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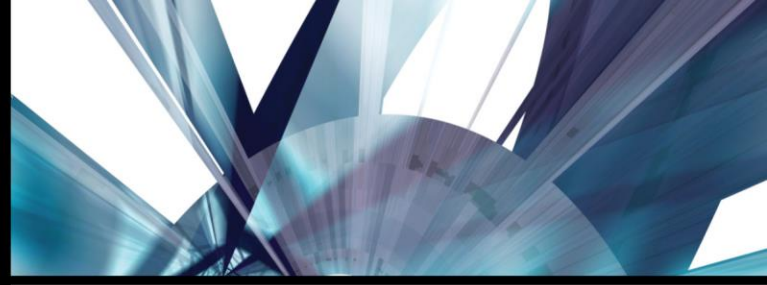

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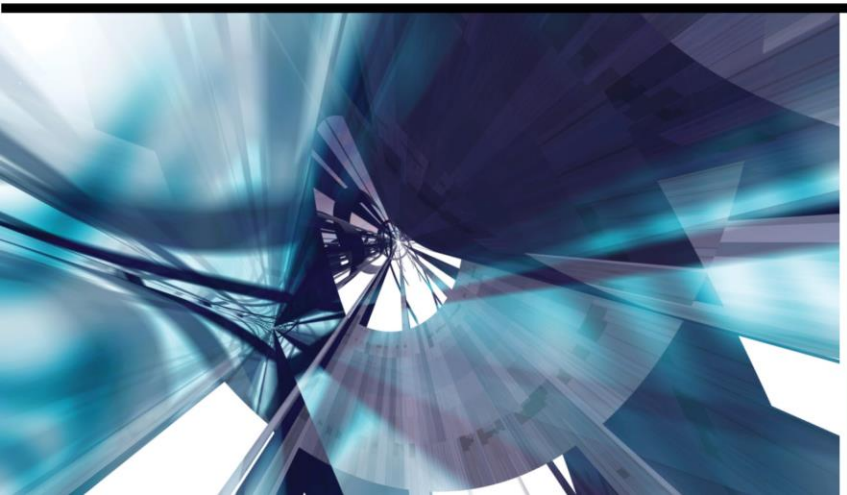

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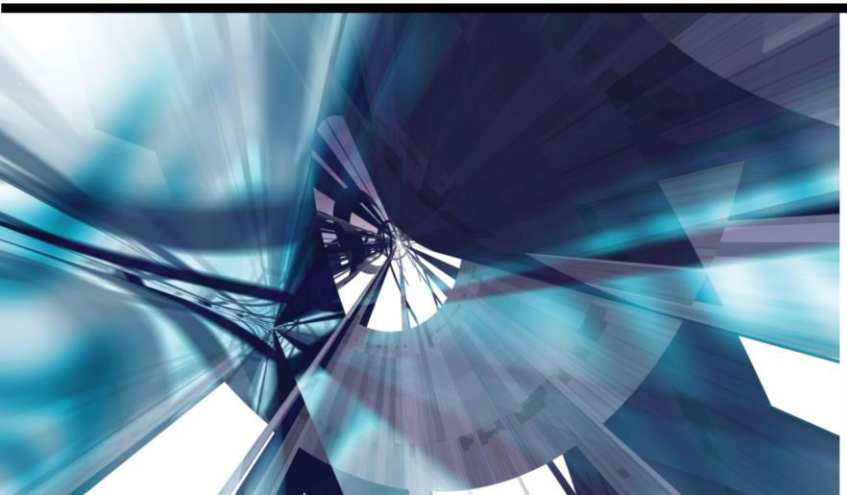
THE VOICE OF FOOD RETAIL

PEOPLE I PROPERTY I REPUTATION

PREVENTING AND DEFENDING RETAIL PHARMACY MISFILLS: FROM A RISK MANAGER'S PERSPECTIVE



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THE VOICE OF FOOD RETAIL

Unfortunately, prescription misfills are a growing problem amongst retail community pharmacies in the United States. Prescription misfills are a widespread problem which can, in the worst case, cause harm, and even death, to customers.

- Risk management is an integral part of a retail pharmacy's standard business practice.
- Risk management activities include identifying and evaluating risks, followed by implementing the most advantageous methods of reducing and eliminating these risks.
- The first step in the process of protecting yourself and reducing liability exposure is to learn about the risks that confront today's retail pharmacies.
- Risk management involves being proactive and implementing procedures to help prevent misfills in your retail pharmacy.
- Once these types of claims arise, the most critical step is acting as quickly as possible to fully investigate the claim so that it can be properly defended.

- This presentation is intended to inspire risk managers, pharmacists and legal counsel nationwide to carefully examine their practices, develop effective risk prevention programs and develop a strategic action plan in the event of a pharmacy misfill.

THE IDEAL PHARMACY?

Fallibility is a part of the human condition.
We can't change the human condition.
We can change the conditions under which people work…

James Reason, "Human Error"

Pharmacy is a “no mistakes” profession. No pharmacist wants to make a mistake, especially one that can result in injury with devastating consequences. Negligence and the making of mistakes are usually viewed as being different, but in pharmacy they are the ***same***.

- Pharmacies may be legally liable for their pharmacists and their technician's errors. As a consequence retail pharmacies may face lawsuits from patrons resulting in monetary damage awards and/or actions by regulatory agencies against the pharmacist themselves. This could place their professional license in jeopardy.

- In 2000, 2.9 billion retail prescriptions were filled in the U.S., up 62% from a decade earlier.
- In 2005, 3.6 billion outpatient prescriptions were dispensed; this is an increase of 71% from 2.1 billion in 1994, compared with a population growth of only 9% over the same period.

If, error rates are increasing at the same time that the number of prescriptions dispensed is rising, the potential risk to the public is alarming and the potential for lawsuits against retail pharmacies is also alarming.

Example:

- A pharmacist dispensed the wrong medication for gout and the patient went into a coma and eventually suffered a stroke and died. The pharmacy chain that employed the pharmacist was ordered to pay the patient's estate **$31.3 million**. In another case, a patient mistakenly received a dose of medicine that was 10 times too high, resulting in cerebral hemorrhage and death; the family received a damage award of **$25.8 million**.

- *Judgmental error* is one of discretion in counseling, screening, or patient drug monitoring.

- *Mechanical error* is an error in the preparation and processing of the prescription.

- An analysis of claims against pharmacists found that mechanical errors accounted for 86% of liability claims.

- By far the most common type of error in this type of litigation is the allegation that the wrong drug was dispensed (52%).

  - Dispensing the wrong dose of the correct drug.
  - Providing incorrect directions on the label.

- In a nationwide survey of 1,000 community pharmacists conducted in 1996, more than half of the pharmacists reported making a dispensing error in the previous 60 days.

- The typical *retail pharmacist* admitted to making an average of 2.5 errors during the previous two-month period, and 8% believed that they made more than six.

- About one in four pharmacists believed that his or her error rate had increased during the previous year.

- More than half of the pharmacists reported that they dispensed the wrong dose, and more than 25% reported that they dispensed the wrong drug.

- 47% of pharmacists dispensing fewer than 100 prescriptions per day reported making an error.

- 60% of those dispensing 100 or more prescriptions per day were aware of a mistake.

- Among independent pharmacists, about half caught the error themselves, with 38% caught by the patient or family member.

- Among ***retail store pharmacists***, only 26% caught the error themselves, with 68% being discovered by the patient.

- An investigation by a Boston newspaper of 51 Massachusetts pharmacies in 1999 revealed that 4% of prescriptions dispensed by community pharmacists contained errors.

- 88% of these involved the wrong drug or strength.

- The AP found complaints on misfilled prescriptions in all states nationwide are on the rise, with some resulting in permanent injury or death.
- 45 million prescriptions are incorrectly filled each year.

The competitive nature of the large drugstore chains, emphasis on high volume and profitability, and overworked pharmacists as reasons for the increase in prescription errors.

- Incorrect dosages;
- Dangerous instructions;
- Wrong pills.
- 5 out of 100 prescriptions were filled wrong;
- 274,000 misfilled prescriptions per day in our country.

- A double dose of Coumadin (a blood thinner);
- An under dose of an asthma medication;
- Wrong labeling;
- Wrong pills;
- Double dose of an anti-seizure mediation;

According to the Primetime survey, 274,000 prescriptions are incorrectly filled each day.

Civil Liability

- Pharmacy and Retail Pharmacy chains are liable for their pharmacists' and technicians'' mistakes under the theory of *negligence*.

- Pharmacists have a legal duty to provide patients with the best care possible.

- A pharmacy will be liable if he or she breached that duty in a manner that caused harm to the customer.

- Know the law.

- Work in conjunction with your legal counsel.

CAUSES OF ERRORS

- High prescription volume.
- Shortage of support personnel.
- Look-alike/sound-alike drug names.
- Fatigue/ Overworked.

Causes continue…

- Distractions or Interruptions

Most Common Causes of Errors Cited By Pharmacists

- Too many telephone calls (62%)
- Overload/unusually busy day (59%)
- Too many customers (53%)
- Lack of concentration (41%)
- No one available to double-check (41%)
- Staff shortage (32%)
- Similar drug names (29%)
- No time to counsel (29%)
- Illegible prescription (26%)
- Misinterpreted prescription (24%)

WORKLOAD

- A study released by the Pharmacy Manpower Project showed that the workload for America's pharmacists increased measurably between 2000 and 2004.

- A perception that the growing workload has negatively affected their ability to reduce medication errors was cited by 36% of the pharmacists surveyed in the study

At the Impatient Pharmacy

STRESS

- Stress may increase the rate of information processing.
- Lead to exceeding the optimal capacity for processing information.
- Thinking about stressful events may distract attention away from critical tasks.
- Lead to alterations in work patterns and shortcuts that may promote inaccurate behavior.
- Can also cause cognitive systems to default to responses that emphasize past habits instead of recently learned adaptive strategies.

SLOWER PERIODS IN WORK

- In another research report, pharmacists were found to be most vulnerable to making an error when they were *less* busy, or during a dramatic shift in the number of prescriptions presented (i.e., going from high to low and vice versa).

HIGH PERSCRIPTION VOLUME

- High prescription volume was named by 84% of the surveyed employee pharmacists, with overwork and fatigue named by 80%.

- The average retail pharmacist's workload increased by 57% between 1991 and 2000, such that the typical pharmacist filled a prescription an average of every five minutes compared with every eight minutes in 1991.

SIMILAR DRUG NAMES

- A busy pharmacist can easily substitute the wrong drug for one with a similar name when reading an illegible prescription, receiving a prescription over the phone, or simply picking up the wrong or adjacent bottle from the shelf. Look-alike/sound-alike drugs exist between brand names of different drugs, generic names of different drugs, or between a brand and a generic name.

HOW TO PREVENT ERROR IN YOUR PHARMACY

Excessive Work Load

- A rule enacted in North Carolina states that employers cannot require pharmacists to work more than 12 continuous hours per day. If a pharmacist works for 8 continuous hours, the rule states that the employer must offer the pharmacist the opportunity to take one 30-minute meal break and one additional 15-minute break during the shift. Employers who violate the rule may be sanctioned by the pharmacy board.

- The California Pharmacists Association proposed a similar contract calling for a rest break every three to four hours.

- The Arizona State Board of Pharmacy endorsed a proposal that would encourage pharmacy owners and managers to allow pharmacy personnel to “close and secure” a pharmacy for a maximum of 30 minutes at midshift, allowing personnel to relax, have a meal, or otherwise occupy themselves

- The North Carolina board set 150 prescriptions per pharmacist per day as the limit for safe prescription dispensing. Any pharmacy dispensing more than this limit could be subject to disciplinary action should a medication error occur.

- Iowa has set a guideline of not more than 14.2 prescriptions an hour per pharmacist.

- The California Pharmacists Association proposed contract requested that pharmacists not routinely dispense more than an average of 15 prescriptions per hour.

It is not unreasonable to expect that more states will examine workplace issues and seek to reduce errors—and protect the public—through regulatory guidelines.

CHECKS AND BALANCES SYSTEM

- A “triple check plus two” system:
  - when it is taken off the shelf;
  - when it is placed in the container;
  - and when the order is filled.
- In addition, the National Drug Code (NDC) number in the computer system should be checked against the prescription bottle, and the prescription should be checked again during counseling.

COUNSELING

- One estimate from North Carolina suggests that half of medication-related deaths could have been prevented by appropriate and timely counseling.

Counseling Cont.…

- A “show and tell” technique in which the patient is shown the drug while the pharmacist asks three key questions:

1)What did the physician tell you the drug is for?;

2) How were you told to take the medication?; and

3) What directions did the physician provide for taking the medication?

The pharmacist can then compare this information with the drug and label and recognize discrepancies

REDUCING STRESS

- Providing a comfortable waiting area, rope off area around counter, make designated lines for pick up/drop off and have a counseling area.

- Not storing drugs with similar names near each other, specifically identifying and segregating drugs that have a non-oral route of administration.

- Circling the number of tablets in a bottle if different from 100, and taking the prescription or label to the shelf when retrieving the drug instead of relying on recall.

www.ismp.org

Includes lists of confused drug names, error-prone abbreviations, high-alert medications, and other useful information.

Self Regulatory Practices

Do Nothing vs. Punishment

- Do you move them to a different store?
- Reprimand them?
- Terminate them?

How to deal with the Media

- There are two courts in this world, and the court of public opinion is just as powerful as the court of law.

- What is the smartest thing I can do to protect my company?

SUMMARY AND CONCLUSION

Fix The Problem With Specific Techniques

- Select and use techniques that put theory into practice;
- Use the techniques to catch or absorb errors;
- Recommit to existing policies;
- Develop new techniques with consensus of all involved.

SUMMARY AND CONCLUSION, CONT…

- Proper training and supervision of employees;
- Proper documentation and quality control efforts;
- Maintenance of adequate levels of personnel, and;
- Efforts to promote counseling.

"It may be part of human nature to err, but it is also part of human nature to create solutions, find better alternatives, and meet the challenges ahead."

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