks to help prevent medication errors through the collection and dissemination of information about their circumstances and causes.

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
1	P	01/02/04	Lisinopril 10mg dispensed in place of Lipitor 10mg. Lisinopril 10mg is an ACE inhibitor (angiotension converting enzyme inhibitor) utilized to control hypertension. Lipitor 10 mg is a cholesterol-lowering agent.	Incorrect Medication	Negative patient outcomes involving adverse effects from receiving maintenance doses of Lisinopril incorrectly are symptoms of annoying cough, angioedema and low blood pressure. Other consequences due to lack of treatment with Lipitor would include possible increase in cholesterol levels.	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians.</p> <ol style="list-style-type: none"> 1) "Baker Cassette" procedure (automated medication retrieval system) reviewed for correct medication retrieval. 2) Medication verification process reviewed. 3) CEUs completed on "Prescription Errors and Legal Responsibility" of a pharmacist. 4) Submitted ISMP medication error report. 5) Completed CEU on "Medication Error Prevention".

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
2	S	01/16/04	A prescription for Cardura 4mg indicated for the control of hypertension was incorrectly dispensed with Coumadin 4mg indicated for anticoagulation (blood thinner).	Incorrect Medication	A 69-year-old patient incorrectly received Coumadin 4mg for an approximate period of one month. The patient was admitted to an emergency room and hospitalized for five days for side effects related to Coumadin toxicity. The patient was diagnosed with a small vessel (Lacuna) stroke.	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians.</p> <ol style="list-style-type: none"> 1) Prescription verification process. The pharmacist will verify the medication filled, verify the original hard copy of the prescription, then verify the directions and match the NDC numbers of the medication against the NDC numbers of the filled medication. 2) Verification of labels on all containers dispensed utilizing bar code scanning technologies will be followed. 3) Patient counseling procedure. Prescription will be reviewed with the patient to verify the correct medication and directions. 4) Communication of error to all pharmacy personnel and all pharmacies within the corporation. 5) Submitted an ISMP medication error report. 6) Completed continuing education on "Medication Error Prevention".

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
3	S	02/11/04	Naproxen, a NSAID (non-steroidal anti-inflammatory drug), was dispensed to patient with allergy to this class of medication. Pharmacy conversion to new computer program failed to flag patient allergy.	Failure to Verify Allergy	Naproxen was ordered by the physician and dispensed to a patient who was allergic to NSAIDS. The patient ingested five doses of Naproxen. The patient developed a severe rash and blistering of the skin. The patient was hospitalized with a diagnosis of toxic epidural necrosis and transferred to the burn unit with 70% skin involvement due to drug induced reaction.	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians.</p> <ol style="list-style-type: none"> 1) Data Entry Process. All patient profiles for the facility where patient resided were reviewed and corrected as needed for correct drug allergy data entry. 2) Faxed Orders. Policy and procedures were reviewed. 3) Allergy fields on faxed orders reviewed and corrected as needed. 4) New order verification process. All new medications orders will be checked for allergies. 5) Final Check verification process. Scanning technology will be utilized when verifying orders against allergies listed on profile. 6) Submitted an ISMP medication error report. 7) Completed continuing education on "Medication Error Prevention".

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
4	I	03/11/04	A prescription for Ativan 0.5mg was incorrectly dispensed with Ativan 1mg. The pharmacy dispenses medications utilizing the "blister pack" system. The correct label was affixed to the incorrect strength of Ativan.	Incorrect Strength	A prescription for Ativan 0.5 mg was incorrectly dispensed with Ativan 1mg to an elderly patient. A two-fold increase in dose was ingested for two doses prior to discovery by a nurse at a long-term care facility.	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians.</p> <ol style="list-style-type: none"> 1) Data Entry Process. A computer upgrade will be installed to include imaging software, a visual display of drug verification and bar code scanning of product. 2) Faxed Orders. Policy and procedures reviewed. 3) Medication packaging "blister pack" system* reviewed and bar code scanning of label and card for verification process will be used prior to labeling. 4) Communication. Error was shared with all pharmacy personnel. 5) Final Check verification process. Scanning technology will be utilized when verifying orders. 6) Submitted an ISMP medication error report. 7) Completed continuing education on "Medication Error Prevention". <p>*Blister pack system is a multiple quantity packaging system.</p>

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
5	IH	05/04/04	A prescription for Cefzil Suspension, an antibiotic, was reconstituted with insufficient amount of water resulting in a higher concentration of dose.	Incorrect Strength	An infant received a concentrated dose of Cefzil Suspension for a period of four days in error due to the improper reconstitution of the medication. The infant suffered stomach distress and was seen by the pediatrician. The mother made the discovery after noticing an insufficient supply for a ten day course of antibiotic	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians.</p> <ol style="list-style-type: none"> 1) Proper reconstitution of suspensions reviewed utilizing a calibrated water dispenser. 2) Prescription verification. Reconstituted products will be visually inspected for appropriate consistency. 3) Dispensing procedures reviewed. 4) Patient counseling procedure reviewed. 5) Communication. Error information was shared with all pharmacy personnel and all pharmacies within the corporation. 6) Submitted an ISMP medication error report 7) Completed continuing education on "Medication Error Prevention".

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
6	IH	05/04/04	Ativan 0.5mg was prescribed, dispensed and administered to a patient who was allergic to benzodiazepines.	Failure to Verify Allergy	Ativan 0.5mg was ordered, dispensed and administered in a long term care facility. The patient had a documented allergy to benzodiazepines recorded on pharmacy and nursing charts.	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians.</p> <ol style="list-style-type: none"> 1) Patient records have been updated with all allergies and allergies will be verified with original physician's order. 2) Verification of labels on all containers dispensed. 3) Communication, this error was shared with all pharmacy personnel. 4) Submitted an ISMP medication error report. 5) Completed continuing education on "Medication Error Prevention".

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
7	IH	05/05/04	Haldol 5mg, an antipsychotic drug, was incorrectly dispensed for Haldol 0.5mg tablets.	Incorrect Strength	A prescription for Haldol 0.5 mg was incorrectly dispensed with Haldol 5mg to a 14-year-old patient. Ingestion occurred and the patient had side effects requiring admission to an emergency room. The side effects of a ten-fold increase in dose can be mild to severe.	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians.</p> <ol style="list-style-type: none"> 1) During product selection the pharmacist will carry the hard copy (new prescription) or label (refill prescription) to the shelf to verify the product selected against the hardcopy or verify the NDC against the refill label. Using pharmacies look-alike-sound-alike system. 2) Separated the different strengths of Haldol with a yellow check NDC sticker. 3) Communicated to pharmacy staff the importance of making the pharmacy more organized and efficient to prevent prescription errors from occurring. 4) Reduce the pressure on pharmacist by having technicians assist as much as they can with the fill process: entering prescriptions, calling insurance companies and ordering. 5) A medication error report submitted to ISMP.

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
8	IH	05/20/04	Two prescriptions for Carafate and Protonix for the same patient were labeled and dispensed incorrectly due to cross labeling. Both medications are indicated for the treatment of ulcers.	Incorrect Labeling	The Carafate prescription had the directions for the Protonix prescription and vice versa for the Carafate prescription. As a result, the patient ingested both medications incorrectly for a period of two weeks prior to discovery. The patient complained of feeling ill and required a follow-up appointment with primary physician. The patient ingested a four-fold increase of Protonix and a four-fold reduction in prescribed dose of Carafate.	The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians. 1) DUR review on all prescriptions for allergies, drug interactions and dosing. 2) Prescription image scanning for identification. 3) Barcode scanning to verify prescription. 4) Staffing. Pharmacist shift overlap coverage. 5) Policy and Procedure review. 6) Submitted an ISMP medication error report.

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
9	IH	05/20/04	A prescription for Zithromax Oral Suspension, an antibiotic, was dispensed with the incorrect patient's name and directions.	Incorrect Patient	A prescription was incorrectly dispensed to a five-year-old child resulting in a three-fold increase in the dose of the intended medication Zithromax Oral Suspension. The label on the suspension bottle directed a 600mg dose rather than the prescribed 190mg dose. The incorrect dose caused an acute episode of vomiting before the error was corrected. The prescription included two separate labels - one (incorrect amount and incorrect patient) attached to the prescription bottle and the second (correct) attached to the packaging box.	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians.</p> <ol style="list-style-type: none"> 1) Prescription verification process. The pharmacist will verify the medication filled, verifying the original hard copy of the prescription, then verifying the directions and matching the NDC numbers of the medication against the NDC numbers of the filled medication. 2) Verification of labels on all containers dispensed. 3) Patient counseling procedure. The prescription will be reviewed with the patient to verify the correct medication and directions. 4) Communication. Error was shared with all pharmacy personnel and all pharmacies within the corporation. 5) Submitted an ISMP medication error report. 6) Completed continuing education on "Medication Error Prevention".

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
10	IH	05/26/04	A prescription for Serzone 200mg, an antidepressant, was incorrectly dispensed with Monopril 40mg, an antihypertensive.	Incorrect Medication	The patient ingested two doses of the incorrect medication Monopril. The patient became dizzy, lightheaded and tired and experienced a fall with subsequent shoulder pain. Symptoms of hypotension are consistent with the patient's complaint.	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians.</p> <ol style="list-style-type: none"> 1) NDC cross verification on stock bottle, label and receipt by highlight, circle or underlining the NDC number. 2) A root cause analysis was submitted that identified prescription identification and verification process failure as root contributors. 3) Medication references reviewed. 4) Submitted ISMP medication error report.

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
11	I	05/26/04	A prescription for Zantac Syrup, indicated for the treatment of ulcers or gastroesophageal reflux disease (GERD), was incorrectly dispensed with Albuterol Syrup, a bronchodilator used to control asthma.	Incorrect Medication	A refill prescription for Zantac Syrup was incorrectly dispensed to a 4-month-old infant with Albuterol Syrup. Ingestion occurred for a three-day period before discovery by parent. Potential for harm exists due to ingestion of the unintended medication. The potential side effects are mild to severe and can include sleeplessness, agitation and abnormal cardiac effects.	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians. Adherence to basket system.</p> <ol style="list-style-type: none"> 1) Medications dispensed from liquid stock bottles are entered into the computer so the stock bottle can be scanned. 2) Stock bottle remains in the basket throughout the dispensing process. 3) The stock bottle is checked against the printed label. 4) All prescriptions for liquids are opened and eyed carefully at verification point. 5) Imaging scanning is checked with liquid stock bottles. 6) Review of technician training. 7) Submitted ISMP medication error report.

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
12	IH	06/08/04	A prescription for Omeprazole 10mg, indicated for gastroesophageal reflux disease (GERD), was incorrectly dispensed with Fluoxetine 10mg, an antidepressant. Patient ingested the incorrect medication for 14 days.	Incorrect Medication	The potential for harm exists due to the length of time the incorrect medication was taken prior to discovery. The 14-day period is the time it usually takes for the medication Fluoxetine to begin having a therapeutic effect and reach blood levels capable of exhibiting a response. The side effects from Fluoxetine range from mild to severe.	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians.</p> <ol style="list-style-type: none"> 1) Prescription verification process. The pharmacist will verify the medication filled, verifying the original hard copy of the prescription, then verifying the directions and matching the NDC numbers of the medication against the NDC numbers of the filled medication. 2) Verification of labels on all containers dispensed utilizing bar code scanning technologies will be followed. 3) Patient counseling procedure. The prescription will be reviewed with the patient to verify the correct medication and directions. 4) Communication. Error was shared with all pharmacy personnel and all pharmacies within the corporation. 5) Submitted an ISMP medication error report. 6) Completed continuing education on "Medication Error Prevention".

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
13	IH	06/08/04	Prescription for Tegretol 200mg tablets was incorrectly dispensed instead of Tegretol 100mg tablets.	Incorrect Strength	Tegretol 200 mg, an anticonvulsant with a high alert narrow therapeutic index medication utilized for the control of seizures, was incorrectly dispensed to a six year old instead of Tegretol 100mg. The patient ingested a two-fold increase in dose for two days when symptoms of toxicity presented. A 911 call was placed on day three for severe symptoms of toxicity requiring admission to ER for observation and treatment.	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians.</p> <p>In this case, the pharmacy did not scan the prescription NDC number to the stock bottle resulting in the contents of the prescription not matching the labeled strength. The pharmacy has initiated a three-point checking system.</p> <ol style="list-style-type: none"> 1) Every prescription NDC number is scanned into the computer. 2) The NDC numbers are visually checked to verify that they match the product being dispensed. 3) Every prescription dispensed is visually checked so that the prescription contents match the label on the bottle. 4) Communication. Error was shared with all pharmacy personnel. 5) Submitted an ISMP medication error report. 6) Completed continuing education on "Medication Error Prevention".

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
14	IH	06/28/04	Zantac syrup was incorrectly dispensed in place of Zyrtec syrup. Zantac syrup contains ranitidine 15mg/ml indicated for the treatment of ulcers or gastroesophageal reflux disease (GERD). Zyrtec syrup contains cetirizine 1mg/ml indicated for allergic rhinitis or chronic urticaria (rash).	Incorrect Medication	An eight-year-old patient ingested 22 days of the incorrect medication Zantac syrup prior to discovery by a parent. Negative patient outcome is two fold. Lack of efficacy of intended medication originally prescribed and exposure of medication not intended for use. The medication Zyrtec is prescribed for the relief of allergy symptoms. The negative impact to patient was the emergent symptoms of allergies. Exposure to an unintended prescribed medication (Zantac) may also cause mild to severe side effects.	The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians. Corrective action plan: 1) The separation of Zyrtec and Zantac on the shelf. 2) Diagnosis will be requested to match drug with treatment condition. 3) Voice mail prescriptions will be checked with faxed copy. 4) Verification process reviewed. 5) Drug Utilization Review (DUR) process reviewed. 6) Quality assurance process reviewed. 7) Patient counseling procedure reviewed. 8) Incident with corrective action has been communicated to staff. 9) Submitted an ISMP medication error report. 10) Completed continuing education on "Medication Error Prevention".

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
15	IH	07/13/04	A prescription for Zonegran 25mg was incorrectly dispensed with Zonegran 100mg.	Incorrect Strength	The ingestion of the incorrect strength (four-fold increase) of Zonegran to a four year-old patient occurred over a two-month period prior to discovery and, resulted in symptoms of drowsiness, lethargy and irritability, missed school and an urgent follow-up neurology evaluation.	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians. Corrective action plan was submitted that identified product selection, NDC number and dose verification process failures as root contributors.</p> <ol style="list-style-type: none"> 1) Pharmacist will verify the NDC number by highlighting and checking on all prescriptions dispensed. 2) Communication of error and staff training regarding system changes. 3) Submitted an ISMP medication error report. 4) Completed continuing education on "Medication Error Prevention".

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
16	P	07/06/04	A prescription for Zarontin Syrup 250mg/5ml was incorrectly dispensed with Neurontin Syrup 250mg/5ml.	Incorrect Medication	The incorrect medication Neurontin Syrup was dispensed in place of Zarontin Syrup to a nine-year-old patient. Parent discovered the error four days after the prescription was filled. Both medications are indicated for epilepsy at different doses and both have side effects that require monitoring.	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians. Corrective action plan submitted identified failure to receive and read back verbal prescription and circumvention of the DUR “duplication of therapy” warning as root contributors.</p> <ol style="list-style-type: none"> 1) Reviewed the DUR policy for “duplicate therapy”. Pharmacist reviewed the importance of the DUR process and the need to reconcile all warnings prior to filling a prescription. 2) Pharmacist and technician reviewed the policy on verbal orders and to read back all verbal orders to double check accuracy. 3) Submitted an ISMP medication error report. 4) Completed continuing education on “Medication Error Prevention”.

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
17	I	07/09/04	A prescription for Seroquel 100mg, an antipsychotic, was incorrectly dispensed with Toprol XL 100mg, an antihypertensive.	Incorrect Medication	The medication Toprol XL 100mg was incorrectly dispensed and ingested for two doses by the patient. The potential to cause harm existed in the form of possible lowered blood pressure relative to the patient's baseline blood pressure. The patient was also deprived adequate treatment with the intended medication Seroquel.	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians.</p> <p>Corrective action plan:</p> <ol style="list-style-type: none"> 1) Reviewing company's work flow procedures for filling prescriptions. 2) Obtaining patient information at the drop-off window while the patient is physically present. 3) Matching printed label with their hard copy after label prints and matching NDC numbers on the label with NDC number stock drug. 4) Keeping bench clear of unnecessary clutter. 5) Utilize computer in verification process of the directions, DUR and cross checking typed label against hardcopy and drug dispensed. 6) Staff communication of error and corrective action plan. 7) Submitted an ISMP medication error report. 8) Completed continuing education on "Medication Error Prevention".

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
18	IH	08/02/04	A prescription for Alprazolam 0.5mg, an anxiolytic, was incorrectly dispensed for Vioxx, an anti-inflammatory.	Incorrect Medication	The medication Alprazolam, indicated for the control of anxiety, was incorrectly dispensed to an 82-year-old patient who had the same last name of the patient for whom the prescription was intended. The medication was ingested for four days causing lethargy and sedation. Excessive sedation had the potential to create an unsafe episode for this patient in the form of unsteady gait and possible fall as well as the lack of arthritis medication. The potential for Alprazolam to interact with several of the other medications taken by the patient could also be clinically relevant.	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians.</p> <p>A root cause analysis was submitted that identified patient identification and verification process failure as root contributors.</p> <ol style="list-style-type: none"> 1) During the DUR process, the computer will check the dosage against the patient's name and date of birth. NDC cross verification on stock bottle, label and receipt. 2) Verification of labels on all containers dispensed. 3) Patient counseling the prescription will be reviewed with the patient to verify the correct name, medication and directions. 4) Communication. Error was shared with all pharmacy personnel and all pharmacies within the corporation. 5) Submitted an ISMP medication error report. 6) Completed continuing education on "Medication Error Prevention".

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
19	IH	08/04/04	A prescription for Phenobarbital 64.8 mg was incorrectly dispensed with Phenobarbital 32.4 mg.	Incorrect Strength	The patient received the correct drug (Phenobarbital) but at half the strength prescribed resulting in sub-therapeutic treatment for seizure control. The patient ingested 58 tablets of the wrong dose for approximately one month before having a grand-mal seizure and was taken to a local emergency facility. Phenobarbital 64.8mg is a round, scored, white tablet with the imprint "5013v". Because of the size of the imprint and the glare of the lighting, the "5012v" on the incorrectly dispensed 32.4mg tablet was misread as "5013v" (the imprint on the prescribed 64.8mg tablet).	The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians. <ol style="list-style-type: none"> 1) Verification processed reviewed. 2) Patient's history review and verify scanned hardcopy of prescription (use zoom feature). 3) NDC cross verification on stock bottle. 4) Physically verify contents of prescription. 5) Pharmacy Policy and Procedures reviewed for medication dispensing process, medication errors, verification process and DUR process. 6) Medication references reviewed. 7) Submitted ISMP medication error report. 8) Completed continuing education on "Medication Error Prevention".

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
20	IH	09/02/04	<p>Zyrtec syrup was incorrectly dispensed in place of Zantac syrup. Zantac syrup contains ranitidine 15mg/ml indicated for the treatment of ulcers or GERD (gastroesophageal reflux disease). Zyrtec syrup contains cetirizine 1mg/ml indicated for allergic rhinitis or chronic urticaria (rash).</p>	Incorrect Medication	<p>This error occurred in a two-month-old patient who received 30 days of the incorrect medication Zyrtec syrup that was discovered by a parent on refill. Lack of efficacy of intended medication originally prescribed and exposure to medication not intended for use were implications for patient outcomes, including undue sedation of patient.</p>	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians.</p> <ol style="list-style-type: none"> 1) Adherence to basket system. Medications dispensed from liquid stock bottles are entered into the computer so the stock bottle can be scanned. 2) Stock bottle remains in the basket throughout the dispensing process. 3) The stock bottle is checked against the printed label. 4) All prescriptions for liquids are opened and eyed carefully at verification point. 5) Imaging scanning is checked with liquid stock bottles. 6) Shelf dividers are placed between Zantac and Zyrtec. 7) The medication error and corrective action plan was communicated to staff. 8) Submitted ISMP medication error report. 9) Completed two CEUs in "Medication Error Prevention".

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
21	IH	09/09/04	A prescription for Augmentin Suspension Extra Strength 600mg/5ml was incorrectly reconstituted with insufficient amount of water resulting in a higher concentration of dose dispensed.	Incorrect Strength	The Augmentin Suspension Extra Strength 600mg/5ml was mixed with half of the required water for reconstitution. The five year-old patient received five days of medication before parent discovery of the thick consistency. The patient was seen by the pediatrician for evaluation.	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians.</p> <ol style="list-style-type: none"> 1) Reconstitution of suspensions utilizing the "Fillmaster" water dispenser. 2) Prescription verification. Reconstituted products will be visually inspected for appropriate consistency. 3) Dispensing procedures reviewed. 4) Patient counseling procedure reviewed. 5) Communication. Error was shared with all pharmacy personnel and all pharmacies within the corporation. 6) Submitted an ISMP medication error report. 7) Completed continuing education on "Medication Error Prevention".

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
22	IH	09/15/04	A prescription for Zithromax Suspension, an antibiotic, was incorrectly reconstituted with insufficient amount of water resulting in a higher concentration of dose dispensed.	Incorrect Strength	A three year-old child received an incorrectly concentrated dose of Zithromax. The child developed stomach cramps and vomited.	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians.</p> <ol style="list-style-type: none"> 1) Proper reconstitution of suspensions reviewed utilizing a calibrated water dispenser. 2) Prescription verification. Reconstituted products will be visually inspected for appropriate consistency. 3) Dispensing procedures reviewed. 4) Patient counseling procedure reviewed. 5) Submitted an ISMP medication error report. 6) Completed continuing education on "Medication Error Prevention."

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
23	IH	09/24/04	Zantac syrup incorrectly dispensed in place of Zyrtec syrup. Zantac syrup contains ranitidine 15mg/ml indicated for the treatment of ulcers or gastroesophageal reflux disease (GERD). Zyrtec syrup contains cetirizine 1mg/ml indicated for allergic rhinitis or chronic urticaria (rash).	Incorrect Medication	This error occurred in a child who received three days of the incorrect medication Zantac syrup that was discovered by parent. The child suffered side effects of abdominal pain, gagging, vomiting and a prolonged nosebleed. Lack of efficacy of intended medication originally prescribed and exposure of medication not intended for use were implications for patient outcomes. Emergent symptoms of allergies from lack of prescribed Zyrtec may be mild to severe in nature. Impact of exposure to Zantac may be mild to severe in nature.	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians.</p> <ol style="list-style-type: none"> 1) Adherence to basket system. Medications dispensed from liquid stock bottles are entered into the computer so the stock bottle can be scanned. 2) Stock bottle remains in the basket throughout the dispensing process. 3) The stock bottle is checked against the printed label. 4) All prescriptions for liquids are opened and eyed carefully at verification point. 5) Imaging scanning is checked with liquid stock bottles. 6) Shelf dividers are placed between Zantac and Zyrtec. 7) The medication error and corrective action plan was communicated to staff. 8) Submitted ISMP medication error report. 9) Completed approved CEUs in "Medication Error Prevention".

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
24	P	09/27/04	A prescription for Paxil 40mg daily was prescribed and Paxil 40mg twice daily was incorrectly labeled and dispensed due to a failure to verify a poorly written prescription.	Incorrect Directions	The outcome of the error could have caused potential harm due to a two-fold increase in prescribed dose. The maximum recommended daily dose of Paxil is 60mg and the incorrect directions indicated two doses of 40 mg per day (80mg per day total). Increased potential for side effects occurs at higher than recommended doses.	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians. Corrective action plan submitted identified poorly written prescription, circumvention of the DUR high dose warning and failure to consult prescriber as root contributors.</p> <ol style="list-style-type: none"> 1) Prescription verification process. The pharmacist will verify the original prescription hard copy for appropriate dose and directions relevant to the medication dispensed. Pharmacist reviewed policy and procedures for prescription verification and the importance to never override warning flags without clarification of prescription. 2) Reviewed the Drug Utilization review (DUR) policy for minimum/maximum dose check. 3) Prescribing physician has been consulted and has agreed to clarify future prescriptions to prevent future misinterpretation. 4) Submitted an ISMP medication error report. 5) Completed continuing education on "Medication Error Prevention".

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
25	P	10/01/04	A prescription for Epi-pen Jr. 0.15mg was incorrectly dispensed with Epi-pen 0.3mg. The attached label directions were correct for the medication; however, the label was attached to the wrong formulation strength of Epi-pen.	Incorrect Strength	The incorrect strength of Epi-pen (autoinjector) was dispensed incorrectly at a dose two times the prescribed dose for an 18-month-old patient. Epi-pen 0.3mg was dispensed for Epi-pen Jr. 0.15mg. Epi-pen contains epinephrine utilized in emergencies for severe allergic reactions or life threatening anaphylaxis.	The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians. Corrective action plan was submitted that identified product selection, NDC number and dose verification process failures as root contributors. <ol style="list-style-type: none"> 1) Pharmacist will verify the NDC number by highlighting and checking on all prescriptions dispensed. 2) Communication of error and staff training regarding system changes. 3) Submitted an ISMP medication error report. 4) Completed continuing education on "Medication Error Prevention".

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
26	IH	10/04/04	A compounded prescription for Nitroglycerin 0.2% Ointment was incorrectly dispensed with Nitroglycerin 2% Ointment.	Incorrect Strength	The incorrect strength of Nitroglycerin Ointment was dispensed to the patient and applied as directed. The ten-fold increase in dose resulted in the patient experiencing side effects of headache and dizziness. The incident was reported to physician for appropriate follow-up evaluation and care.	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians. Corrective action plan submitted identified failure in data entry and verification of the Nitroglycerin compounded product against the prescription. The pharmacist only verified the NDC number on the stock ointment tube with the label that was entered incorrectly. Counseling was not offered.</p> <ol style="list-style-type: none"> 1) Data entry, after the prescription is entered in the computer the original hard copy will follow the final product for verification. 2) The pharmacist will verify the medication filled, verifying the original hard copy of the prescription, then verifying the directions and matching the NDC numbers of the medication against the NDC numbers of the filled medication. 3) Patient counseling procedure. The prescription will be reviewed with the patient to verify the correct medication and directions. 4) Communication. Error was shared with all pharmacy personnel. 5) Pharmacy will implement the "Best Practices" criteria into policy. 6) Submitted an ISMP medication error report. 7) Completed continuing education on "Medication Error Prevention".

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
27	IH	10/25/04	An original prescription for Clonazepam 0.5mg/ Take six tablets at bedtime and one tablet as needed was incorrectly labeled and dispensed with Clonazepam 0.5mg/ Take four tablets at bedtime and one tablet as needed. On refill, the error was discovered but then filled incorrectly with Clonazepam 1mg/ Take six tablets at bedtime and one tablet as needed (incorrect strength). The prescription error was discovered by patient and subsequently corrected.	Incorrect Label	A prescription was incorrectly labeled and dispensed with the wrong directions for the medication Clonazepam. The patient received a sub-therapeutic dose of the intended medication for two weeks requiring a follow up with the physician. The patient discovered the error at the time of refill, which was also dispensed incorrectly with the incorrect strength (see case # 28). The potential for harm exists due to the inadequate treatment of the intended dose prescribed by the physician.	The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians. <ol style="list-style-type: none"> 1) Data Entry Process. New scanners will be utilized to scan hard copies of prescriptions. 2) Prescription verification process. The pharmacist will verify the medication filled, verifying the original hard copy of the prescription, then verifying the directions and matching the NDC numbers of the medication against the NDC numbers of the filled medication. 3) Verification of labels on all containers dispensed. 4) Patient counseling procedure, the prescription will be reviewed with the patient to verify the correct medication and directions. 5) Communication. Error was shared with all pharmacy personnel. 6) Submitted an ISMP medication error report. 7) Completed continuing education on "Medication Error Prevention".

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Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
28	P	10/25/04	A refill prescription for Clonazepam 0.5mg was incorrectly dispensed with Clonazepam 1mg. The prescription error was discovered by the patient and subsequently corrected.	Incorrect Strength	The incorrect strength of Clonazepam was dispensed at twice the prescribed dose. The two-fold increase dose had the potential to cause harm due to the risk of side effects such as, lethargy, ataxia and excessive sedation resulting in negative outcomes if ingested.	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians.</p> <ol style="list-style-type: none"> 1) Data Entry Process. New scanners will be utilized to scan hard copies of prescriptions. 2) Prescription verification process. The pharmacist will verify the medication filled, verifying the original hard copy of the prescription, then verifying the directions and matching the NDC numbers of the medication against the NDC numbers of the filled medication. 3) Verification of labels on all containers dispensed. 4) Patient counseling procedure. Prescription will be reviewed with the patient to verify the correct medication and directions. 5) Communication. Error was shared with all pharmacy personnel. 6) Submitted an ISMP medication error report. 7) Completed continuing education on "Medication Error Prevention".

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
29	IH	11/02/04	A prescription for Hydroquinone 4% Cream was incorrectly compounded and dispensed containing sunscreen and Hydroquinone 4% Cream.	Incorrect Strength	A prescription for plain Hydroquinone 4% Cream was compounded incorrectly by adding sunscreen and Hydroquinone 4% Cream. The compound resulted in a rash to the area applied due to the unintended ingredients of the compounded cream that contained sunscreen. The patient received medical attention and subsequent treatment for the rash.	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians.</p> <ol style="list-style-type: none"> 1) Data Entry Process. New scanners will be utilized to scan hard copies of prescriptions. 2) Prescription verification process. The pharmacist will verify the medication filled, verifying the original hard copy of the prescription, then verifying the directions and matching the NDC numbers of the medication against the NDC numbers of the filled medication. 3) Verification of labels on all containers dispensed. 4) Patient counseling procedure. Prescription will be reviewed with the patient to verify the correct medication and directions. 5) Communication. Error was shared with all pharmacy personnel. 6) Submitted an ISMP medication error report. 7) Completed continuing education on "Medication Error Prevention".

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
30	IH	10/01/04	A prescription for Allopurinol 300mg/ Take one tablet a day, was incorrectly dispensed with Allopurinol 300mg/ Take one tablet four times a day. A dose of 1200mg daily was ingested rather than the intended 300mg daily dose.	Incorrect Directions	The incorrect directions on this prescription for resulted in ingestion for an 87-year-old patient for approximately one week. The patient experienced side effects from the four-fold increase in dose of Allopurinol (1200mg daily rather than 300mg daily), including constant thirst, lethargy, disruptive sleep and overall discomfort requiring a visit to the physician. The physician discovered the error and treated the patient accordingly.	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians.</p> <ol style="list-style-type: none"> 1) Prescription verification process. The pharmacist will verify the medication filled, verifying the original hard copy of the prescription, then verifying the directions and matching the NDC numbers of the medication against the NDC numbers of the filled medication. 2) Reviewed the Drug Utilization (DUR) policy for minimum/maximum dose check and to match medication with diagnosis. 3) Patient counseling procedure. Prescription will be reviewed with the patient to verify the correct medication and directions. 4) Communication. Error was shared with all pharmacy personnel 5) Submitted an ISMP medication error report. 6) Completed continuing education on "Medication Error Prevention".

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
31	P	11/17/04	A prescription for Atenolol 25mg, a beta-blocker utilized for hypertension, was incorrectly dispensed with Atenolol 50mg tablets.	Incorrect Strength	<p>A prescription was incorrectly dispensed with a two-fold increase in dose of the intended medication. A two-fold increase in dose can result in lowered blood pressure.</p> <p>Note: The refill for this prescription was filled with the incorrect amount of tablets (30) rather than the prescribed 60 tablets.</p>	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians.</p> <ol style="list-style-type: none"> 1) Data Entry Process. All patient demographic information is verified at prescription drop off. Hard copy prescriptions are scanned into the computer system 2) Prescription verification process. The scan image of medication is checked with the dispensed medications, if no image is available the actual stock medication stock bottle utilized for verification. The pharmacist will verify the medication filled, verifying the original hard copy of the prescription, then verifying the directions and matching the NDC numbers of the medication against the NDC numbers of the filled medication. 3) Verification of labels on all containers dispensed. 4) Patient counseling procedure. Prescription will be reviewed with the patient to verify the correct medication and directions. 5) Communication. Error was shared with all pharmacy personnel. 6) Submitted an ISMP error report.

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
32	I	08/05/04	A prescription for Darvocet N-100mg, an analgesic, was incorrectly dispensed with Doxycycline 100mg, an antibiotic.	Incorrect Medication	A prescription for Darvocet N-100mg was received as a verbal order from a prescriber and reduced to writing by a pharmacist using the abbreviation "DCN-100", which abbreviation was mistaken to indicate "Doxycycline 100mg" by the filling pharmacist. The 90-year-old patient ingested two doses of Doxycycline 100mg prior to discovery by a family member. The potential for harm exists if the patient developed photosensitivity or was allergic to Doxycycline. Unintended side effects or reactions could also occur if the medication is taken over an extended period.	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians.</p> <ol style="list-style-type: none"> 1) Data Entry Process. Abbreviations will not be used on call-in prescriptions. 2) Prescription verification process. The pharmacist will verify the original prescription hard copy, directions are relevant to the medication dispensed i.e. the directions for Darvocet N-100mg are not relevant for the antibiotic Doxycycline. Match the NDC numbers. 3) Verification of labels on all containers dispensed. 4) Patient counseling. Prescription will be reviewed with the patient to verify the correct medication and directions. 5) Communication. Error was shared with all pharmacy personnel. 6) Submitted an ISMP medication error report. 7) Completed continuing education on "Medication Error Prevention".

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
33	IH	11/24/04	A prescription for Chlorpromazine 100mg, an antipsychotic utilized to control schizophrenia and negative behaviors, was incorrectly dispensed with Chlorpropamide 100mg, a hypoglycemic utilized to control elevated blood sugar in diabetic patients.	Incorrect Medication	The patient received the incorrect medication Chlorpropamide 100mg for a month, resulting in uncontrolled behaviors due to the lack of antipsychotic medication Chlorpromazine 100mg treatment and possibly due to low blood sugars caused by the Chlopropamide.	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians. Identified root contributors:</p> <ul style="list-style-type: none"> • The pharmacy's computer system abbreviated the first eight characters of the drug name that are the identical. • The drug names sound alike. • The physician's prescription misspelled the drug. <ol style="list-style-type: none"> 1) Data Entry Process. All patient demographic information is verified at prescription drop off. 2) Prescription verification process. The cause of this QRE was determined to be a breakdown in the verification process checking the hard copy prescription. The drug name was entered incorrectly and the remaining verification process could not be completed properly. 3) Verification of labels on all containers dispensed. 4) Communication. Error was shared with all pharmacy personnel. 5) Submitted an ISMP medication error report. 6) Completed CEUs on "Medication Error Prevention".

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
34	IH	04/16/04	A prescription for Tri-Sprintec tablets was incorrectly dispensed with Sprintec tablets. Both medications contain ethinyl estradiol and norgestimate at different strengths and are not interchangeable. Tri-Sprintec and Sprintec are classified as birth control pills; however, they may be utilized to control adrenal disease by some endocrinologists.	Incorrect Medication	A prescription was incorrectly dispensed with Sprintec rather than Tri-Sprintec as prescribed to control symptoms associated with adrenal disease. The patient ingested approximately a 30-day supply prior to discovery when the prescription was refilled. The patient required a follow-up visit with the endocrinologist.	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians.</p> <ol style="list-style-type: none"> 1) Prescription verification process. The pharmacist will verify the medication filled, verifying the original hard copy of the prescription, then verifying the directions and matching the NDC numbers of the medication against the NDC numbers of the filled medication. 2) Verification of labels on all containers dispensed utilizing bar code scanning technologies will be followed. 3) Patient counseling procedure. Prescription will be reviewed with the patient to verify the correct medication and directions. 4) Communication. Error was shared with all pharmacy personnel. 5) Submitted an ISMP medication error report. 6) Completed continuing education on "Medication Error Prevention".

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
35	I	05/07/04	A prescription for Wellbutrin SR 100mg was incorrectly dispensed with Wellbutrin SR 150mg. Wellbutrin SR is classified as an antidepressant.	Incorrect Strength	The incorrectly dispensed Wellbutrin SR 150mg rather than Wellbutrin SR 100mg, represented a dose increase of 50% over the intended prescribed dose. Ingestion of the incorrect strength occurred for 30 days prior to discovery when the prescription was refilled. The unintended side effects from a 50% increased dose of Wellbutrin SR over a 30-day period range from mild to severe.	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians.</p> <ol style="list-style-type: none"> 1) Adherence to basket system. Hard copy of the original prescription will be placed in basket through filling process. 2) Medications dispensed from stock bottles are entered into the computer so the stock bottle can be verified. 3) Stock bottle remains in the basket throughout the dispensing process. 4) The stock bottle is checked against the hard copy prescription and printed label. 5) Imaging scanning is checked with all prescriptions. 6) Completed continuing education on "Medication Error Prevention". 7) Submitted ISMP medication error report.

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
36	P	03/11/04	A prescription for Dilantin Kapseals 100mg was prescribed and incorrectly dispensed with Phenytoin extended release 100mg capsules. Dilantin 100mg and Phenytoin 100mg extended release capsules are classified as anticonvulsants.	Incorrect Medication	The patient's neurologist prescribed Dilantin 100mg Kapseals as an anticonvulsant to control seizures. This brand name drug is not interchangeable as prescribed with any other generic medication. The pharmacist dispensed a generic medication in error because standard dispensing protocols set by the pharmacy were not followed. The patient's caregiver discovered the error prior to ingestion.	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians. The pharmacist and technicians reviewed standard prescription filling procedures involving hard copy verification and product selection when preparing prescriptions.</p> <ol style="list-style-type: none"> 1) The interchangeable medication policy and regulations were also reviewed for this product. 2) The stock bottle is checked against the hard copy prescription and printed label. 3) Computer upgrade, medications imaging and scanning devices are not available at the pharmacy for prescription verification. The pharmacy has contacted the software company for upgrades to the system such as bar code and imaging scanning for prescriptions. 4) Completed continuing education on "Medication Error Prevention". 5) Submitted ISMP medication error report.

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
37	I	05/20/04	A prescription for Avandia 2mg tablets was incorrectly dispensed with Amaryl 2mg tablets. Avandia and Amaryl tablets are classified as antidiabetic agents that have different mechanisms of action and chemical structure.	Incorrect Medication	The patient's physician prescribed Avandia 2mg as an antidiabetic agent to control elevated blood glucose and symptoms of diabetes. The patient ingested the incorrect medication (Amaryl 2mg) for 30 days before discovery at refill and required a follow-up visit to the physician. The medication prescribed by the physician is not interchangeable with another medication and may have negative consequences when taken for an extended period of time.	The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians <ol style="list-style-type: none"> 1) Prescription verification process. The pharmacist will clarify with the prescribing physician questions concerning the medication prescribed on the original hard copy of the prescription and make appropriate corrections. Match the NDC numbers of the medication against the NDC numbers of the filled medication. 2) Verification of labels on all containers dispensed. 3) Patient counseling procedure, the prescription will be reviewed with the patient to verify the correct medication and directions. 4) Communication. Error was shared with all pharmacy personnel. 5) Submitted an ISMP medication error report. 6) Completed continuing education on "Medication Error Prevention".

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
38	I	05/19/04	A prescription for Fluphenazine 10mg tablets, an antipsychotic, was incorrectly dispensed with Trihexyphenidyl 2mg tablets, an anticholinergic.	Incorrect Medication	The patient's physician prescribed Fluphenazine 10mg twice daily as an antipsychotic. The patient ingested 21 doses of the incorrect medication Trihexyphenidyl for approximately ten days before discovery by a healthcare provider. The patient was evaluated at a hospital. The potential for harm exists due to the lack of treatment with the intended prescribed antipsychotic medication for a ten-day period and exposure to an unintended medication.	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians.</p> <ol style="list-style-type: none"> 1) Medication Labeling. Medication labeling system has been changed to allow only a pharmacist to print labels for medication requested. 2) Labeling. Only a pharmacist will affix labels for blister card medication. The labels are self-adhesive; the pharmacist must also secure the label with 2 staples to ensure that there is no transfer of labels from one blister card to another. 3) Barcode scanning. The barcode on the label will be checked against the barcode on the stock bottle. 4) Drug utilization. The patient's medication profile is checked for duplicate therapy, allergies and medication interactions. 5) Submitted an ISMP medication error report. 6) Completed continuing education on "Medication Error Prevention".

APPENDIX D: Analysis of Quality Related Event (Medication Error) Reports Reviewed by the Massachusetts Board of Registration in Pharmacy

Case #	Category of Event	Date	Case Description	Type of Error	Patient Outcomes	Corrective Actions
39	IH	06/28/04	A prescription for Relafen 500mg tablets, an anti-inflammatory agent, was incorrectly dispensed with Methocarbamol 500mg tablets, a muscle-relaxing agent.	Incorrect Medication	The patient's physician prescribed Relafen 500mg tablets an anti-inflammatory to treat arthritis. The patient ingested the incorrect medication Methocarbamol for one-day before becoming ill with symptoms of lethargy, weakness and mild nausea. The patient, a nurse who had taken the medication several years, discovered the error by checking the Physician's Desk Reference (PDR). The potential for harm exists due to the lack of treatment with the prescribed Relafen for a three-day period and exposure to an unintended medication that resulted in side effects.	<p>The following medication use processes were reviewed and corrected by the pharmacy, pharmacists and technicians.</p> <ol style="list-style-type: none"> 1) Patient Counseling. The pharmacy reviewed the procedures and regulation pertaining to patient counseling. All questions pertaining to medication are to be directed to the pharmacist. 2) Prescription Verification Process. The pharmacist will verify the original prescription hard copy against the labeled vial for appropriate medication, patient, dose and directions relevant to the medication dispensed. The barcode on the label will be checked against the barcode on the stock bottle. 3) Communication. Error was shared with all pharmacy personnel. 4) Submitted an ISMP medication error report. 5) Completed continuing education on "Medication Error Prevention".