

Reducing Dispensing Errors

Quality Control Measures in Managed Care

&

Current Legislative Initiatives Impacting Pharmacy

What are they? How do you use them?

Kenneth R. Baker, BS Pharm, JD

Renaud Cook Drury Mesaros, PA

Phoenix, AZ

Goals

- Review new and proposed state and federal legislative initiatives impacting pharmacy, particularly quality assurance initiatives.
- Examine how to use these initiatives to advantage [i.e., reduce medication errors in pharmacy]
 - protections and pitfalls contained in recording and using near-miss and error data.
 - how the proposals can protect information from discovery and
 - what information can not be protected.

Objectives

Upon completion, participants should be able to...

- understand new federal legislation designed to improve quality and protect data
- understand new state board initiatives for CQI
- implement CQI program under these initiatives
- record near-misses and errors to comply and use the law to pharmacy's advantage.
- use data collected to constantly improve quality system

True? or False?

True? or False?

I need government to tell me I need a CQI plan?

Multiple Choice

Multiple Choice

Our pharmacy has a CQI plan because

1. We do not want to make medication errors.
2. We want to save money.
3. We don't want to talk to lawyers.
4. Government

Reducing Med Errors

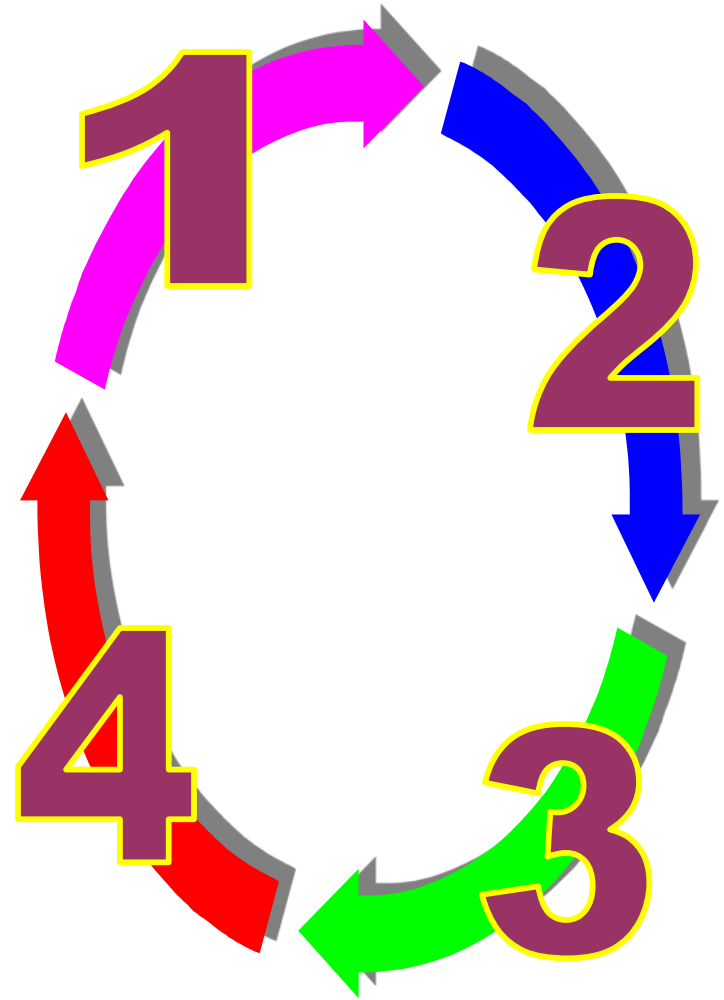
overcoming

the

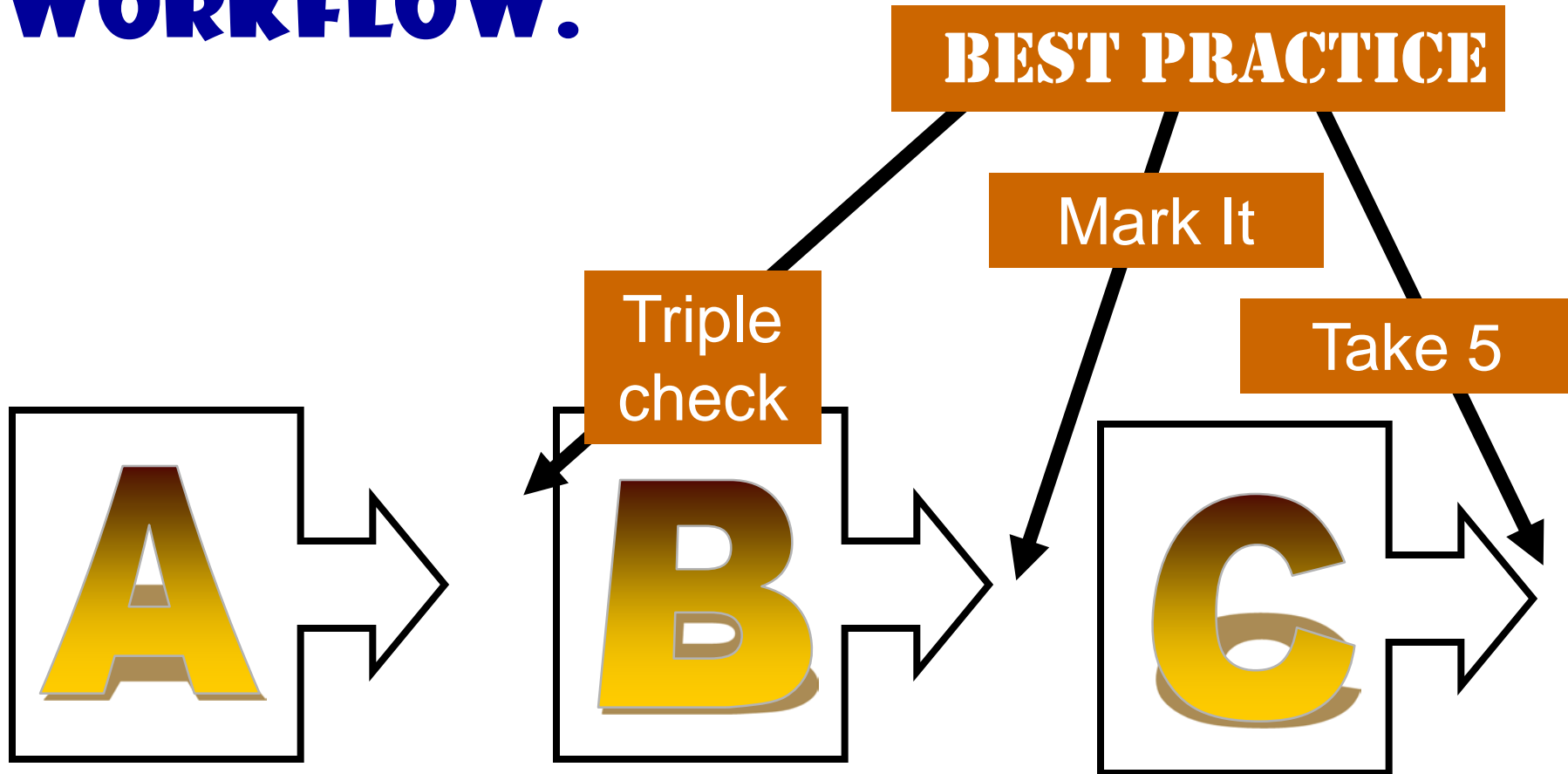
problems

YOU ALL HAVE A CQI PROGRAM! - (THE "C" PART ?)

1. Identify the Risk
2. Select the Best Practices
3. Train & Implement
4. Monitor, record errors & near misses
– make changes



1, 2 & 3 - AN ORGANIZED WORKFLOW.



**THE WEAKNESS IN MOST
PHARMACY PROGRAMS IS IN #4.
THIS IS WHERE THE LAWS WILL
HELP.**

Discoverability



4

Monitor, record
errors & near
misses – make
changes

True? or False?

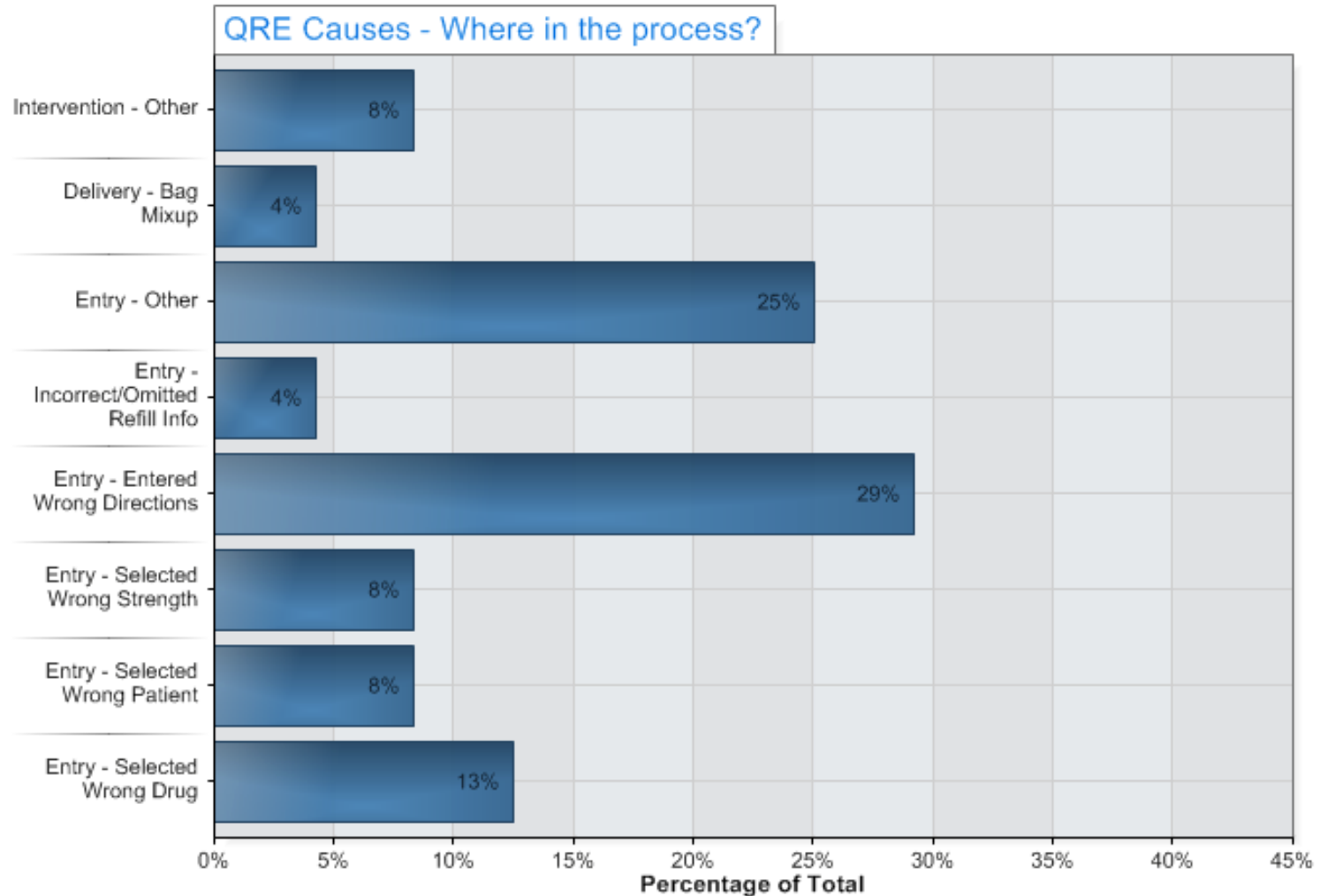
For an effective CQI plan we must collect and analysis data for near misses and errors?

Multiple Choice

We don't collect & analysis all QRE data because

1. We make so much money we don't need to save.
2. We like to talk to lawyers.
3. It takes too much time.

Why is the data important?



Why not just error data?

ROOT CAUSE ANALYSIS

[analysis of one event – useful for preventing reoccurrence of single event. Prevent one error from reoccurring.]

FAILURE MODE AND EFFECT ANALYSIS

[Analysis of vulnerabilities within the system to develop methods to reduce the risk of future errors]

Large Volume - Time Limited

ROOT CAUSE ANALYSIS

Valuable for selected errors, but too time consuming and information received too limited to utilize for each medication error. **Problem: More Time**

FAILURE MODE AND EFFECT ANALYSIS

Statistical analysis of large numbers, not individual incidents. Shows large vulnerabilities in system. Better for overall quality improvement. **Benefit: Less Time**

ROOT CAUSE ANALYSIS

CA Regulations: “All medication errors discovered shall be subject to a quality assurance review.”

1. Record date, location, participants (in review or error)
2. Pertinent data and other information relating to the medication error reviewed and documentation of patient contact
3. Findings and determinations generated by quality assurance review
4. Recommended changes

Can not use Incident Reports or lose discoverability protection. Board has access to reports.

Ken Baker

www.kenbakerconsulting.com

FAILURE MODE & EFFECT ANALYSIS

AZ Regulations: “collect, record & utilize QRE data.”

1. More data, no requirements as to what to be collected or recorded.
2. Purpose is statistical analysis
3. Same information for error & near miss. (~ 30 seconds)
4. Do not analyze each individually, but graph of total for month (quarter, year)

Incident Reports separate, maintain discoverability protection – only for QA use.

Board has no access to data, only need to prove collecting & using.

RENAUD COOK DRURY MESAROS, PA

True? or False?

True? or False?

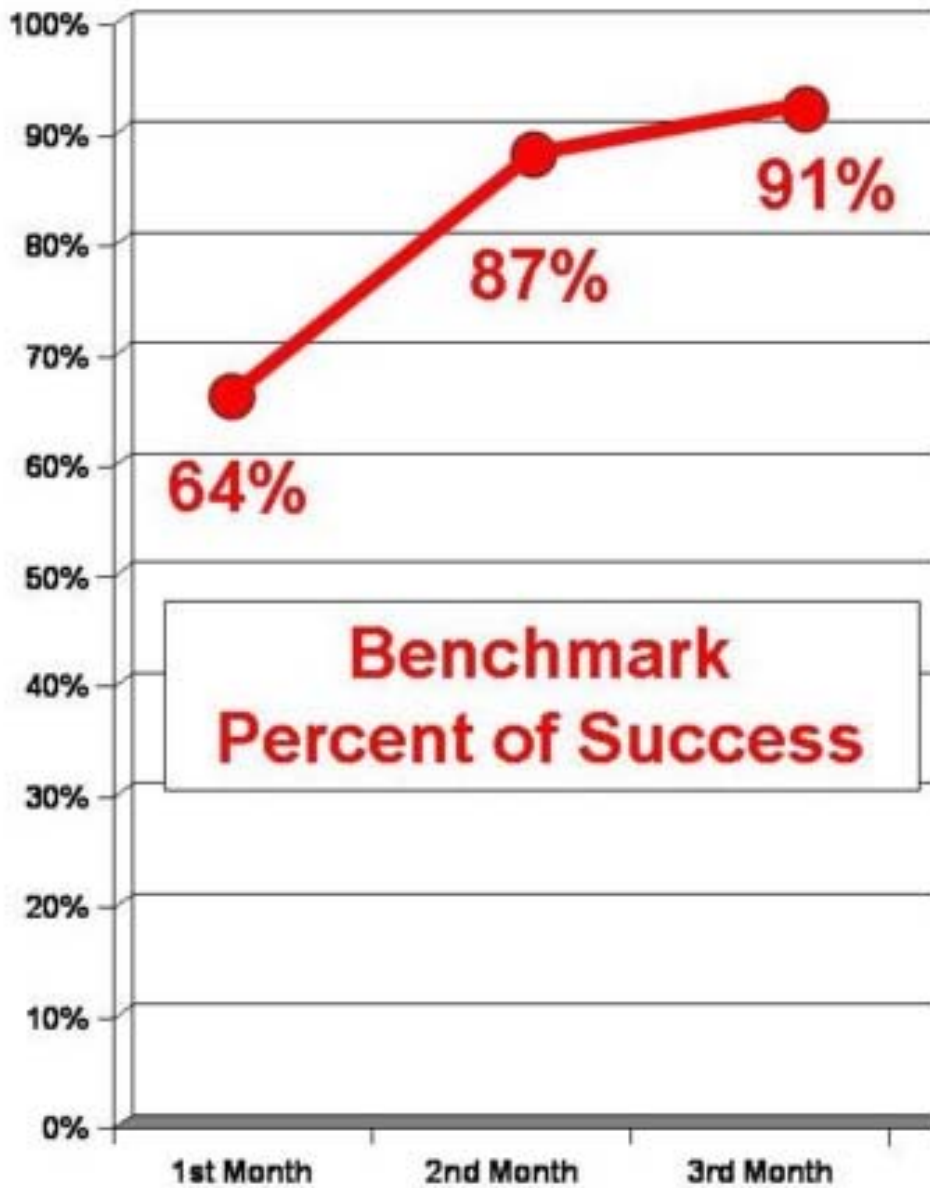
- While all QRE data is valuable in maintaining an effective pharmacy CQI program, the easiest to use and most effective is statistical data that can be graphed and compared for trends and to show vulnerabilities in the system over time.



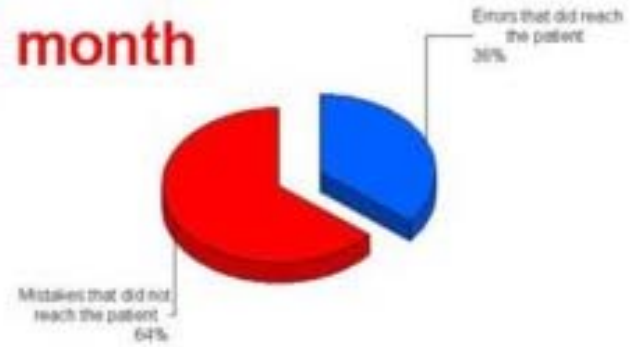
True? or False?

True? or False?

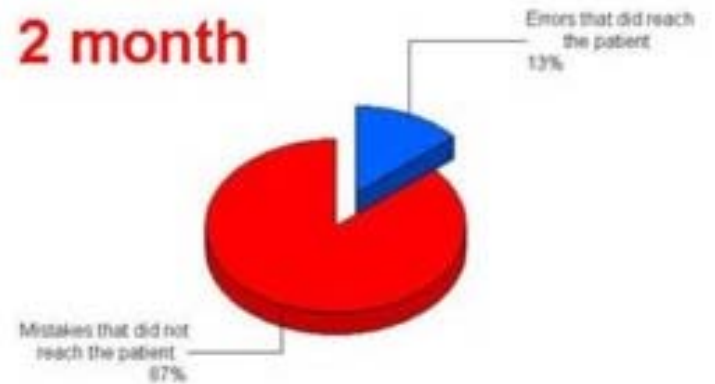
- Every pharmacy should post a monthly “success rate”.



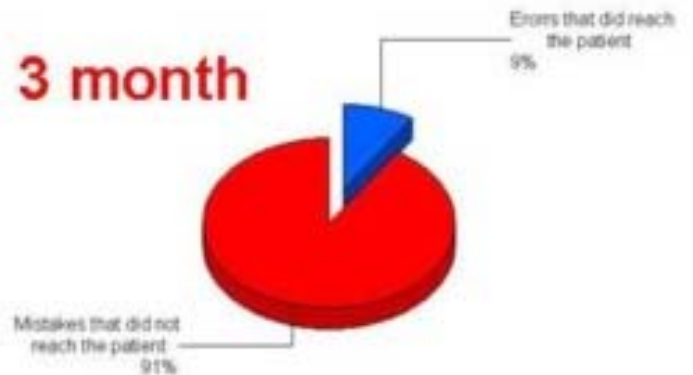
1 month



2 month



3 month



Arizona Statute:

§ 32-1973 quality assurance

- “each pharmacy shall implement ... a CQI program ... to identify methods for addressing ... medication errors”
- “Records that are generated as a component of a pharmacy's ongoing quality assurance program and that are maintained for that program are peer review documents and are not subject to subpoena or discovery in an arbitration or civil proceeding.
- “This subsection does not prohibit ... discoverability of any records that are not generated only as a component of a pharmacy's ongoing quality assurance program and maintained only for that program.”
- Hospitals exempt from rule

True? or False?

True? or False?

- Quality Related Event or QRE is the term used to include all errors that move beyond the control of the pharmacy and “near-misses”, potential errors that are discovered and rectified while still in the control of the pharmacy.

AZ State Laws & Regs



Arizona CQI Rules [under study]

Definitions

- **"Continuous quality improvement program"** - planned process designed by a pharmacy permittee to identify, evaluate, and prevent medication errors.
- **"Medication error"** unintended variation from a prescription or drug order.
- **"Quality-related event"** or "QRE" means:
 - A medication error or
 - would have resulted in a medication error except that intervention by a pharmacy staff member prevented delivery of the potential medication error to the patient or care-giver

Arizona CQI Rules [under study]

Each pharmacy permittee shall implement or participate in a continuous quality improvement (CQI) program.

A pharmacy permittee and pharmacist-in-charge shall ensure that:

1. The pharmacy develops, implements, and utilizes a CQI program ...;
2. QRE data generated is utilized on a regular (quarterly) basis; and
3. Training records, policies and procedures, and other program records or documents, other than QRE data, are maintained for a minimum of two years in the pharmacy or in a readily retrievable manner.

Arizona CQI Rules [under study]

A pharmacy permittee and pharmacist-in-charge shall:

1. Ensure that policies and procedures for ... CQI program prepared, implemented, and complied with;
2. Review biennially and, if necessary, revise
3. Document the review required
4. policies and procedures written or electronic manual;
and
5. Make the policies and procedures available [for] employee reference and inspection by the Board.

Arizona CQI Rules [under study]

The policies and procedures address a planned process to:

1. Train all pharmacy personnel in ... CQI program;
2. Identify and document QRE;
3. Record, measure, and analyze data collected to:
 1. causes and contributing factors relating to QRE, and
 2. Improve the quality of patient care;
4. Utilize the findings ... to prevent or reduce QRE; and
5. Communicate periodically, and at least annually, with pharmacy personnel to review findings and inform of any changes ... as a result of CQI program findings.

Arizona CQI Rules [under study]

- The Board's regulatory oversight activities regarding a pharmacy's CQI program are limited to
 - inspection of the pharmacy's CQI policies and
 - procedures and enforcing the pharmacy's compliance with those policies and procedures.
- A pharmacy's compliance with this section shall be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.

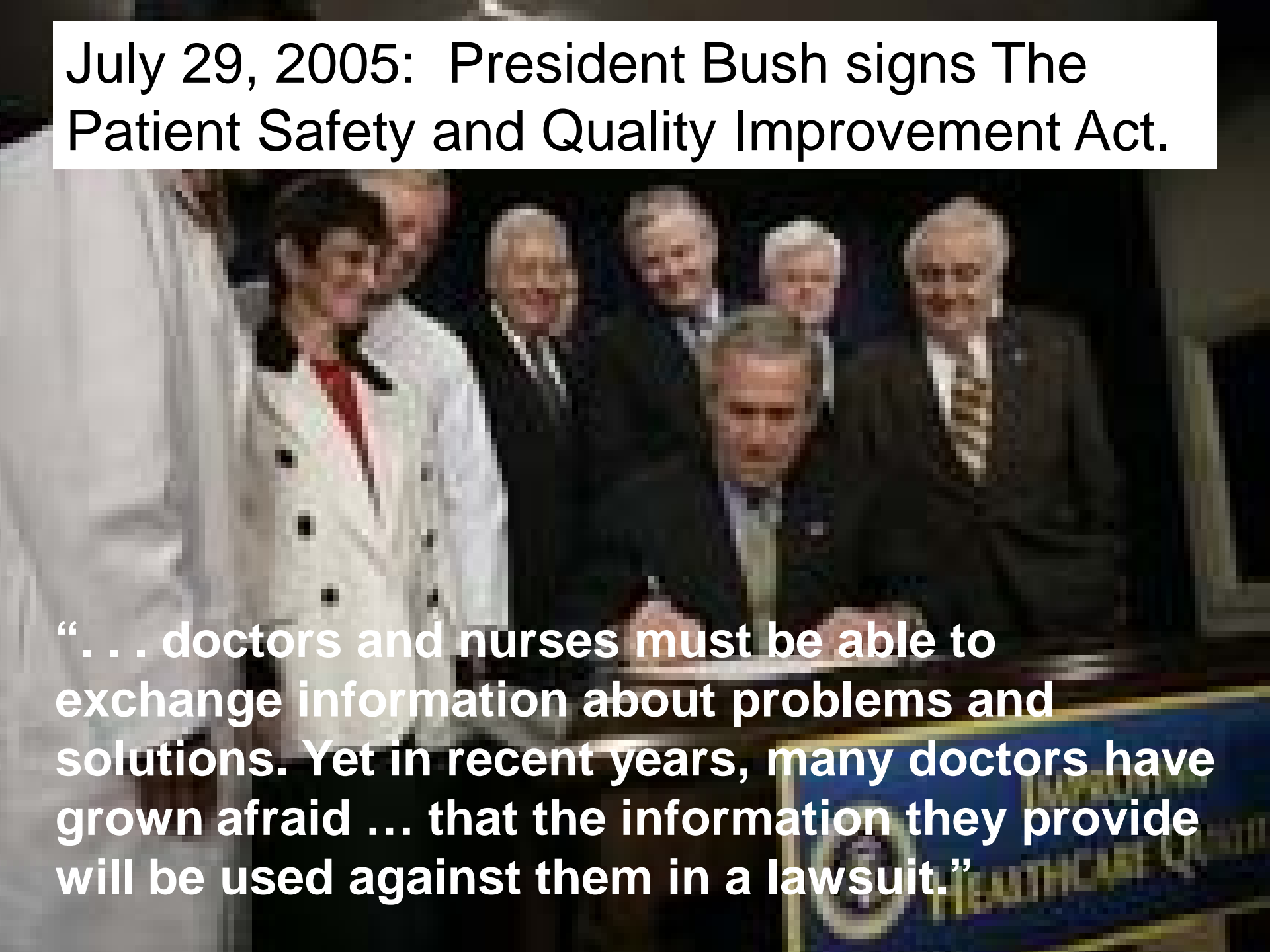
True? or False?

True? or False?

- Under proposed federal regulations, if the law is followed, most medical peer review data, including pharmacy peer-review error data, will be protected against attorney discovery.

MOST?

July 29, 2005: President Bush signs The Patient Safety and Quality Improvement Act.

A photograph showing President George W. Bush seated at a desk, signing a document. He is wearing a dark suit and a light-colored tie. Behind him stand several other men in suits, some looking on. To the left, a woman in a light-colored jacket is partially visible. The background is dark, and the scene appears to be in a formal setting like the White House.

“... doctors and nurses must be able to exchange information about problems and solutions. Yet in recent years, many doctors have grown afraid ... that the information they provide will be used against them in a lawsuit.”

Patient Safety Act

Goal: “encourage the expansion of voluntary, provider-driven initiatives to improve the safety and quality of patient care.”

AHRQ: The Agency for Healthcare Research and Quality administers the provisions dealing with PSOs.

OCR: The Office for Civil Rights administers the confidentiality enforcement program.

Federal privilege and confidentiality for patient safety work product

Patient safety work product includes patient, provider and reporter identifying information that is collected, created or used for patient safety activities.

Fines for “knowing or reckless impermissible disclosures of patient safety work product”.

Patient Safety & HIPAA

- Patient Safety Organizations (PSOs) will be business associates of a HIPAA covered entity [see 42 USC 299b-22(i)(1)]
- Patient safety activities performed by a PSO for a HIPAA covered entity are deemed to be health care operations

Who can become a PSO?

- public or private entities,
- for-profit, or not-for-profit,
- The statute prohibits insurers and components of insurers from becoming PSOs,
- NPRM would prohibit public or private entities with regulatory authority over providers (such as accreditation and licensure bodies) from becoming PSOs.
- Open Question: should components of regulatory entities be prohibited?

How to be a PSO

- An entity simply certifies that it is in compliance with the requirements for becoming a PSO.
- See: statute and § 3.102 Proposed Rule.

Privilege & Confidentiality

- Privilege protections: judicial system, limit or forbid the use of protected information in criminal, civil, administrative, or other proceedings.
- Office for Civil Rights (OCR): administer and enforce confidentiality of patient safety work product

Network of Patient Safety Databases

- The Patient Safety Act authorizes HHS to develop network of patient safety databases
- PSOs, providers, or others voluntarily contribute non-identifiable patient safety work product.
- interactive, evidence-based management resource for providers, PSOs, and other entities.
- AHRQ to use data from the network to analyze national and regional statistics, including trends and patterns, regarding patient safety events.

Terms & Words

- Identifiable patient safety work product:
Allows ID of provider, patient, reporter
- Nonidentifiable patient safety work product
- Patient safety organization (PSO)
- Patient safety work product
- Provider: provider of health care services,
including--

Provider includes

- **Facility:** hospital, nursing facility, home health, hospice, ambulatory surgical center, pharmacy, physician or other health care practitioner's office, long term care facility, behavior health residential treatment facility, clinical laboratory, or health center; or
- **Individuals:** physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, pharmacist, or other individual health care practitioner; or
- any other HHS lists

PRIVILEGE - patient safety work product

Shall be privileged and shall not be subject to a Federal, State, or local civil, criminal, or administrative

1. subpoena or order, including against a provider;
2. discovery, including disciplinary hearing against a provider;
3. Freedom of Information Act;
4. admitted as evidence in any proceeding, or
5. admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under State law.

Exceptions: Privilege & confidentiality shall not apply to . . .

1. Disclosure of relevant patient safety work product for use in a criminal proceeding
 - in camera determination contains evidence of a criminal act and
 - material to the proceeding and
 - not reasonably available from any other source.
2. Necessary for “Equitable relief” including reinstatement, back pay, and restoration of benefits
3. Disclosure authorized by each provider identified.

Exception from privilege.--voluntary disclosure of non-identifiable patient safety work product

Exceptions from confidentiality

1. to carry out patient safety activities.
2. nonidentifiable patient safety work product.
3. authorized research, evaluation
4. regulated by the Food and Drug Administration.
5. Voluntary disclosure to accrediting body.
6. HHS determines necessary.
7. to law enforcement authorities relating to a crime if reasonably believes information necessary.
8. With respect to a person other than PSO, disclosure does not include materials that--
 - (i) assess quality of care of an identifiable provider; or
 - (ii) describe or pertain to actions or failures by provider.

Continued Protection After Disclosure

**continues as privileged and confidential
& not waived . . .**

- **Exception**

- if disclosed in a criminal proceeding, the confidentiality protections no longer apply to the work product so disclosed; and
- disclosure of nonidentifiable patient safety work product

Accrediting Body

- **shall not** take an accrediting action against a provider based on the good faith participation of the provider
- **may not** require a provider to reveal its communications with any patient safety organization

Reporter (employee) Protected

Provider may not take employment action because individual in good faith reported information--

1. to provider with intention to reported to a PSO; or
2. directly to a patient safety organization.

Adverse employment action includes--

- loss of employment;
- failure to promote an individual, or
- failure to provide benefit; or
- adverse evaluation or decision made in relation to accreditation, certification, credentialing, or licensing of the individual.

Enforcement

Civil monetary penalty.—”knowing or reckless violation” up to \$10,000 per violation. [Not both PSA and HIPAA for a single act or omission]

Equitable relief

- a civil action may be brought by employee to enjoin any act or practice & for equitable relief (including reinstatement, back pay, and restoration of benefits).

Against state employees.--State may not assert the PSWP privilege unless before assertion, the State consented to be subject to an employment action above and that consent has remained in effect.

Patient Safety Act does not

- Preempt or limit any stronger privileges
 - (federal, state or by contract)
- preempt any State law requiring a provider to report information not PS work product; or
- affect reporting to FDA regarding safety of a product or activity regulated

NETWORK OF PATIENT SAFETY DATABASES

Evidence-based management resource.

- aggregate and analyze nonidentifiable data.
- access for researchers.

Data Standards

- common formats including elements, common and consistent definitions, and standardized computer interface

Use of Information.

- analyze national and regional statistics, including trends and patterns of health care errors; annual quality reports

PATIENT SAFETY ORGANIZATION CERTIFICATION AND LISTING

- An entity that seeks to be a patient safety organization shall submit an initial certification to the Secretary that the entity--
- "(A) has policies and procedures in place to perform each of the patient safety activities described in section 921(5); and
- "(B) upon being listed under subsection (d), will comply with the criteria described in subsection (b).
- "(2) Subsequent certifications.-- An <<NOTE: Deadlines.>> entity that is a patient safety organization shall submit every 3 years after the date of its initial listing under subsection (d) a subsequent certification to the Secretary that the entity--
- "(A) is performing each of the patient safety activities described in section 921(5); and
- "(B) is complying with the criteria described in subsection (b).
- "(b) Criteria.--
- "(1) In general.--The following are criteria for the initial and subsequent certification of an entity as a patient safety organization:
- "(A) The mission and primary activity of the entity are to conduct activities that are to improve patient safety and the quality of health care delivery.

Criteria for PSO

1. The **mission** and activity to improve safety and quality
2. **qualified staff** including medical professionals.
3. (24 months) **contracts** with more than 1 provider.
4. **not** a component of health insurance company
5. fully **disclose--**
 - relationship with provider that contracts with the PSO;
 - PSO independent.
6. **collects in standardized manner** that permits valid comparisons of similar cases among similar providers.
7. **utilization** of patient safety work product for the purpose of providing direct feedback and assistance to providers to effectively minimize patient risk.

Additional criteria for component organizations

If PSO is a component of another organization, additional criteria for certification :

1. maintains patient safety work product **separately**.
2. **not make an unauthorized disclosure** to the rest of the organization in breach of confidentiality.
3. The mission of the entity does **not create a conflict of interest** with the rest of the organization.

Patient Safety Work Product

- data, reports, records, memoranda, analyses (e.g. as root cause analyses),
- or written or oral statements:
 - reported to PSO; or
 - developed by a PSO for improving patient safety, quality, or outcomes; or
 - deliberations or analysis of, or identify the fact of reporting pursuant to, a patient safety evaluation system.

Not Patient Safety Work Product

- medical record, billing and discharge information
- information collected, maintained, or developed separately (Not made so by simply by reporting)
- Nothing in this part shall be construed to limit--
 - discovery or admissibility in a criminal, civil, or administrative proceeding;
 - reporting of information to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes; or
 - provider's recordkeeping obligation

- authorized to provide health care services, including--
- "(i) a hospital, nursing facility, comprehensive outpatient rehabilitation facility, home health agency, hospice program, renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner's office, long term care facility, behavior health residential treatment facility, clinical laboratory, or health center; or
- "(ii) a physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, pharmacist, or other individual health care practitioner; or
- "(B) any other individual or entity specified in regulations promulgated by the Secretary

True? or False?

True? or False?


To be effective as a long-term continuous quality improvement tool, the time requirements for staff should be limited to an average of approximately

- one minute per QRE plus
- no more than one to two hours per month for analysis and posting of data plus
- not more than three hours per quarter in peer review with staff.

The Regs . . .

**The devil is in
the details . . .**





Where do you
go from here?

The devil is in the details . . .