NJHA's PATIENT SAFETY ORGANIZATION ("PSO")

A 2013 Update

Outline for Today's Presentation

- **Evolution of Patient Safety laws**
- **NJ Patient Safety Act**
- **PSO basics & NJHA PSO**
- **Benefits of being in NJHA PSO**

Source: New Jersey Hospital Association

Evolution of Patient Safety

Source: New Jersey Hospital Association

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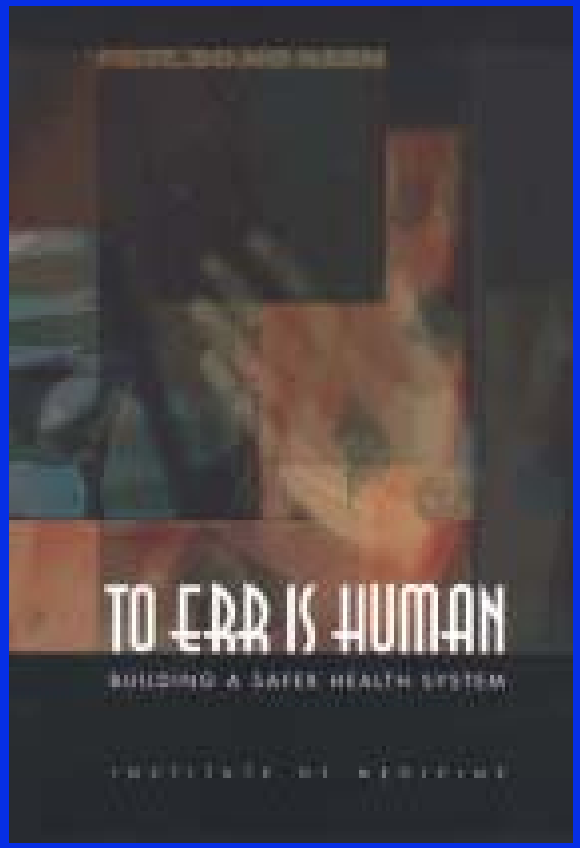
‘99 IOM Report – To Err is Human



Landmark Study

44,000 – 98,000 people die in hospitals each year as a result of medical errors that could have been prevented.

Source: New Jersey Hospital Association

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IOM: Conclusions

- Medical errors may be under reported - fear of malpractice suits, disciplinary actions, loss of employment.
- Majority of medical errors not a result of individual recklessness.
- Errors caused by faulty systems and processes.
- Blaming an individual doesn't make the system safer or prevent the same error from being committed again.

Source: New Jersey Hospital Association

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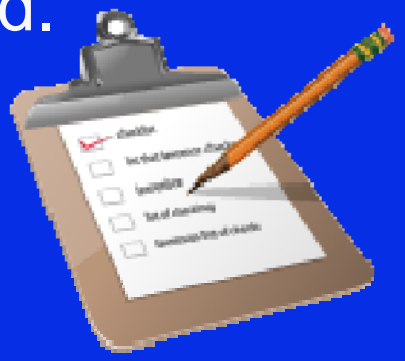
IOM: Recommendations

- Identify and learn from errors
- Develop a nationwide/public mandatory reporting system
- Encourage healthcare organizations to develop and participate in voluntary reporting
- Congress should enact laws to protect the confidentiality of certain information collected.



Source: New Jersey Hospital Association

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New Jersey Patient Safety Act

- New Jersey's response to IOM
- Effective in late 2004
- Mandatory and Voluntary Adverse Event Reporting System
- Data is submitted to NJ Dept. of Health
- Must have a Patient Safety Committee & Plan
- Provides confidentiality protection if followed

Source: New Jersey Hospital Association

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NJ Patient Safety Act – State Reporting System

- **Must** report "Serious Preventable Adverse Events"
- **May** report other "Adverse Events" or "Near Misses"
- **Must** have Patient Safety Committee for analysis of adverse events
- Committee **must** develop Patient Safety Plan
- State de-identifies collected data
- Uses to alert providers of harmful practices to avoid

Source: New Jersey Hospital Association

New Jersey Hospital Association NJHA

Confidentiality At Issue

- NJ Courts considering NJ Act's Confidentiality & Privilege protections for first time
- Appellate Court upheld protections with caveats:
  - documents must have been created & used exclusively for the Act
  - hospital must have followed the requirements of the law
- If not, court will apply a fact based test and review whether document is factual or evaluative
- Supreme Court to rule this year.

Source: New Jersey Hospital Association

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U.S. Patient Safety and Quality Improvement Act of 2005

- Federal response to IOM Report
- Known as the Patient Safety Act
- Authorized creation of Patient Safety Organizations (PSOs)
- Allows for voluntary reporting and sharing of patient safety information, through the PSO, without fear of legal discovery

Source: New Jersey Hospital Association

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Agency for Healthcare Research and Quality (AHRQ)

- AHRQ administers the Patient Safety Act
- Final rules at www.pso.ahrq.gov/regulations/regulations.htm
- Certifies PSOs
- Ensures PSOs meet their obligations
- Provides resources: www.pso.ahrq.gov

Source: New Jersey Hospital Association

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NJHA created a PSO

NJHA's Institute for Quality & Patient Safety certified and listed as a PSO with AHRQ on January 20, 2010

http://www.pso.ahrq.gov/listing/psolist.htm.

Source: New Jersey Hospital Association

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What is a PSO?

- Entity that improves patient safety and health care quality.
- Staff with expertise in analyzing patient safety events.
- Provides standardized patient safety data collection practices.
- Protects communications from disclosure as authorized by law.

Source: New Jersey Hospital Association

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PSOs' Purpose & Characteristics

- Serve as independent, external experts
- Do not receive federal funding
- PSOs can't be:
  - insurance companies
  - regulatory agencies
  - licensing entities
  - accreditation agencies
  - organizations that require reporting of patient safety data

Source: New Jersey Hospital Association

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PSO is Voluntary *for Now*

- Currently participation is voluntary
- However in Missouri…..
- However ACA….

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Affordable Care Act Requirement

As of January 1, 2015, a qualified health plan may contract with a hospital with >50 beds only if such hospital utilizes a patient service organization. (ACA Section 1311)

Meaning it will be required by contracts.

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PSOs' Patient Safety Activity

- Collection and analysis of patient safety work product (PSWP)
- Developing and disseminating patient safety recommendations and best practices
- Using submissions to provide feedback and assistance
- Preserve confidentiality and security
- Provide qualified staff
- Operate evaluation system & give feedback to participants

Source: New Jersey Hospital Association

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What is Patient Safety Work Product?

- Data or documents assembled for and submitted to a PSO are called **Patient Safety Work Product (PSWP)**
- PSWP is protected by confidentiality and privilege safeguards under the Patient Safety Act.

Source: New Jersey Hospital Association

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PSO Privilege Protections

Subject to certain specific exceptions, PSWP may not be used in the following legal proceedings:

- Criminal
- Civil
- Administrative
- Disciplinary

Source: New Jersey Hospital Association

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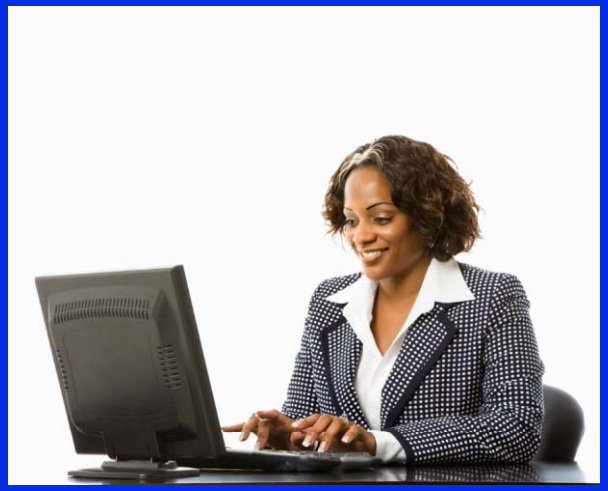
PATIENT SAFETY EVALUATION SYSTEM ("PSES")

Must design system:

- To collect
- To manage
- To analyze
- To report



Patient Safety Work Product ("PSWP") to the PSO

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What is PSWP?

Subjective Reports

Staff Impressions

Objective Facts not part of Mandatory Reporting

Source: New Jersey Hospital Association

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What documents are PSWP?

- Peer Review Documents
- Clinical Practice Protocols
- Evaluations of staff, equipment
- Root Cause Analyses
- Written or Oral Statements

Source: New Jersey Hospital Association

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What documents are PSWP?

- **Quality and Safety Reports**
- **Committee Minutes; Deliberations, Recommendations**
- **Notes, Checklists**
- **Outcome data**

Source: New Jersey Hospital Association

Original Source Documentation is not PSWP

- Medical Records
- Billing Information
- Mandatory Reporting Data
- Discharge Information
- Information on a Criminal Act
- Original Patient/Provider Information

Source: New Jersey Hospital Association

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Benefits of the NJHA PSO

#1 Legal Protections to Promote Reporting

#2 Collaborative Entity to Assist to Improve Safety

#3 Standardized Data Reporting & Collection

#4 Participate in National Repository

Source: New Jersey Hospital Association

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Benefit #1
Legal Protections to Promote Reporting

Key to voluntary patient safety data collection.

Source: New Jersey Hospital Association

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PSO Legal Protections

- Confidentially: store and protect voluntarily reported patient safety documents and data.
- Privilege: limits or forbids the use of information from legal discovery or disclosure

Source: New Jersey Hospital Association

What is Privilege?

Allows the holder of the privilege to refuse demands for information from third parties such as trial lawyers, government agencies and accrediting bodies in connection with legal and regularity proceedings.

Source: New Jersey Hospital Association

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Storing Documents in PSOs

- Patient Safety Evaluation System designee logs in
- Designee reports incident to PSO
- Download the PSWP documents related to the incident to NJHA PSO secure website
- Document storage is completely voluntary

Source: New Jersey Hospital Association

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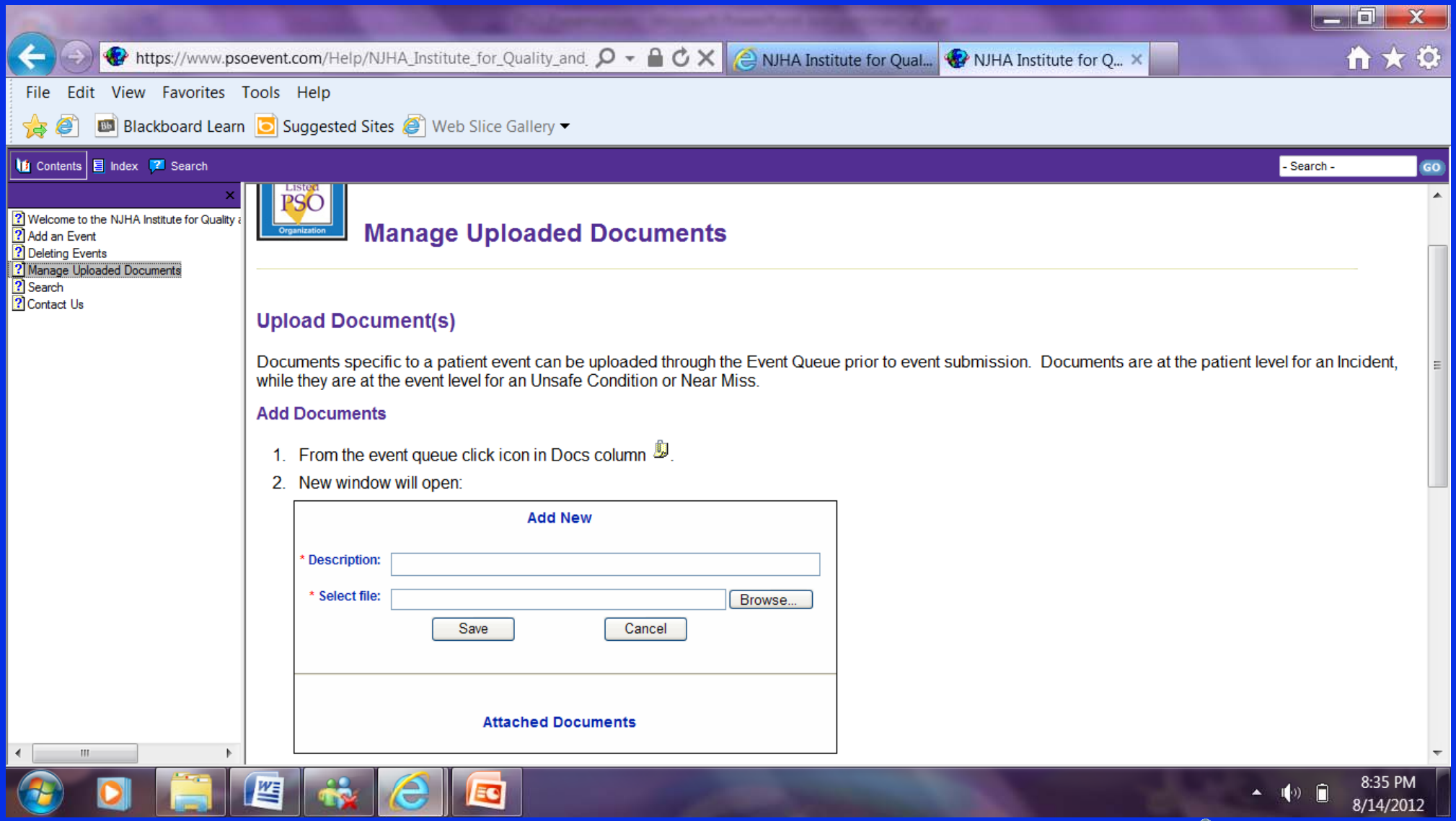
NJHA Website to Store Data



Greater Protection

When healthcare providers submit patient safety documents to PSOs, there is greater protection from legal discovery and disclosure. But see Applegrad for now.

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Legal Implications

- PSWP can be shared with an attorney, but can't be used in litigation once submitted to the PSO.
- Any data collected for external reporting to regulatory agencies, is not PSWP and doesn't receive protection.
- PSO is characterized as a "business associate" for the purposes of HIPAA.

Source: New Jersey Hospital Association

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Benefit #2
Collaborative Environment

Healthcare organization can talk about and work on ways to prevent “adverse events” in a protected environment.

Source: New Jersey Hospital Association

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PSO Collaborative Activities

- Collect data on the prevalence and details of errors.
- Analyze sources of error by root cause analysis.
- Propose and disseminate methods for error prevention.
- Design and conduct pilot projects to study safety initiatives.
- Raise awareness and inform the public, health professionals, providers, purchasers and employers.
- Advocate for regulatory and legislative changes.

Source: New Jersey Hospital Association

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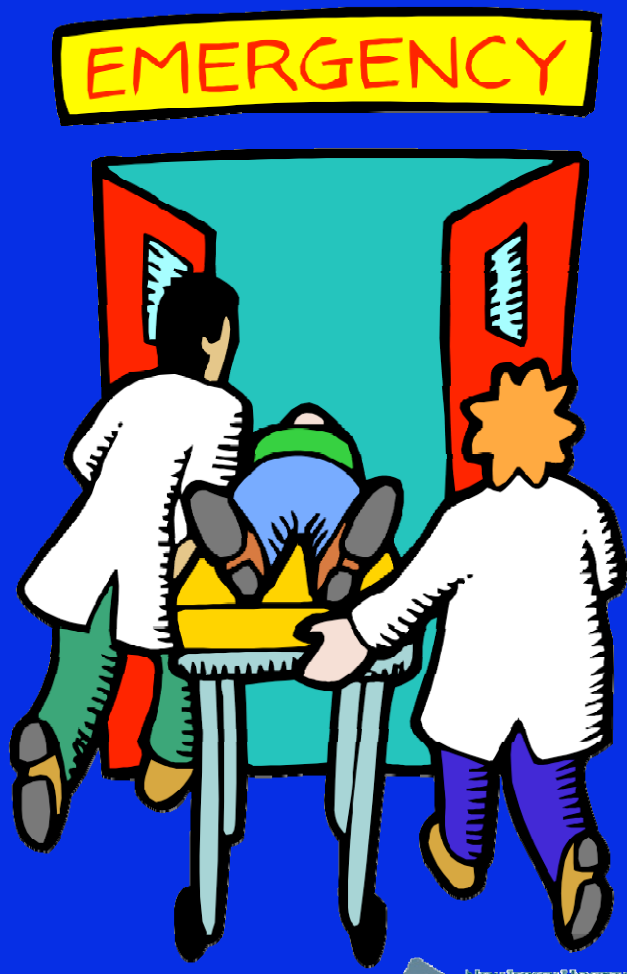
Readmission Rates

- ACA designates PSOs to help hospitals with high readmission rates to help improve their performance.
- ACA calls for the Department of Health and Human Services (HHS) to support PSOs in this work.



Source: New Jersey Hospital Association

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Benefit #3
Standardized Data Collection

- PSOs are required to collect data in a standardized electronic manner.
- PSOs can use nationally standardized common data formats for reporting patient safety events.
- NJHA PSO uses ARHQ common data formats

Source: New Jersey Hospital Association

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Common Format

- AHRQ developed and posted instructions for the common data format
- Easy to use with important prompts
- Recent CMS request to increase use of common format.

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Common Format

- Currently limited to two care settings
  - acute care hospitals
  - skilled nursing facilities
- Future versions are being developed for:
  - ambulatory settings (i.e. surg centers)
  - physician and practitioner offices.
- Types of events:
  - Incidents
  - Near misses or close calls
  - Unsafe conditions

Source: New Jersey Hospital Association

NJHA PSO Database

- NJHA developed a Web based patient safety database
- Utilizes AHRQ Common Formats
- Password protected
- Encrypted
- Data is submitted de-identified and can be submitted anonymously

Source: New Jersey Hospital Association

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Database Event Categories

Event Specific Categories	
Medications or Other Substances	Falls
Perinatal Events	Pressure Ulcers
Surgery or Anesthesia	Healthcare Associated Infections
Blood or Blood Products	Device of Medical/Surgical Supplies
Venous Thromboembolism, DVTs and PEs (pilot)	Readmission Rates (pilot)

Source: New Jersey Hospital Association

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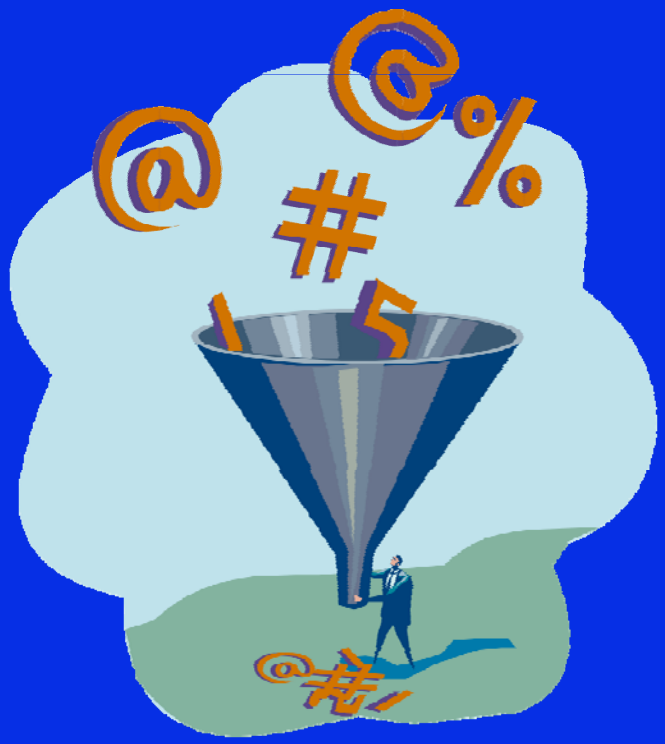
Benefit #4
Be Part of National Repository

- PSOs can populate an AHRQ national repository, the National Patient Safety Database (NPSD)
- NJHA can send data to AHRQ through its data base.
- PSO members can decide voluntarily whether or not to submit data to AHRQ.



Source: New Jersey Hospital Association

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Summary - PSO Benefits

#1 Provides confidential and privilege protections for healthcare providers on patient safety documents.

#2 Offers a full array of activities to improve patient safety and develop best practices.

#3 Standardized data reporting and collection.

#4 Ability to be part of a national repository.

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NJHA PSO Information

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Source: New Jersey Hospital Association