

Designing An Effective Quality Improvement Program

Edward D. Rickert, R.Ph., J.D.
Smith, Rickert & Smith
8383 W. Belmont, Suite 304
River Grove, IL 60171-1083
708-456-4500
edr@smithrickert.com

Introduction

- Overview of Issues Surrounding An Effective QA Program
- Emphasis On Medication Error Reporting
- Perspective of Pharmacist - Attorney Who Has Represented Pharmacists and Pharmacies in Civil and Administrative Matters

Topics of Discussion

- Legislative and Regulatory Approaches To Medication Error Reporting
- Peer Review Protections
- Other Legal Protections
- How To Set Up Internal Error Reporting System To Maximize Protection

Overview of QI Issues

- Purpose: Identify causes of errors, and design a plan to minimize the risk of those errors occurring again.
- Overwhelming majority of claims against pharmacies arise from dispensing errors.

Overview of QI Issues

- Pharmacists Mutual Claims Study
- Claims Information From 1989 through 1999.
 - ◆ Wrong Drug - 49.7%
 - ◆ Wrong Strength - 25.1%
 - ◆ Wrong Directions - 7.5%
 - ◆ DUR - 7.5%
 - ◆ Counseling - 5.4%

Overview of QI Issues

**Plaintiff's
Lawyers
Are Lazy!**

Overview of QI Issues

**Plaintiff's
Lawyers
Are Smart!**

Issues With Internal Error Reporting Systems

Survey

- Does Your Chain Require Preparation Of An Incident Report Following Discovery Of A Medication Error?
- Are Copies Of The Reports Reviewed By Management?
- Are Reports Discussed With The Pharmacist That Made The Error?

Issues With Internal Error Reporting Systems

Survey (continued)

- Has Your Chain Ever Disciplined A Pharmacist For Medication Errors?
- Has Your Chain Ever Taken Non-Disciplinary Measures In Response To Medication Errors?
- Does Your Chain Maintain Copies Of Incident Reports?

Issues With Internal Error Reporting Systems

Survey (continued)

- Do You Agree That Management Must Take Steps To Ensure That Medication Errors Are Avoided?
- Do You Believe That An Error Rate Of 0.0016% Is Evidence That Your Error Reduction Activities Are Effective?

Issues With Internal Error Reporting Systems

Survey (continued)

- Do You Believe That Your Chain Exhibits A Conscious Disregard For The Safety Of Its Patients?
- *Harco v. Holloway* - Alabama Supreme Court

Legislative and Regulatory Approaches To Medication Error Reporting

- Every State Is Looking At Error Reporting
 - ◆ Legislative
 - ◆ Administrative
- The Federal Government Is Looking At The Issue
- 2 General Types:
 - ◆ punitive
 - ◆ non-punitive

Legislative and Regulatory Approaches To Error Reporting - Federal Bills

HR 3672 - Medication Error Prevention Act of 2000

- Establishes USP as the error reporting clearinghouse
- Protects all information reported to USP from discovery in civil and regulatory matters

Legislative and Regulatory Approaches To Error Reporting - Federal Bills

SB 2038 - Medication Error Reduction Act of 2000

- Provides grant money to the states for establishment of error reporting systems
- Limits use of information to evaluation of ability to reduce errors
- Information is treated as confidential and inadmissible as evidence in any civil or criminal actions

Legislative and Regulatory Approaches To Error Reporting - State Approaches

- Non-Punitive:
 - ◆ Goal is to improve care
 - ◆ Records collected and created are privileged and protected from discovery
 - ◆ Legal protections must be granted by legislature or judiciary, or have a legislative basis

Legislative and Regulatory Approaches To Error Reporting - State Approaches

- Punitive:
 - ◆ Stated goal is to improve care and protect public
 - ◆ Licensee can be disciplined for errors which are reported
 - ◆ No legal protection for records collected and created
 - ◆ “Plaintiff friendly”

Legislative and Regulatory Approaches To Error Reporting - State Approaches

- Punitive - Example:
 - ◆ Requires internal reporting of all errors caused by administration of incorrect medicine
 - ◆ Report must be readily retrievable, open for inspection and kept for three years
 - ◆ Deaths associated with dispensed medications must be reported

Legislative and Regulatory Approaches To Error Reporting - State Approaches

- Punitive - Example:
 - ◆ Reports generated and maintained by pharmacy are not protected from discovery in the event of litigation
 - ◆ Pharmacy and pharmacist are subject to discipline
 - ◆ Discipline is determined on case by case basis

Legislative and Regulatory Approaches To Error Reporting - State Approaches

- Non-Punitive - Example:
 - ◆ Allows creation of pharmacy peer review committees
 - ◆ Purpose is to evaluate quality of services, competence of pharmacists and to suggest improvements in pharmacy systems

Legislative and Regulatory Approaches To Error Reporting - State Approaches

- Non-Punitive - Example:
 - ◆ All proceedings and records of the peer review committee are confidential
 - ◆ All communications to the committee are privileged
 - ◆ Not admissible as evidence in any civil or administrative proceeding unless committee waives privilege

Peer Review Protections

- Peer Review
- Nearly always created by statute
 - ◆ Evaluation of quality of care or professional competence
 - ◆ Activities that are encompassed by peer review laws vary from state to state
 - ◆ Protections vary from state to state

Peer Review Protections

- Designed to foster full disclosure, and full and frank discussions
- Documents made by or for a peer review committee are confidential and privileged unless:
 - ◆ Made in the “regular course of business”, or
 - ◆ Waived

Peer Review Protections

- All fifty states have peer review statutes that specifically apply to doctors and hospitals
- Many states have statutes that apply to dentists, nurses, and physician assistants
- Only a handful of states have statutes that specifically apply to pharmacies and pharmacists

Peer Review Protections

- Activities must be reviewed by a committee set up specifically for peer review
- Disclosure of information to persons or entities outside of the Peer Review Committee can result in waiver
- Participation by non-committee members can result in waiver

Peer Review Protections

- Can a medication error incident report be protected as a peer review document?
 - ◆ Relates to quality of care?
 - ◆ Prepared for purpose of evaluating care or competence?
 - ◆ Prepared in “ordinary course of business”?
 - ◆ Waiver?

Peer Review Protections

- Incident reports, as commonly used in the retail setting, most likely do not fall within the statutory definition of a “peer review” document
- Need to implement changes in the system in order to create protection

Peer Review Protections

- Peer Review protection in absence of legislation
 - ◆ *Bredice v. Doctor's Hospital* - D.C. District Court (1970)
 - ◆ *Laws v. Georgetown University Hospital* - D.C. D. Ct. (1987)
 - ✦ “Peer review” protection created or expanded by court based on public policy considerations
 - ◆ Common law “critical self-analysis”

Other Legal Protections

- Attorney/Client Privilege
 - ◆ Communications between an attorney and a client for purposes of rendering legal advice are privileged
- Attorney Work Product
 - ◆ Materials prepared in anticipation of litigation are protected
- “Undue Burden”

Other Legal Protections

- Attorney/Client Privilege
 - ◆ Are medication error incident reports prepared for counsel for purposes of obtaining legal advice?
 - ◆ Does counsel even see the report until a claim is made?
 - ◆ Are reports prepared by a “client”?
 - ◆ Are reports used for other purposes?

Other Legal Protections

- Work Product Doctrine
 - ◆ Are all medication error incident reports prepared “in anticipation of litigation”?
 - ◆ Are reports generated in the regular course of business?
 - ◆ Is the prospect of litigation “identifiable and substantial”?

Undue Burden

“Defendant objects to this request on the grounds that it is overly broad and unduly burdensome, and seeks information that is irrelevant, and not likely to lead to the discovery of admissible evidence”

Tips For Maximizing Legal Protection

- Set up meaningful review plan, designed to improve system
- Use medication error reports to improve system, not to punish pharmacists
- Identify incident reports as a “quality of care report” or “peer review report”

Tips For Maximizing Legal Protection

- Identify each page of the report as “Confidential and Privileged”
- Restrict access to report to those named to the peer review committee
- Require reports for “near misses”
- Don’t be a “pack-rat” - don’t retain what you no longer need

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QUESTIONS?